OHSU Health Services

Amyotrophic Lateral Sclerosis (ALS) Agents
Prior Authorization Guidelines

Affected Medication(s)

- Radicava ORS (edavarone) oral suspension

FDA Approved Indication(s)

- Treatment of amyotrophic lateral sclerosis (ALS) in adults

Dosing

- Radicava: 105 mg orally once daily for 14 days, followed by 14-day drug-free period, then 105 mg once daily for 10 days within a 14-day period, followed by a 14-day drug-free period

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation with Radicava for the same diagnosis?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member at least 18 years of age?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the treatment prescribed by or in consultation with a neurologist?
    a. If yes, continue to #6
    b. If no, clinical review required
6. Has the member been diagnosed with ALS defined by the revised El Escorial criteria, Awaji criteria, or Gold Coast criteria? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required

Last Reviewed: 11/09/22, 5/10/23, 5/8/24
Effective Date: 1/15/23, 6/15/23, 6/15/24

OHSUHealth Services

7. Is the member currently on riluzole therapy or have a documented contraindication or intolerance to riluzole?
    a. If yes, continue to #8
    b. If no, clinical review required
8. Does the member have a disease duration of less than or equal to 2 years?
    a. If yes, continue to #9
    b. If no, clinical review required
9. Does the member have a forced vital capacity (%FVC) of greater than or equal to 80% of predicted?
    a. If yes, continue to #10
    b. If no, clinical review required
10. Does the member have a baseline documentation of the revised ALS Functional Rating Scale (ALSFRS-R) score with greater than 2 points in each of the 12 items?
    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 or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the treatment prescribed by or in consultation with a neurologist?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Has the member experienced a documented positive response to therapy? (ex. decline of functional abilities has slowed in a clinically meaningful way, no tracheostomy, no assisted ventilation required) (Provide supporting documentation)
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

Last Reviewed: 11/9/22, 5/10/23, 5/8/24
Effective Date:1/15/23, 6/15/23, 6/15/24

1. RELYVRIO (sodium phenylbutyrate and taurursodiol), for oral suspension [package insert]. Cambridge, MA: Amylyx Pharmaceuticals, Inc; 2022.
2. Drugs@FDA: FDA Approved Drug Products. 2022. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 31 Oct. 2022].
3. Miller, Robert G., et al. "Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: drug, nutritional, and respiratory therapies (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology." Neurology 73.15 (2009): 1218-1226.
4. EFNS Task Force on Diagnosis and Management of Amyotrophic Lateral Sclerosis:, et al. "EFNS guidelines on the clinical management of amyotrophic lateral sclerosis (MALS)–revised report of an EFNS task force." European journal of neurology 19.3 (2012): 360-375.
5. Writing Group; Edaravone (MCI-186) ALS 19 Study Group. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. Lancet Neurol. 2017;16(7):505-512.

OHSU Health Services

Anti-Obesity Agents
Prior Authorization Guidelines

Affected Medication(s)

- Wegovy subcutaneous solution
- Saxenda subcutaneous solution
- Zepbound subcutaneous solution
- Phentermine oral capsule
- Qsymia oral capsule
- Contrave oral tablet

FDA Approved Indication(s)

Wegovy/Qsymia

- As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial BMI of ≥30 kg/m^2 (obesity), or ≥27 kg/m^2 (overweight) in the presence of at least one weight-related comorbid condition (i.e. hypertension, type 2 diabetes mellitus, dyslipidemia) and pediatric patients ≥12 years of age with an initial BMI at the ≥95th percentile standardized for age and sex (obesity)
- Risk reduction of major adverse cardiovascular events (cardiovascular death, nonfatal MI, nonfatal stroke) in adults with established cardiovascular disease and either obesity or overweight **(Wegovy only)**

Saxenda

- As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index of ≥30 kg/m^2 (obesity) or ≥27 kg/m^2 (overweight) in the presence of at least 1 weight-related comorbid condition (i.e. hypertension, type 2 diabetes mellitus, dyslipidemia) and pediatric patients ≥12 years of age with body weight >60 kg and an initial BMI corresponding to ≥30 kg/m^2 for adults (obesity) by international cut-offs

Zepbound

- As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial BMI of ≥30 kg/m2 (obesity) or ≥27 kg/m2 (overweight) in the presence of ≥1 weight-related comorbid condition (i.e. cardiovascular disease, dyslipidemia, hypertension, obstructive sleep apnea, type 2 diabetes mellitus)

Phentermine

- Short-term (few weeks) in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity with an initial body mass index ≥30 kg/m^2 or ≥27 kg/m^2 in the presence of other risk factors (i.e. diabetes, hyperlipidemia, controlled hypertension)

Last Reviewed: 5/10/23, 1/10/24, 5/8/24
Effective Date: 6/15/23, 2/15/24, 6/15/24

Contrave

- Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of ≥30 kg/m^2 or ≥27 kg/m^2 in the presence of at least one weight-related comorbid condition (i.e. type 2 diabetes mellitus, dyslipidemia)

Dosing

- See corresponding package insert for dosing

Initial 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 diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #4
4. What indication is the medication being requested for?
    a. Weight Management, continue to corresponding criteria
    b. Risk reduction of major adverse cardiovascular events, continue to corresponding criteria

Weight Management

1. Does the member meet one of the following baseline requirements? (Provide documentation of BMI)
    - BMI ≥95th percentile standardized for age and sex
    - BMI ≥ 30 kg/m^2
    - BMI ≥ 27 kg/m^2 with at least ONE weight-related comorbid condition (hypertension, dyslipidemia, type 2 diabetes mellitus, etc.)

    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member completed at least 6 months of intensive counseling (defined as face-to-face contact more than monthly) to address health behavior and lifestyle modifications including physical activity

goals, nutritional education, and behavior change OR has completed the Diabetes Prevention Program (DPP)? (Provide supporting documentation)

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

3. Does the treatment plan include on-going, age appropriate health behavior and lifestyle modifications with routine care provider visits? (Provide supporting documentation)

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

4. Have other causes of weight gain (i.e. medical conditions, medications, etc.) been ruled out? (Provide supporting documentation)

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

5. Is the requested drug Contrave, Qsymia, or phentermine?

   a. If yes, approve for 6 months
   b. If no, continue to #6

6. Has the member had at least a separate 12-week trial with inadequate response, intolerance, or contraindication to TWO or more of the following: Contrave, Qsymia, or phentermine? (Provide supporting documentation of age appropriate therapies tried)

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

Risk reduction of major adverse cardiovascular events

1. Is Wegovy the requested drug?

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

2. Is the member 45 years of age or older?

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

3. Does the member have a BMI of 27 kg/m^2 or greater AND established cardiovascular disease (history of myocardial infarction, stroke, or symptomatic peripheral arterial disease)? (Provide supporting documentation)

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

4. Is the member's current cardiovascular-related drug regimen (i.e. statin, antiplatelet, ACE-I, etc.) optimized and is the member adherent to this therapy? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Has the member enrolled in a program to address health behavior and lifestyle modifications including physical activity goals, nutritional education, and behavior change? (Provide supporting documentation)
    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 supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there clinical documentation confirming positive response to therapy as defined as 5% weight loss or more from baseline? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the treatment plan include on-going, age appropriate health behavior and lifestyle modifications? (Provide supporting documentation)
    a. If yes, approve for 6 months
    b. If no, clinical review required

Note:

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

References:

1. Wegovy (semaglutide) [Prescribing Information]. Plainsboro, NJ: Novo Nordisk, Inc. March 2024.
2. Saxenda (liraglutide) [Prescribing Information]. Plainsboro, NJ: Novo Nordisk, Inc. June 2022.
3. Zepbound (tirzepatide) [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. November 2023.

Last Reviewed: 5/10/23, 1/10/24, 5/8/24
Effective Date: 6/15/23, 2/15/24, 6/15/24

4. Adipex-P (phentermine) [Prescribing Information]. Overland Park, KS: Teva Neuroscience, Inc.; September 2020.
5. Contrave (naltrexone/bupropion) [Prescribing Information]. Brentwood, TN: Currax Pharmaceuticals LLC. December 2022.
6. Hampl, Sarah E., et al. "Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents with Obesity." Pediatrics (2023).

Last Reviewed: 5/10/23, 1/10/24, 5/8/24
Effective Date: 6/15/23, 2/15/24, 6/15/24

OHSU Health Services

Aranesp (darbepoetin alfa)
Prior Authorization Guidelines

Affected Medication(s)

- Aranesp subcutaneous injection solution

FDA Approved Indication(s)

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

Dosing

- Refer to package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for use to treat an FDA approved or major compendia supported indication?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the request a renewal of a previously approved Aranesp (darbepoetin alfa) prior authorization and the indication is for the same as previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #4
4. Have serum ferritin, transferrin saturation, hematocrit (Hct), and hemoglobin (Hb) lab values been completed within 30 days of planned administration? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20%? (Provide supporting documentation)
    a. If yes, continue to #6

Last Reviewed: 4/2/19, 3/11/20, 7/14/21, 7/13/22, 7/12/23
Effective Date: 5/1/19, 1/1/20, 9/1/21

b. If no, clinical review required

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

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

8. Which indication is Aranesp (darbepoetin alfa) being requested for?
    a. Anemia secondary to myelodysplastic syndrome (MDS), continue to corresponding criteria
    b. Anemia secondary to Myeloproliferative Neoplasms (MPN) – Myelofibrosis, continue to corresponding criteria
    c. Anemia secondary to chemotherapy treatment, continue to corresponding criteria
    d. Anemia secondary to chronic kidney disease (non-dialysis patients), approve for 3 months
    e. Other indication, continue to corresponding criteria

<u>Anemia secondary to myelodysplastic syndrome (MDS)</u>

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

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

<u>Anemia secondary to Myeloproliferative Neoplasms (MPN) – Myelofibrosis</u>

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

<u>Anemia secondary to chemotherapy treatment</u>

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

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

3. Are there two or more additional months of planned chemotherapy remaining? (Provide supporting documentation)
    a. If yes, approve for 6 months or until completion of chemotherapy course, whichever is less
    b. If no, clinical review required

Other Indications

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

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

Reauthorization Criteria

1. Was the last dose of Aranesp (darbepoetin alfa) less than 60 days ago?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within 1 year) provided with documentation of significant clinical response to therapy? (Response to therapy includes stabilized hemoglobin and a decreased need for blood transfusions compared to pre-treatment) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is there documentation of an absence of unacceptable toxicity from the drug? (Examples include pure red cell aplasia, severe allergic reactions (anaphylaxis, angioedema, bronchospasm, etc), severe

cardiovascular events (stroke, myocardial infarction, congestive heart failure, thromboembolism, uncontrolled hypertension), seizures, increased risk of tumor progression/recurrence in members with cancer, etc.) (Provide supporting documentation)

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

4. Were lab values obtained within 30 days of the date of administration (unless otherwise indicated)? (hemoglobin and hematocrit) (Provide supporting documentation)

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

5. Does the member have adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% measured within the previous 3 months? (Provide supporting documentation)

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

6. Have other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) been ruled out? (Provide supporting documentation)

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

7. Does the member meet the diagnosis and clinical requirements for at least one of the following below? (Provide supporting documentation)

   - Anemia secondary to myelodysplastic syndrome (MDS) with hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) <36%
   - Anemia secondary to myeloproliferative neoplasms (MF, post-PV myelofibrosis, post-ET myelofibrosis) with hemoglobin (Hb) <10 g/dL and/or Hematocrit (Hct) <30%
   - Anemia secondary to palliative 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

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. Aranesp [package insert] Thousand Oaks, CA; Amgen Inc; January 2018. Accessed March 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) darbepoetin alfa. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2018.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Cancer-and Chemotherapy-Induced Anemia Version 1.2018. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2018.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myelodysplastic Syndrome Version 1.2018. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2018.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myeloproliferative Neoplasms Version 2.2018. 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. Younossi ZM, Nader FH, Bai C, et al. A phase II dose finding study of darbepoetin alpha and filgrastim for the management of anaemia and neutropenia in chronic hepatitis C treatment. Journal of Viral Hepatitis 2008; 15(5):370-8
7. Cervantes F, Alvarez-Laran A, Hernandez-Boluda JC, et al. Darbepoetin-alpha for the anaemia of myelofibrosis with myeloid metaplasia. British Journal of Haematology, 134: 184–186. doi:10.1111/j.1365-2141.2006.06142.x

Last Reviewed: 4/2/19, 3.11.20, 7/14/21, 7/13/22, 7/12/23
Effective Date: 5/1/19, 1/1/20, 9/1/21

8. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Erythropoiesis Stimulating Agents (ESAs) (L34633). Centers for Medicare & Medicaid Services, Inc. Updated on 09/20/2017 with effective dates 10/1/2017. Accessed March 2018.
9. CGS Administrators, Inc. Local Coverage Determination (LCD): Erythropoiesis Stimulating Agents (ESAs) (L34356). Centers for Medicare & Medicare Services. Updated on 02/26/2018 with effective dates 10/01/2017. Accessed March 2018.
10. First Coast Service Options, Inc. Local Coverage Determination (LCD): Erythropoiesis Stimulating Agents (ESAs) (L36276). Centers for Medicare & Medicare Services. Updated on 02/22/2018 with effective dates 02/08/2018. Accessed March 2018.
11. National Coverage Determination (NCD); Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21). Centers for Medicare & Medicaid Services, Inc. Updated on 12/3/2015 with effective dates 10/01/2015. Accessed March 2018.

OHSU Health Services

Arikayce® (amikacin)
Prior Authorization Guidelines

Affected Medication(s)

- Arikayce Inhalation vial

FDA Approved Indication(s)

- In adults, who have limited or no alternative treatment options, for the treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy

Dosing

- Once daily inhalation of the contents of one 590 mg/8.4 mL ARIKAYCE vial (590 mg of amikacin) using the Lamira Nebulizer System

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request a renewal of a previously approved Arikayce (amikacin) prior authorization and provided indication is for the same as previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is Arikayce (amikacin) being requested for an FDA approved indication?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have Mycobacterium avium complex (MAC) lung disease as confirmed by positive sputum culture? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the member 18 years of age or older?
    a. If yes, continue to #6

Last Reviewed: 9/24/19, 3/11/20, 7/14/21, 7/13/22, 7/12/23
Effective Date: 10/1/19, 1/1/20, 9/1/21

b. If no, clinical review required

6. Has the member trialed a minimum of 6-months of a multidrug background regimen (listed below) with failure confirmed by sputum culture? (Note: failure defined as continued positive sputum culture) (Provide supporting documentation)

   - Clarithromycin/azithromycin + ethambutol + rifampin/rifabutin
   - Clarithromycin/azithromycin + ethambutol + rifampin/rifabutin + parenteral streptomycin/amikacin

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

7. Is the treatment being prescribed by or in consultation with an ID specialist or pulmonologist?

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

Reauthorization Criteria

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

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

2. Were updated chart notes (within the past 6 months) with documentation of negative sputum cultures received? (Note: treatment should be continued until sputum cultures are consecutively negative for at least 12 months)

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

3. Is the treatment being prescribed by or in consultation with an ID specialist or pulmonologist?

   a. If yes, approve for 12 months reauthorization
   b. If no, clinical review required

Note:

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

References:

1. ARIKAYCE (amikacin liposome inhalation suspension) for oral inhalation [package insert]. Midlothian, VA: PARI Pharma; 2018.

Last Reviewed: 9/24/19, 3/11/20, 7/14/21, 7/13/22, 7/12/23
Effective Date: 10/1/19, 1/1/20, 9/1/21

2. Drugs@FDA: FDA Approved Drug Products. 2018. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed Nov 5. 2018].
3. Griffith, David E., et al. "An official ATS/IDSA statement: diagnosis, treatment, and prevention of nontuberculous mycobacterial diseases." American journal of respiratory and critical care medicine 175.4 (2007): 367-416.
4. Daley, Charles L., et al. "Treatment of nontuberculous mycobacterial pulmonary disease: an official ATS/ERS/ESCMID/IDSA clinical practice guideline: executive summary." Clinical Infectious Diseases 71.4 (2020): e1-e36.

Last Reviewed: 9/24/19, 3/11/20, 7/14/21, 7/13/22, 7/12/23
Effective Date: 10/1/19, 1/1/20, 9/1/21

OHSU Health Services

Benznidazole
Prior Authorization Guidelines

Affected Medication(s)

- Benznidazole oral tablet

FDA Approved Indication(s)

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

Dosing

- Weight based dosing with maximum of 200 mg twice daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved benznidazole prior authorization with the same indication?
    a. If yes, clinical review required
    b. If no, continue to #3
3. Is benznidazole being requested for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is a lab result confirming *T. cruzi* infection provided? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the requested treatment being prescribed by or in consultation with an infectious disease specialist or a cardiologist?
    a. If yes, approve for 60 days
    b. If no, clinical review required

Last Reviewed: 7/17/18, 3/11/20, 7/14/21, 7/13/22, 7/12/23
Effective Date: 8/15/18, 1/1/20

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. Benznidazole (benznidazole) [Prescribing Information]. Florham Park, NJ: Exeltis USA. August 2017.
2. Benznidazole. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed July 5, 2018.
3. Bern C, Montgomery SP, Herwaldt BL. Evaluation and treatment of Chagas disease in the United States: a systematic review. JAMA. 2007;298(18):2171-2181. Available at: https://jamanetwork.com/journals/jama/fullarticle/209410. Accessed July 6, 2018.
4. Nunes, Maria Carmo Pereira, et al. "Chagas cardiomyopathy: an update of current clinical knowledge and management: a scientific statement from the American Heart Association." Circulation 138.12 (2018): e169-e209.

Last Reviewed: 7/17/18, 3/11/20, 7/14/21, 7/13/22, 7/12/23
Effective Date: 8/15/18, 1/1/20

OHSU Health Services

Bylvay (odevixibat) & Livmarli (maralixibat)
Prior Authorization Guidelines

Affected Medication(s)

- Bylvay (odevixibat) capsule / pellet
- Livmarli (maralixibat) tablet

FDA Approved Indication(s)

Bylvay

- Treatment of pruritus in patients ≥3 months of age with progressive familial intrahepatic cholestasis (PFIC) (NOTE: May not be effective in PFIC type 2 patients with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3))
- Treatment of cholestatic pruritis in patients 12 months of age and older with Alagille Syndrome (ALGS)

Livmarli

- Treatment of cholestatic pruritus in patients 3 months of age and older with Alagille syndrome (ALGS)

Dosing

- Refer to package insert for specific dosing recommendations
  Re

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the request a renewal of a previously approved Bylvay (odevixibat) or Livmarli (maralixibat) prior authorization and provided indication is the same as previous approval?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3
3. What diagnosis is the medication being requested for?
   a. Progressive Familial intrahepatic cholestasis (PFIC), continue to corresponding criteria
   b. Alagille syndrome (ALGS), continue to corresponding criteria

Progressive Familial Intrahepatic Cholestasis

Last Reviewed: 9/8/21, 1/11/23, 9/13/23
Effective Date: 11/1/21, 10/15/23

OHSUHealth Services

1. Does the member have a diagnosis of familial intrahepatic cholestasis (PFIC) Type I or II confirmed by presence of a mutation in the *ATP8B1 (FIC$_1$)* or *ABCB11* gene, liver biopsy or ultrasound or biliary lipid analysis? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member 3 months of age or older?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a clinical history of cholestasis and have the other main causes of cholestasis been ruled out (e.g. biliary atresia, Alagille syndrome, alpha1antitrypsine deficiency, cystic fibrosis, sclerosing cholangitis and extrahepatic bile duct obstruction)? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have documentation of an inadequate response, intolerance, or contraindication to at least TWO of the following: ursodiol, cholestyramine or rifampin? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Has the member previously undergone partial or total biliary diversion surgery that has been ineffective in relieving pruritus OR is medical rationale provided why the member cannot undergo surgery? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the medication prescribed by, or in consultation with, a hepatologist or an appropriate biliary specialist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

<u>Alagille Syndrome</u>

1. Does the member have documentation of Alagille syndrome confirmed by genetic testing with JAG1 or NOTCH2 mutation present or liver biopsy? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required

2. Has the member previously trialed a maximum tolerated dose of all of the following for at least 4 weeks with treatment failure, or is there a documented intolerance or contraindication to all of the following: rifampin, ursodiol, and cholestyramine/colesevelam? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the request for Bylvay (odevixibat)?
    a. If yes, continue to #4
    b. If no, continue to #5
4. Has the member previously trialed a maximum tolerated dose of Livmarli (maralixibat) for at least 4 weeks with treatment failure, or is there a documented intolerance or contraindication to Livmarli (maraliximab)? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is there documentation member is experiencing moderate to severe pruritus despite current therapy? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the requested drug being prescribed by, or in consultation with, a gastroenterologist or specialist experienced in treating Alagille syndrome?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within 1 year) with documentation of improvement in pruritis symptoms from baseline received? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, a hepatologist or an appropriate biliary specialist?
    a. If yes, approve for 12 months reauthorization

b. If no, clinical review required

Note:

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

References:

1. BYLVAY (odevixibat) capsule/pellets [package insert]. Boston, MA: Albireo Pharma, Inc.; 2023.
2. LIVMARLI™ (maralixibat) oral solution, [package insert]. Foster City, CA: Mirum Pharmaceuticals, Inc; March 2023.
3. Roy-Chowdhury J, Roy-Chowdhury N. Inherited disorders associated with conjugated hyperbilirubinemia. In: UpToDate, K. Lindor, S. Grover (Eds), UpToDate, Waltham, MA. (Accessed on August 27, 2021.)
4. Davit-Spraul, Anne, et al. "Progressive familial intrahepatic cholestasis." Orphanet journal of rare diseases 4.1 (2009): 1-12.
5. Gunaydin, Mithat, and Asudan Tugce Bozkurter Cil. “Progressive familial intrahepatic cholestasis: diagnosis, management, and treatment.” Hepatic medicine: evidence and research vol. 10 95-104. 10 Sep. 2018, doi:10.2147/HMER.S137209
6. Gonzales, Emmanuel, et al. "Efficacy and safety of maralixibat treatment in patients with Alagille syndrome and cholestatic pruritus (ICONIC): a randomized phase 2 study." The Lancet 398.10311 (2021): 1581-1592.
7. Poupon R, Chopra S. Pruritus associated with cholestasis. In: UpToDate, K. Lindor, S. Grover (Eds), UpToDate, Waltham, MA. (Accessed on September 7, 2023.)

OHSU Health Services

Cablivi® (caplacizumab-yhdp)
Prior Authorization Guidelines

Affected Medication(s)

- Cablivi (caplacizumab-yhdp) subcutaneous solution

FDA Approved Indication(s)

- Treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

Dosing

Should be administered upon initiation of plasma exchange therapy:

- First day of treatment: 11 mg bolus intravenous (IV) injection at least 15 minutes prior to plasma exchange followed by an 11 mg subcutaneous (SC) injection after completion of plasma exchange on day 1
- Subsequent days of treatment during daily plasma exchange: 11 mg SC injection once daily following plasma exchange
- Treatment after plasma exchange period: 11 mg SC injection once daily continuing for 30 days following the last daily plasma exchange. Treatment may be extended for a maximum of 28 days if patient have signs of persistent underlying disease such as suppressed ADAMTS13 activity levels remain present after initial treatment course.

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 diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program?
    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 acquired TTP based confirmed by severe ADAMTS13 deficiency with ADAMTS13 activity levels of less than 10% and thrombocytopenia and/or microangiopathic

Last Reviewed: 5/13/20, 9/8/21, 9/14/22, 9/13/23
Effective Date: 6/1/20, 11/1/21

hemolytic anemia OR a PLASMIC score of 6-7? (Provide ADAMTS13 activity level or PLASMIC score for review)

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

5. Was the therapy started upon initiation of plasma exchange therapy in combination with an immunosuppressant (i.e. corticosteroids or rituximab)?

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

6. Has the member received, or planning to receive, the IV bolus dose?

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

7. Is this medication being prescribed by, or in consultation with, a hematologist?

   a. If yes, approve up to 30 days following the last day of plasma exchange therapy
   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. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 21 Jan. 2019].
2. Caplacizumab-yhdp (Cablivi) [package insert]. Cambridge, MA: Genzyme Corporation; 2019.
3. Cully M, Hunt BJ, Benjamin S, et al. Guidelines on the diagnosis and management of thrombotic thrombocytopenic purpura and other thrombotic microangiopathies. Br J Haematol. 2012;158(3):323-35.
4. Schwartz J, Padmanabhan A, Aqui N, et al. Guidelines on the use of therapeutic apheresis in clinical practice-evidence-based approach from the writing committee of the American society for apheresis: The Seventh special issue. J Clin Pher. 2016 Jun;31(3):149-62.
5. Bendapudi PK, Hurwitz S, Fry A, et al. Derivation and external validation of the PLASMIC score for rapid assessment of adults with thrombotic microangiopathies: a cohort study. Lancet Haematology. 2017;4(4):e157
6. Zheng ZL, Vesely SK, Cataland SR, et al. ISTH guidelines for treatment of thrombotic thrombocytopenic purpura. J Thromb Haemost. 2020;18(10):2496-2502.

Last Reviewed: 5/13/20, 9/8/21, 9/14/22, 9/13/23
Effective Date: 6/1/20, 11/1/21

OHSU Health Services

Calcipotriene
Prior Authorization Guidelines

Affected Medication(s)

- Calcipotriene 0.005% solution
- Calcipotriene 0.005% cream

FDA Approved Indication(s)

- Indicated for treatment of plaque psoriasis

Dosing

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

Initial Authorization Criteria

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

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

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

4. Does the member currently have severe inflammatory skin disease defined as having functional impairment (e.g. inability to use hands or feet or actives of daily living, or significant facial involvement preventing normal social interaction AND one or more of the following: At least 10% of body surface area involved AND/OR Hand, face, foot, or mucous membrane involvement?
    a. If yes, continue to #5
    b. If no, clinical review required

Last Reviewed: 7/23/19, 3/11/20, 7/14/21, 9/14/22, 7/12/23
Effective Date: 9/15/19, 1/1/20, 11/15/22

OHSUHealth Services

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

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

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

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

9. Is the requested treatment dose appropriate?
    a. If yes, continue to #10
    b. If no, clinical review required

10. Is the treatment being prescribed by or in consultation with an appropriate specialist?
    a. If yes, approve for 3 months
    b. If no, clinical review required

Note:

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

References:

1. Dovonex (calcipotriene cream) [Prescribing Information]. Madison, NJ: LEO Pharma Inc. October 2018.

Last Reviewed: 7/23/19, 3/11/20, 7/14/21, 9/14/22, 7/12/23
Effective Date: 9/15/19, 1/1/20, 11/15/22

2. Dovonex. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed July 10, 2019.

3. Oregon Health Plan. Prioritized List of Health Services. January 1, 2019. Available at: https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx. Accessed June 28, 2021.

4. Elmets, Craig A., et al. "Joint AAD–NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures." Journal of the American Academy of Dermatology 84.2 (2021): 432-470.

OHSU Health Services

Camzyos (mavacamten)
Prior Authorization Guidelines

Affected Medication(s)

- Camzyos (mavacamten) oral capsule

FDA Approved Indication(s)

- Treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms

Dosing

- Starting dose is 5 mg once daily with titration to 2.5, 5, 10, or 15 mg once daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Camzyos (mavacamten) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is Camzyos (mavacamten) being requested for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member 18 years of age or older? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have documentation of NYHA class II to III obstructive hypertrophic cardiomyopathy (HCM) and are they experiencing symptoms? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 7/13/22, 7/12/23
Effective Date: 9/15/22

OHSUHealth Services

6. Does the patient have documentation of a left ventricular ejection fraction (LVEF) of 55% or greater? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Does the patient have documentation of a LVOT peak gradient of 50 mmHg or greater at rest or with provocation? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Has the member previous trialed all of the following classes of medications at maximally indicated doses unless intolerance or contraindication is present? (Provide supporting documentation)
        - Non-vasodilating beta-blocker (i.e. atenolol, bisoprolol, metoprolol, propranolol)
        - Non-dihydropyridine calcium channel blocker (i.e. verapamil, diltiazem)
        - Disopyramide
    a. If yes, continue to #9
    b. If no, clinical review is required
9. Is Camzyos (mavacamten) being prescribed by, or in consult with, a cardiologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of significant clinical response to prior therapy received? (i.e. improvement NYHA Class II-III symptoms) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have an updated echocardiogram (within that past year and since starting therapy) showing LVEF of at least 50%?
    a. If yes, continue to #4
    b. If no, clinical review required

4. Is Camzyos (mavacamten) being prescribed by, or in consult with, a cardiologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. CAMZYOS (mavacamten) capsules, [package insert]. Brisbane, CA: MyoKardia, Inc.; 2022.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 26 May. 2022].
3. Olivotto, Iacopo, et al. "Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomised, double-blind, placebo-controlled, phase 3 trial." The Lancet 396.10253 (2020): 759-769.
4. Ommen, Steve R., et al. "2020 AHA/ACC guideline for the diagnosis and treatment of patients with hypertrophic cardiomyopathy: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines." Journal of the American College of Cardiology 76.25 (2020): e159-e240.

OHSU Health Services

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

- Refer to package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Cholbam (cholic acid) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a diagnosis of peroxisomal disorder? (Provide documentation to support confirmation of diagnosis)
    a. If yes, continue to #5
    b. If no, continue to #8
5. Does the member have manifestations of at least one of the following? (Provide supporting documentation)

Last Reviewed: 1/10/24
Effective Date: 2/15/24

- Liver disease (ex. jaundice or elevated liver enzymes)
- Steatorrhea
- Complications from decreased fat-soluble vitamin absorption

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

6. 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 #7

7. Was a baseline liver function test received? (Provide lab results)

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

8. 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 3 months unless otherwise specified
b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)

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

2. Is there evidence of improvement in member's condition (i.e. liver function tests, improvement in steatorrhea, etc.) from baseline as assessed by specialist prescribing the requested drug? (Provide supporting documentation)

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

3. Is there evidence of complete biliary obstruction? (Provide supporting documentation)

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

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. Cholbam [Prescribing Information]. Baltimore, MD: Asklepion Pharmaceuticals LLC; March 2023.
2. Wanders, R. Peroxisomal disorders. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed December 6, 2023.
3. Bile acid synthesis disorders. National Organization for Rare Diseases. Updated 2020. Available at: https://rarediseases.org/rare-diseases/bile-acid-synthesis-disorders. Accessed on December 6, 2023.
4. Zellweger spectrum disorders. National Organization for Rare Diseases. Updated 2020. Available at: https://rarediseases.org/rare-diseases/zellweger-spectrum-disorders. Accessed on December 6, 2023.
5. Fawaz R, Baumann U, Ekong U, et al. Guideline for the evaluation of cholestatic jaundice in infants: joint recommendations of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition. J Pediatr Gastroenterol Nutrition. 2017;64(1):154-168.

OHSU Health Services

Ciprofloxacin/Dexamethasone Otic Suspension
Prior Authorization Guidelines

Affected Medication(s)

- Ciprofloxacin 0.3% and dexamethasone 0.1% otic suspension

FDA Approved Indication(s)

- For the management of Acute Otitis Media (AOM) in pediatric patients (age 6 months and older) with tympanostomy tubes due to *Staphylococcus aureus, Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis,* and *Pseudomonas aeruginosa*
- For the management of Acute Otitis Externa (AOE) in pediatric (age 6 months and older), adult and elderly patients due to *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

Dosing

- Instill 4 drops into affected ear(s) twice daily for 7 days

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
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 tympanostomy tubes that is currently in place? (Provide supporting documentation)
    a. If yes, approve for 3 months
    b. If no, continue to #4
4. Did the member have inadequate response to all formulary alternatives for treatment of AOE? (Provide supporting documentation)
    a. If yes, approve for 3 months
    b. If no, clinical review required

Last Reviewed: 11/26/19, 7/14/21, 7/13/22, 7/12/23
Effective Date: 2/1/20, 9/1/21

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. Ciprodex [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation November 2020.

Last Reviewed: 11/26/19, 7/14/21, 7/13/22, 7/12/23
Effective Date: 2/1/20,

OHSU Health Services

Continuous Glucose Monitors (CGMs)
Prior Authorization Guidelines

Affected Medication(s)

- Dexcom
- FreeStyle Libre

FDA Approved Indication(s)

- Dexcom: For use in people two years and older with any type of diabetes including type 1, type 2, or gestational diabetes
- FreeStyle Libre: For use in people with diabetes age 4 and older

Dosing

- Refer to corresponding package insert for specific dosing instructions

Initial Authorization Criteria

1. What is the diagnosis that the medication is being requested for?
    a. Adults with type 1 diabetes mellitus not on insulin pump management, continue to corresponding criteria
    b. Adults with type 1 diabetes on insulin pump management, continue to corresponding criteria
    c. Women with type 1 diabetes who are pregnant or who plan to become pregnant within six months without regard to HbA1c levels, approve for 12 months
    d. Children and adolescents under age 21 with type 1 diabetes, continue to corresponding criteria
    e. Individuals with type 2 diabetes or gestational diabetes, continue to corresponding criteria

<u>Adults with Type 1 Diabetes (T1DM) NOT on Insulin Pump Management</u>

1. Does the member meet/continue to meet all the following requirements? (Provide supporting documentation)
    - Received or will receive diabetes education specific to the use of continuous glucose monitoring
    - Baseline HbA1c levels greater than or equal to 8.0%, frequent or severe hypoglycemia, or impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM)

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

OHSUHealth Services

Adults with Type 1 Diabetes (T1DM) on Insulin Pump Management (including the CGM-enabled insulin pump)

1. Does the member meet/continue to meet all the following requirements? (Provide supporting documentation)
    - Received or will receive diabetes education specific to the use of continuous glucose monitoring
    - Used the device for at least 50% of the time at their first follow-up visit

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

Children and Adolescents Under Age 21 with Type 1 Diabetes

1. Does the member meet/continue to meet all the following requirements? (Provide supporting documentation)
    - Received or will receive diabetes education specific to the use of continuous glucose monitoring
    - Used the device for at least 50% of the time at their first follow-up visit (for reauthorization)

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

Individuals with Type 2 Diabetes or Gestational Diabetes

1. Does the member meet/continue to meet all the following requirements? (Provide supporting documentation)
    - Use short- or intermediate-acting insulin injections
    - Received or will receive diabetes education specific to the use of continuous glucose monitoring
    - Has one of the following at the time of CGM therapy initiation:
        - Baseline HbA1c levels greater than or equal to 8.0%
        - Frequent or severe hypoglycemia
        - Impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM)
        - Diabetes-related complications (peripheral neuropathy, end-organ damage)
    - Used the device for at least 50% of the time for a 90-day period by their first follow-up visit within 3-6 months (for reauthorization)

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

Note:

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

References:

1. Oregon Health Plan. Prioritized List of Health Services. January 1, 2024. Available at: https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx. Accessed December 29, 2023.

OHSU Health Services

Corlanor (ivabradine)
Prior Authorization Guidelines

Affected Medication(s)

- Corlanor (ivabradine) oral tablet
- Corlanor (ivabradine) oral solution

FDA Approved Indication(s)

- Adults:
  - To reduce the risk of hospitalization for worsening heart failure in adult 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.
- Pediatric:
  - For treatment of stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate.

Dosing

- Adults:
  - Starting dose 5 mg twice daily
  - Adjust dose to achieve resting heart rate between 50 and 60 bpm
  - Max: 7.5mg twice daily
- Pediatrics <40kg:
  - Starting dose of 0.05 mg/kg twice daily
  - Adjust to target heart rate per package insert
  - Max: 0.2mg/kg twice daily for patients 6 months-1 year, 0.3mg/kg twice daily for patients 1 year and older (up to 7.5 mg twice daily)
- Pediatrics 40 kg and greater:
  - Starting dose of 2.5 mg twice daily
  - Adjust to target heart rate per package insert
  - Max: 7.5 mg twice daily

Initial Authorization Criteria

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

Last Reviewed: 5/12/21, 3/9/22, 5/10/23, 5/8/24
Effective Date: 7/1/21, 5/1/22, 6/15/24

OHSUHealth Services

2. Is the request for renewal of a previously approved Corlanor (ivabradine) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a confirmed diagnosis of symptomatic chronic heart failure with a LVEF of ≤35% for adults or ≤45% for pediatrics? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the member 6 months of age or older?
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the member in normal sinus rhythm with a resting heart rate meeting one of the following? (Provide supporting documentation)
        - Age 6 months to 1 year: ≥105 bpm
        - Age 1 to 3 years: ≥95 bpm
        - Age 3 to 5 years: ≥75 bpm
        - Age 5 years and older: ≥70 bpm
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the request for a pediatric patient with dilated cardiomyopathy?
    a. If yes, continue to #9
    b. If no, continue to #8
8. Has the member previously trialed at least one of the following from each class at the maximum tolerated doses with an inadequate response, intolerance, or contraindication and do they plan to continue treatment at maximum tolerated doses? (Provide supporting documentation)
        - Beta Blocker: carvedilol 25mg twice daily, metoprolol succinate 200mg/day
        - ACE inhibitor/ ARB: captopril 50mg three times daily, enalapril 10mg twice daily, lisinopril 20-40mg/day, ramipril 5mg twice daily, losartan 150mg/day
        - Mineralocorticoid receptor agonist: spironolactone 25mg/day
    a. If yes, continue to #9
    b. If no, clinical review required

OHSUHealth Services

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

Reauthorization Criteria

1. Is Corlanor (ivabradine) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for a pediatric patient with dilated cardiomyopathy?
    a. If yes, continue to #4
    b. If no, continue to #3
3. Does the member continue to be adherent to maximally tolerated doses with their beta blocker, ACE/ARB/neuprilysin inhibitor, and mineralocorticoid therapies? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the requested medication being prescribed by, or in consultation with, a cardiologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 19 April. 2021].
2. Corlanor™ (ivabradine) oral tablet [package insert]. Thousand Oaks, CA: Amgen, Inc 2019.
3. Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DE Jr, Drazner MH, Fonarow GC, Geraci SA, Horwich T, Januzzi JL, Johnson MR, Kasper EK, Levy WC, Masoudi FA, McBride PE, McMurray JJ, Mitchell JE, Peterson PN, Riegel B, Sam F, Stevenson LW, Tang WH, Tsai EJ, Wilkoff BL; American College of Cardiology Foundation; American Heart Association Task Force on Practice Guidelines. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American

Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013 Oct 15;62(16):e147-239. doi: 10.1016/j.jacc.2013.05.019. Epub 2013 Jun 5. PMID: 23747642.

4. Yancy, Clyde W., et al. "2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America." Journal of the American College of Cardiology 70.6 (2017): 776-803.

OHSUHealth Services

COVID-19 Test Kit
Prior Authorization Guidelines

Affected Medication

- COVID-19 Test Kits

Indication

- Detection of the presence or absence of SARS-CoV-2 antigens

Dosing

- Refer to test kit specific instructions for use

Initial Authorization Criteria

1. Is the requested COVID-19 test kit authorized by the FDA? (i.e. FDA approved or Emergency Use Authorization)
    a. If yes, continue to #2
    b. If no, deny. Not FDA approved

2. Were the COVID-19 test kit(s) purchased on or after November 8th 2021?
    a. If yes, continue to #3
    b. If no, clinical review required

3. Has the member received eight (8) or more test kits in the past 30 days?
    a. If yes, continue to #4
    b. If no, approve for up to 8 test kits

4. Does the member have symptoms consistent with COVID-19 (i.e. fever, chills, cough, shortness of breath or difficulty breathing, fatigue, sore throat, etc.)? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, continue to #5

5. Does the member have a confirmed or suspected exposure to COVID-19? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 11/10/21, 3/17/22, 5/10/23, 5/8/24
Effective Date: 1/1/22, 1/15/22

OHSUHealth Services

6. Has rationale been provided for the need for greater than eight (8) test kits per month or why other test kits cannot be used (i.e. Inteliswab Rapid, Quickvue At-Home, BD Veritor System, Binaxnow)? (Provide supporting rationale)
    a. If yes, approve for one test kit
    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. "Coronavirus Disease 2019 (COVID-19) – Symptoms." Centers for Disease Control and Prevention, 22 Feb. 2021, www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.
2. "In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2." U.S. Food and Drug Administration, 25 Oct. 2021, www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2.
3. "CCO Weekly Update - October 25, 2021." The Oregon Health Authority and Department of Human Services, 25 Oct. 2021, content.govdelivery.com/accounts/ORDHS/bulletins/2f81289.

Last Reviewed: 11/10/21, 3/17/22, 5/10/23, 5/8/24
Effective Date: 1/1/22, 1/15/22

OHSU Health Services

Daybue® (trofinetide)
Prior Authorization Guidelines

Affected Medication(s)

- Daybue (trofinetide) oral solution

FDA Approved Indication(s)

- Treatment of Rett syndrome in adults and pediatric patients 2 years of age and older

Dosing

- Refer to package insert for dosing recommendations

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is Daybue® (trofinetide) being requested for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member 2 years of age or older?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have documentation of typical Rett syndrome according to the Rett Syndrome Diagnostic Criteria with a disease-causing mutation in the MECP2 gene as confirmed by genetic testing? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have a current clinically significant cardiovascular, endocrine (such as hypo- or hyperthyroidism, Type 1 diabetes mellitus, or uncontrolled Type 2 diabetes mellitus), renal, hepatic,

respiratory or gastrointestinal disease (such as celiac disease or inflammatory bowel disease)? (Provide supporting documentation)

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

7. Does the member have a history of or current cerebrovascular disease or brain trauma? (Provide supporting documentation)

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

8. Does the member have significant, uncorrected visual or hearing impairment? (Provide supporting documentation)

   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 or neurologist?

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

Reauthorization Criteria

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

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

2. Were updated chart notes (within past year) provided with documentation of clinical response to prior therapy received?

   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 or neurologist?

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

Note:

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

Last Reviewed: 7/12/23
Effective Date: 8/15/23

References:

1. DAYBUE (trofinetide) oral solution, [package insert]. San Diego, CA: Acadia Pharmaceuticals Inc.; 2023.
2. Drugs@FDA: FDA Approved Drug Products. 2023. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 27 Mar. 2023].
3. Neul, J. L., Percy, A. K., Benke, T. A., Berry-Kravis, E. M., Glaze, D. G., Peters, S. U., Jones, N. E., & Youakim, J. M. (2022). Design and outcome measures of LAVENDER, a phase 3 study of trofinetide for Rett syndrome. Contemporary clinical trials, 114, 106704.
4. Fu, C., Armstrong, D., Marsh, E., Lieberman, D., Motil, K., Witt, R., Standridge, S., Nues, P., Lane, J., Dinkel, T., Coenraads, M., von Hehn, J., Jones, M., Hale, K., Suter, B., Glaze, D., Neul, J., Percy, A., & Benke, T. (2020). Consensus guidelines on managing Rett syndrome across the lifespan. BMJ paediatrics open, 4(1), e000717.
5. Jeffrey L. Neul, , Kaufmann, W.E., Glaze, D.G., Christodoulou, J., Clarke, A.J., Bahi-Buisson, N., Leonard, H., Bailey, M.E.S., Schanen, N.C., Zappella, M., Renieri, A., Huppke, P., Percy, A.K. and (2010), Rett syndrome: Revised diagnostic criteria and nomenclature. Ann Neurol., 68: 944-950.

OHSU Health Services

Desmopressin acetate
Prior Authorization Guidelines

Affected Medication(s)

- Desmopressin acetate nasal spray
- Desmopressin acetate subcutaneous solution

FDA Approved Indication(s)

Nasal Spray:

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

Injection Solution:

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

Dosing

Nasal Spray:

- Adults: 10 mcg once daily into one nostril up to 40 mcg once daily (or 40 mcg divided into two or three daily doses)
- Pediatrics 4 years of age and older: recommended starting does is 10 mcg once daily into one nostril. The dose can be titrated up to 30 mcg once daily (or 30 mcg divided into two daily doses, typically with 20 mcg given in the morning and 10 mcg given at nighttime).

Injection Solution (Subcutaneous administration only):

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

Initial Authorization Criteria

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

Last Reviewed: 7/23/19, 3/11/20, 5/12/21, 5/11/22, 11/9/22, 7/12/23
Effective Date: 9/15/19, 1/1/20, 7/1/22, 1/1/23

OHSUHealth Services

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

3. Is desmopressin acetate being requested for treatment of central diabetes insipidus?
    a. If yes, continue to #4
    b. If no, clinical review required

4. Is the medication being administered through an intravenous (IV) route?
    a. If yes, clinical review required (IV medications are not covered under pharmacy benefit)
    b. If no, continue to #5

5. Does the member have documentation of an inadequate response, intolerance, or contraindication to oral tablets OR has medical rationale been provided for the avoidance of oral tablets? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

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

Reauthorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (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 (i.e. control of nocturia associated with DI)? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required

Last Reviewed: 7/23/19, 3/11/20, 5/12/21, 5/11/22, 11/9/22, 7/12/23
Effective Date: 9/15/19, 1/1/20, 7/1/22, 1/1/23

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

Note:

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

References:

1. Drugs@FDA: FDA Approved Drug Products. 2018. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 2 July 2019].
2. DDAVP (desmopressin acetate spray) [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; October 2018.
3. DDAVP (desmopressin acetate oral tablet) [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; January 2018
4. DDAVP (desmopressin acetate injection) [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; August 2018

Last Reviewed: 7/23/19, 3/11/20, 5/12/21, 5/11/22, 11/9/22, 7/12/23
Effective Date: 9/15/19, 1/1/20, 7/1/22, 1/1/23

OHSU Health Services

Diacomit ® (stiripentol)
Prior Authorization Guidelines

Affected Medication(s)

- Diacomit oral capsule
- Diacomit oral powder packet

FDA Approved Indication(s)

- Adjunctive treatment of seizures associated with Dravet syndrome in conjunction with clobazam in patients 6 months of age or older and weighing ≥7 kg
- Note: There is no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome

Dosing

- 50 mg/kg/day, administered in 2 or 3 divided doses

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request a renewal of a previously approved Diacomit (stiripentol) prior authorization and provided indication is for the same as previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is Diacomit (stiripentol) being requested for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Has the patient previously trialed valproate, topiramate, and clobazam and continued to have 4 or more generalized tonic-clonic seizures per month despite optimized therapy? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Will Diacomit (stiripentol) be used in conjunction with clobazam?

Last Reviewed: 9/24/19, 5/13/20, 7/14/21, 9/14/22, 9/13/23
Effective Date: 10/1/19, 7/1/20, 11/15/22

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

6. Is the treatment being 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 documented indication Food and Drug Administration (FDA) approved or supported by major compendia?

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

2. Were updated chart notes (within the past 6 months) with documentation of at least a 50% decrease in the frequency of generalized clonic and tonic-clonic seizures?

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

3. Will Diacomit (stiripentol) be used in combination with clobazam?

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

4. Is the treatment being prescribed by or in consultation with a neurologist?

    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

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

References:

1. Lexicomp [internet database]. Hudson, OH: Wolters Kluwer. Updated periodically. Accessed August 13, 2019.
2. Stiripentol (Diacomit) Capsule and powder for suspension [package insert]. Redwood City, USA: Bicodex Inc; July 2022.

Last Reviewed: 9/24/19, 5/13/20, 7/14/21, 9/14/22, 9/13/23
Effective Date: 10/1/19, 7/1/20, 11/15/22

3. Drugs@FDA: FDA Approved Drug Products. 2019. accessdatafda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 13 Aug. 2019].
4. National Institute for Health and Care Excellence; Epilepsies: Diagnosis and Management Clinical Guidelines. NICE Guideline. May 2021. Available at: https://www.nice.org.uk/guidance/cg137
5. Wilmhurst JM, Gaillard WD, Vinayan KP, et al. Summary of recommendations for the management of infantile seizures: Task force report for the ILAE commission of pediatrics. Epilepsia. 2015; 56(8):1185-1197

Last Reviewed: 9/24/19, 5/13/20, 7/14/21, 9/14/22, 9/13/23
Effective Date: 10/1/19, 7/1/20, 11/15/22

Doptelet® (avatrombopag) & Mulpleta® (lusutrombopag)
Prior Authorization Guidelines

Affected Medication(s)

- Mulpleta (lusutrombopag) oral tablet
- Doptelet (avatrombopag) oral tablet

FDA Approved Indication(s)

- Doptelet:
  - For the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure
  - The treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment
- Mulpleta:
  - For the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure

Dosing

- Doptelet:
  - Chronic liver disease:
    - Platelet count <40: 60 mg for 5 days
    - Platelet count 40-50: 40 mg for 5 days
  - Chronic ITP
    - Starting dose 20mg once daily, refer to package insert for dose adjustments based on platelet counts
- Mulpleta
  - 3 mg for 7 days 8 to 14 days prior to a scheduled procedure

Initial Authorization Criteria

1. Is the request for continuation of Doptelet for the treatment of chronic immune thrombocytopenia?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)

Last Reviewed: 11/9/22, 11/8/23, 5/8/24
Effective Date: 1/15/23, 12/15/23

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. What indication is the medication being requested for?

    a. Thrombocytopenia in adult with chronic liver disease, continue to corresponding criteria
    b. Thrombocytopenia in adult with chronic immune thrombocytopenia, continue to corresponding criteria (Doptelet only)

<u>Thrombocytopenia in adult with chronic liver disease</u>

1. Does the member have a platelet count less than 50 x 10^9? (Provide documentation of platelet count)

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

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

3. Is the treatment being prescribed by, or in consultation with, a hematologist, hepatologist, or gastroenterologist?

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

4. What is the requested medication?

    a. Doptelet (avatrombopag), continue to #5
    b. Mulpleta (lusutrombopag), continue to #6

5. 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

6. Does the member have a previous trial with inadequate response, intolerance, or contraindication to Doptelet? (Provide supporting documentation)

    a. If yes, continue to #7

b. If no, clinical review required

7. 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

Thrombocytopenia in adults with chronic immune thrombocytopenia (ITP)

1. Does the member have a platelet count less than 30 x 10^9/L (30,000/mm) that was taken within the last 30 days? (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 each greater than or equal to 50 x 10^9/L (50,000/mm))? (Provide supporting documentation)

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

3. Is the medication being prescribed by, or in consultation with, a hematologist?

    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. Were updated chart notes (within previous 6 months) provided with documentation of significant clinical response to prior therapy received? (i.e. platelet count greater than or equal to 50 x 10^9/L (50,000/mm))? (Provide supporting documentation)

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

3. Is the treatment being prescribed by, or in consultation with, a hematologist?
    a. If yes, approve for 12 months 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. Doptelet Prescribing Information. Durham, NC: Dova Pharmaceuticals, Inc.; May 2018. Available at: https://www.doptelet.com.
2. Mulpleta Prescribing Information. Florham Park, NJ: Shionogi Inc.; August 2018. Available at: https://www.mulpleta.com/
3. Hayashi H, Beppu T, Shirabe K, Maehara Y, and Baba H. Management of thrombocytopenia due to liver cirrhosis: a review. World J Gastroenterol. 2014; 20(10): 2595-2605.
4. George, PhD, Arnold, MD. Immune thrombocytopenia (ITP) in adults: Second-line and subsequent therapies. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed September 28, 2022.

OHSU Health Services

Duchenne Muscular Dystrophy (DMD) Glucocorticoids Prior Authorization Guidelines

Affected Medication(s)

- Agamree (vamorolone) oral suspension
- deflazacort oral tablet

FDA Approved Indication(s)

- Agamree: Treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older
- Deflazacort: Treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older

Dosing

- Agamree: 6 mg/kg once daily
- Deflazacort 0.9 mg/kg once daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a documented diagnosis of Duchenne muscular dystrophy (DMD) as confirmed by genetic testing? (Provide supporting documentation of diagnosis)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Has the member previously trialed prednisone with inadequate response, intolerance, or contraindication? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review is required

Last Reviewed: 5/8/24
Effective Date: 6/15/24

OHSUHealth Services

6. Is the request for Agamree?
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the member less than 5 years of age?
    a. If yes, continue to #9
    b. If no, continue to #8
8. Has the member previously trialed deflazacort with inadequate response, intolerance, or contraindication? (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, clinical review is required
9. Is the medication being prescribed by, or in consultation with, a provider who specializes in the management of Duchenne muscular dystrophy?
    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 or major compendia supported? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of significant clinical response to therapy received? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by, or in consultation with, a provider who specializes in the management of Duchenne muscular dystrophy?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and

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

References:

1. AGAMREE (vamorolone) oral suspension [package insert]. Burlington, MA: Santhera Pharmaceuticals; 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2022. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 17 Jan. 2024].
3. Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016;86(5):465-472.
4. Guglieri M, Clemens PR, Perlman SJ, et al. Efficacy and Safety of Vamorolone vs Placebo and Prednisone Among Boys With Duchenne Muscular Dystrophy: A Randomized Clinical Trial. JAMA Neurol. 2022;79(10):1005-1014.

OHSU Health Services

Dupixent® (dupilumab)
Prior Authorization Guidelines

Affected Medication(s)

- Dupixent (dupilumab) subcutaneous solution

FDA Approved Indication(s)

- Treatment of patients ages 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
- As an add-on maintenance treatment in patients with moderate-to-severe asthma ages 6 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma
- As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP)
- Treatment of pediatric patients 12 years and older weighting at least 40 kg with eosinophilic esophagitis (EoE)
- Treatment of adult patients with prurigo nodularis

Dosing

- Refer to package insert for dosing information

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Will Dupixent (dupilumab) be used concurrently with other biologic therapy? (Examples: Actemra, Enbrel, Cimzia, Humira, Otezla, Cosentyx, etc.)
    a. If yes, clinical review required
    b. If no, continue to #3
3. Is the request a renewal of a previously approved Dupixent (dupilumab) prior authorization for the same indication that it was previously approved?
    a. If yes, continue to Reauthorization

Last Reviewed: 11/26/19, 7/14/21, 11/10/21, 9/14/22, 11/9/22, 7/12/23, 11/8/23
Effective Date: 1/15/20, 9/1/21, 1/15/23, 12/15/23

b. If no, continue to #4

4. What is the diagnosis that the medication is being requested for?

    a. Atopic dermatitis, continue to corresponding criteria
    b. Moderate to severe asthma, continue to corresponding criteria
    c. Chronic rhinosinusitis, continue to corresponding criteria
    d. Eosinophilic esophagitis, continue to corresponding criteria
    e. Prurigo nodularis, continue to corresponding criteria
    f. Other indication, clinical review required

Atopic Dermatitis

1. Does the member currently have severe inflammatory skin disease defined as having functional impairment (e.g. inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction)? (Provide supporting documentation)

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

2. Does the member have one or more of the following: A) At least 10% body surface area involved AND/OR B) Hand, face, foot or mucous membrane involvement? (Provide supporting documentation)

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

3. Does the member have a documented trial with an insufficient response, intolerance or contraindication to a minimum 4-week trial with at least one of the following? (Provide supporting documentation)

    - Moderate to high potency topical steroids AND a topical non-steroidal agent (i.e. tacrolimus)
    - An oral immunomodulator (i.e. cyclosporine, methotrexate, or oral corticosteroids)

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

4. Is the requested treatment dose appropriate?

    a. If yes, continue to #5

b. If no, clinical review required

5. Is Dupixent (dupilumab) being prescribed by, or in consultation with, a dermatologist, allergist, or immunologist?

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

Moderate to severe asthma

1. Does the member have a baseline forced expiratory volume in 1 second (FEV1) <80% of predicted normal for adults or FEV1 of < 90% in adolescents despite adherence to asthma maintenance regimen? (Provide supporting documentation)

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

2. Has the member experienced 2 or more severe exacerbations within the last 12 months that require systemic steroid therapy, an urgent care visit, or hospitalization despite adherence to asthma maintenance regimen? (Provide documentation of exacerbation history)

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

3. Does the member have a baseline eosinophil count of 300 cells/mcL or above? (Provide supporting documentation)

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

4. Is the member currently on a high-dose inhaled corticosteroids (ICS)? (Provide documentation of medication history)

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

5. Is the member currently on 2 additional asthma controller drugs? (i.e. long-acting inhaled beta-agonist, leukotriene antagonist, or long-acting muscarinic antagonist)

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

OHSUHealth Services

6. Has the member been adherent (≥75% utilization) to current asthma therapy in the past 12 months?
    a. If yes, continue to #7
    b. If no, clinical review required

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

8. Is Dupixent (dupilumab) being prescribed by or in consultation with an allergist or a pulmonologist?

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

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

1. Does the member have documentation of bilateral nasal polyps confirmed by endoscopy with a total nasal polyp score (NPS) of 5 or greater and NPS score of 2 or greater per nostril? (NPS range 0-4 per nostril, 0-8 total)
    - 0 = no polyps
    - 1 = small polyps in the middle meatus not reaching below the inferior border of the middle turbinate
    - 2 = polyps reaching below the lower border of the middle turbinate
    - 3 = large polyps reaching the lower border of the inferior turbinate or polyps medial to the middle turbinate
    - 4 = large polyps causing complete obstruction of the inferior nasal cavity)

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

2. Has the member had two (2) or more of the following symptoms of chronic rhinosinusitis for ≥12 weeks (Provide supporting documentation):
    - Mucopurulent discharge
    - Nasal obstruction and congestion
    - Decreased or absent sense of smell
    - Facial pressure or pain

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

OHSUHealth Services

3. Has the member had prior sino-nasal surgery OR required systemic corticosteroids in the past 2 years? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, continue to #4

4. Has the member tried two (2) separate trials (≥12 weeks) with an intranasal corticosteroid with an inadequate response? (i.e. fluticasone, triamcinolone, mometasone) (Provide therapies tried)
    a. If yes, continue to #5
    b. If no, clinical review required

5. Will the member continue to receive standard treatment therapies (i.e. intranasal corticosteroids) in addition to using Dupixent (dupilumab)? (Provide documentation of treatment plan)
    a. If yes, continue to #6
    b. If no, clinical review required

6. Is Dupixent (dupilumab) being prescribed by or in consultation with an Otolaryngologist, Allergist or Immunologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

<u>Eosinophilic Esophagitis (EoE)</u>

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 diagnosis of eosinophilic esophagitis (confirmed by endoscopic biopsy) defined as greater than or equal to 15 intraepithelial eosinophils per high-power field (eos/hpf)? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required

3. Does the member currently have on-going symptoms of dysphagia (pain when swallowing, drooling, sensation of food getting stuck in the throat, chest pain) despite dietary modifications? (Provide documentation of symptoms)
    a. If yes, continue to #4
    b. If no, clinical review required

4. Does the patient weigh greater than or equal to 40 kg? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required

5. Does the member have a documented trial with an insufficient response, intolerance or contraindication to a minimum 8-week trial of at least one proton pump inhibitor (omeprazole, lansoprazole, pantoprazole, etc.)? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

6. Does the member have a documented trial with insufficient response, intolerance or contraindication to at least one topical (budesonide, fluticasone) or oral glucocorticoid agent? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required

7. Is Dupixent (dupilumab) being prescribed or in consultation with a gastroenterologist or other appropriate specialist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Prurigo Nodularis

1. Does the member currently have severe inflammatory skin disease defined as having functional impairment (e.g. inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction)? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required

OHSUHealth Services

2. Does the member have one or more of the following: At least 10% body surface area involved AND/OR hand, face, foot or mucous membrane involvement? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Has the member had one or more unsuccessful treatments with moderate to high potency corticosteroids? (E.g. betamethasone ointment/cream, clobetasol ointment, intralesional triamcinolone acetonide, etc.) (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, continue to #4
4. Does the member have a contraindication or is clinical rationale provided for avoiding moderate to high potency corticosteroids? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have prior treatment failure(s) with 1 or more topical calcineurin inhibitors? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, continue to #6
6. Does the member have a contraindication or is clinical rationale provided for avoiding topical calcineurin inhibitors? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Has the member had two or more unsuccessful 12-week minimum trials with: cyclosporine, methotrexate, or phototherapy? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Is the requested treatment dose appropriate?
    a. If yes, continue to #9
    b. If no, clinical review required
9. Is Dupixent (dupilumab) being prescribed by, or in consultation with, a dermatologist?
    a. If yes, approve for 6 months

b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia? (Provide 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. Is the requested treatment dose appropriate?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the treatment being prescribed by or in consultation with a specialist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. Dupixent (dupilimab) [package insert]. Bridgewater, NJ/Tarrytown, NY: Sanofi-Aventis U.S. LLC and Regeneron Pharmaceuticals, Inc.; September 2022.
2. Dupixent. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed July 10, 2019.
3. Oregon Health Plan. Prioritized List of Health Services. October 1, 2023. Available at: https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx.

Last Reviewed: 11/26/19, 7/14/21, 11/10/21, 9/14/22, 11/9/22, 7/12/23, 11/8/23
Effective Date: 1/15/20, 9/1/21, 1/15/23, 12/15/23

4. Cloutier MM, et al. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. J Allergy Clin Immunol. 2020 Dec;146(6):1217-1270. doi: 10.1016/j.jaci.2020.10.003. Erratum in: J Allergy Clin Immunol. 2021 Apr;147(4):1528-1530. PMID: 33280709; PMCID: PMC7924476.Orlandi RR, Kingdom TT, Hwang PH, et al. International consensus statement on allergy and rhinology: rhinosinusitis. Int Forum Allergy Rhinol. 2016;6:S22-S209
5. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. Ann Allergy Asthma Immuno. 2014;113:347-385
6. Hamilos DL. Chronic rhinosinusitis: management. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on July 9, 2021)
7. Hirano, Ikuo, et al. "AGA institute and the joint task force on allergy-immunology practice parameters clinical guidelines for the management of eosinophilic esophagitis." Gastroenterology 158.6 (2020): 1776-1786.
8. Elmariah S, Kim B, Berger T, et al. Practical approaches for diagnosis and management of prurigo nodularis: United States expert panel consensus. J Am Acad Dermatol. 2021;84(3):747-760. doi:10.1016/j.jaad.2020.07.025
9. Study of dupilumab for the treatment of patients with prurigo nodularis, inadequately controlled on topical prescription therapies or when those therapies are not advisable (PRIME2)." (2020). Identification No. NCT04202679. Retrieved from https://clinicaltrials.gov/ct2/show/NCT04202679.

OHSUHealth Services

Enspryng® (satralizumab-mwge)
Prior Authorization Guidelines

Affected Medication(s)

- Enspryng subcutaneous solution

FDA Approved Indication(s)

- Treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive

Dosing

- Recommended loading dose for first three administrations is 120mg by subcutaneous injection at weeks 0, 2, and 4, followed by maintenance dosage of 120mg every four weeks

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request a renewal of a previously approved Enspryng (satralizumab-mwge) prior authorization and indication is for the same as previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member currently have documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD) and are they anti-aquaporin-4 (AQP4) antibody positive? (Provide supporting documentation of diagnosis and AQP4 status)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the member 18 years of age or older?
    a. If yes, continue to #6

Last Reviewed: 1/13/21, 1/12/22, 1/11/23, 1/10/24
Effective Date: 3/1/21, 2/15/24

OHSUHealth Services

b. If no, clinical review required

6. Does the member have documentation of 1 relapse in the previous 12 months? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Has the member previously trialed at least TWO of the following for 12 weeks or greater with inadequate response, intolerance, or contraindication: azathioprine, methotrexate, or mycophenolate? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Has the member previously trialed rituximab with inadequate response, intolerance, or contraindication? (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, clinical review required
9. Is the treatment being prescribed by, or in consultation with, a neurologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within the past 6 months) provided with documentation of significant clinical response? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by or in consultation with a neurologist?
    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

OHSUHealth Services

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. ENSPRYNG™ (satralizumab-mwge) injection, [package insert]. San Francisco, CA: Genentech, Inc.; 2020.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 19 Oct, 2020].
3. Sellner, Johann, et al. "EFNS guidelines on diagnosis and management of neuromyelitis optica." European journal of neurology 17.8 (2010): 1019-1032.
4. Traboulsee, A., et al. "Efficacy and safety of satralizumab monotherapy for relapse prevention in neuromyelitis optica spectrum disorder (NMOSD): Results from SAkuraStar, a double-blind placebo-controlled phase 3 clinical study." Journal of the Neurological Sciences 405 (2019): 171.
5. Yamamura, Takashi, et al. "Efficacy of satralizumab (SA237) in subgroups of patients in SAkuraSky: a phase III double-blind, placebo-controlled, add-on study in patients with neuromyelitis optica spectrum disorder (NMOSD)(S43. 008)." (2019): S43-008.

Last Reviewed: 1/13/21, 1/12/22, 1/11/23, 1/10/24
Effective Date: 3/1/21, 2/15/24

OHSU Health Services

Epidiolex (cannabidiol)
Prior Authorization Guidelines

Affected Medication(s)

- Epidiolex (cannabidiol) oral solution

FDA Approved Indication(s)

- Treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS) or tuberous sclerosis complex (TSC) in patients 1 year of age and older

Dosing

- Starting dose: 2.5mg/kg taken twice daily for one week
- Maintenance dose:
  - LGS or DS: 5mg/kg twice daily up to maximum dose 10mg/kg twice daily
  - TSC: 12.5 mg/kg twice daily

Initial Authorization Criteria

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

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

3. Does the member have a diagnosis of Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or seizures associated with tuberous sclerosis complex?
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the member 1 year of age or older?
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the member currently taking at least one other antiepileptic drug with inadequate response? (i.e. valproic acid, lamotrigine, topiramate, felbamate) (Provide supporting documentation)

Last Reviewed: 1/22/19, 3/11/20, 7/14/21, 9/14/22, 9/13/23
Effective Date: 2/15/19, 1/1/20, 9/1/21, 11/15/22

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

6. For members with LGS, has the member had a previous trial with inadequate response, intolerance, or contraindication to clobazam? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required

7. Will the member continue therapy with at least one other antiepileptic drug in combination with Epidiolex (cannabidiol)? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required

8. Have baseline liver function tests (LFT) including serum bilirubin been provided? (If abnormal, verify dose using hepatic impairment dosing recommendations) (Document lab values)
    a. If yes, continue to #9
    b. If no, clinical review required

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

3. Have updated liver function tests (LFT) including serum bilirubin been provided? (If abnormal, verify dose using hepatic impairment dosing recommendations)
    a. If yes, continue to #4
    b. If no, clinical review required

4. Is the treatment being prescribed by, or in consultation with, a neurologist?

a. If yes, approve for 12 months reauthorization
b. If no, clinical review required

Note:

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

References:

1. EPIDIOLEX (cannabidiol) oral solution [package insert]. Carlsbad, CA: Greenwich Biosciences, Inc.; 2018.

2. National Institute of Neurological Disorders and Stroke. Dravet Syndrome Information Page. Available at: https://www.ninds.nih.gov/Disorders/All-Disorders/Dravet-Syndrome-Information-Page.

3. National Institute for Health and Care Excellance (NICE). Epilepsies: diagnosis and management. Available at: https://www.nice.org.uk/guidance/CG137/chapter/Appendix-E-Pharmacological-treatment.

4. Ferrie CD, Patel A. Treatment of lennox-gastaut syndrome. Eur J Paediatr Neurol. 2009 Nov;13(6):493-504.

5. American Academy of Neurology and the American Epilepsy Society. Treatments for Refractory Epilepsy; Guideline Summary for Clinicians. Available at: http://tools.aan.com/professionals/practice/pdfs/clinician_ep_treatment_e.pdf.

6. National Institute of Neurological Disorders and Stroke. Lennox-Gastaut Syndrome Information Page. Available at: https://www.ninds.nih.gov/Disorders/All-Disorders/Lennox-Gastaut-Syndrome-Information-Page.

7. Hancock EC, Cross JH. Treatment of Lennox-Gastaut syndrome. Cochrane Database of Systematic Reviews 2013, Issue 2. Art. No.: CD003277.

8. Wirrell EC. Treatment of Dravet Syndrome. Can J Neurol Sci. 2016 Jun;43 Suppl 3:S13-8. doi: 10.1017/cjn.2016.249. https://www.ncbi.nlm.nih.gov/pubmed/27264138

9. Kim HJ, Kim SH, MD, Kang HC, et al. Adjunctive Levetiracetam Treatment in Pediatric Lennox-Gastaut Syndrome. Pediatr Neurol. 2014 Oct;51(4):527-31. doi: 10.1016/j.pediatrneurol.2014.06.004. Epub 2014 Jun 25. https://www.ncbi.nlm.nih.gov/pubmed/25266616

10. Asadi-Pooya AA. Lennox-Gastaut syndrome: a comprehensive review. Neurol Sci. 2018 Mar;39(3):403-414. doi: 10.1007/s10072-017-3188-y. Epub 2017 Nov 9. https://www.ncbi.nlm.nih.gov/pubmed/29124439

Last Reviewed: 1/22/19, 3/11/20, 7/14/21, 9/14/22, 9/13/23
Effective Date: 2/15/19, 1/1/20, 9/1/21, 11/15/22

OHSU Health Services

Evrysdi (risdiplam)
Prior Authorization Guidelines

Affected Medication(s)

- Evrysdi (risdiplam) oral powder for solution

FDA Approved Indication(s)

- Treatment of spinal muscular atrophy (SMA) in pediatric and adult patients

Dosing

- Less than 2 months of age: 0.15 mg/kg/day
- 2 months to less than 2 years of age: 0.2 mg/kg/day
- 2 years of age and older, weighing less than 20 kg: 0.25 mg/kg/day
- 2 years of age and older, weight 20 kg or more: 5 mg/day

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Evrysdi (risdiplam) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a confirmed diagnosis of SMA type 1, 2, or 3, with four or fewer copies of SMN2? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have advanced SMA disease defined as ventilator dependence >16 hours/day or tracheostomy? (Provide supporting documentation)
    a. If yes, clinical review required

Last Reviewed: 3/10/21, 1/12/22, 1/11/23, 1/10/24
Effective Date: 5/1/21, 3/1/22, 3/15/23, 2/15/24

b. If no, continue to #6

6. Was baseline motor function assessed by one of the following? (Provide supporting documentation)

    - Hammersmith Infant Neurological Examination (HINE-2)
    - Motor Function Measure 32 (MFM32)
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
    - Upper Limb Module (ULM)
    - Revised Upper Limb Module (RULM)
    - Hammersmith Functional Motor Scale (HFMS)

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

7. Does the member have a history of prior treatment with Zolgensma or will this medication be used in combination with Spinraza?

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

8. Is the requested medication being 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 Evrysdi (risdiplam) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)

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

2. Were updated chart notes (within 1 month of reauthorization request date) with documentation of significant clinical response to therapy defined as improvement from baseline in one of the following received? (Provide supporting documentation)

    - Hammersmith Infant Neurological Examination (HINE-2)
    - Motor Function Measure 32 (MFM32)
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
    - Upper Limb Module (ULM)
    - Revised Upper Limb Module (RULM)

- Hammersmith Functional Motor Scale (HFMS)

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

3. Is the requested medication being prescribed by, or in consultation with, a neurologist?

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

Note:

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

References:

1. Drugs@FDA: FDA Approved Drug Products. 2022. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 30 Nov. 2022].
2. EVRYSDI™ (risdiplam) oral solution [package insert]. San Francisco, CA: Genentech, Inc 2022.
3. Glascock, Jacqueline, et al. "Treatment algorithm for infants diagnosed with spinal muscular atrophy through newborn screening." Journal of neuromuscular diseases 5.2 (2018): 145-158.
4. Glascock, Jacqueline, et al. "Revised recommendations for the treatment of infants diagnosed with spinal muscular atrophy via newborn screening who have 4 copies of SMN2." Journal of neuromuscular diseases 7.2 (2020): 97.
5. Michelson, David, et al. "Evidence in focus: Nusinersen use in spinal muscular atrophy: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology." Neurology 91.20 (2018): 923-933.

OHSU Health Services

Fasenra® (benralizumab)
Prior Authorization Guidelines

Affected Medication(s)

- Fasenra (benralizumab) autoinjector

FDA Approved Indication(s)

- As an add-on maintenance treatment for patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype

Note: Fasenra is not indicated for the treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus

Dosing

- 30mg administered subcutaneously every 4 weeks for the first three doses and then once every 8 weeks thereafter

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Will Fasenra (benralizumab) be used concurrently with other biologic therapy? (Example: Xolair, Nucala, Dupixent, Cinqair, etc.)
    a. If yes, clinical review required
    b. If no, continue to #3
3. Is the request for renewal of a previously approved Fasenra (benralizumab) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #4
4. Is Fasenra (benralizumab) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the member 12 years of age or older?
    a. If yes, continue to #6

Last Reviewed: 1/12/22, 1/11/23, 5/10/23, 5/8/24
Effective Date: 3/1/22, 6/15/23, 6/15/24

OHSUHealth Services

b. If no, clinical review required

6. Does the member have severe asthma as defined as one or more of the following? (Provide supporting documentation)
    - Symptoms throughout the day
    - Nighttime awakenings, often 7x/week
    - SABA use for symptom control occurs several times per day
    - Extremely limited normal activities
    - Lung function (percent predicted FEV1) <60%
    - Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

    a. If yes, continue to #7
    b. If yes, clinical review required
7. Does the member have asthma with an eosinophilic phenotype defined as baseline blood eosinophils ≥150 cells/μL within 6 weeks of dosing? (Provide supporting documentation)

    a. If yes, continue to #8
    b. If no, clinical review required
8. Has the member experienced 2 or more severe exacerbations within the last 12 months that require systemic steroid therapy, an urgent care visit, or hospitalization despite adherence to asthma maintenance regimen? (Provide documentation of exacerbation history)

    a. If yes, continue to #9
    b. If no, clinical review required
9. Is the member currently on a high-dose inhaled corticosteroid (ICS)? (Provide documentation of medication history)

    a. If yes, continue to #10
    b. If no, clinical review required
10. Is the member currently on one additional asthma controller drugs? (i.e. long-acting inhaled beta-agonist, leukotriene antagonist, or long-acting muscarinic antagonist) (Provide supporting documentation)

    a. If yes, continue to #11
    b. If no, clinical review required
11. Is the requested treatment dose appropriate?

    a. If yes, continue to #12
    b. If no, clinical review required
12. Is Fasenra (benralizumab) being prescribed by or in consultation with an allergist or a pulmonologist?

OHSUHealth Services

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

Reauthorization Criteria

1. Is the documented indication FDA approved or supported by major compendia? (Verify dosing with package insert)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within 1 year) provided with documentation of improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
    - Use of systemic corticosteroids
    - Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
    - Hospitalizations
    - ER visits
    - Unscheduled visits to healthcare provider
    - Improvement from baseline in forced expiratory volume in 1 second (FEV1)

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

Note:

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

References:

1. Fasenra [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals; February 2021. Accessed December 2021.
2. National Asthma Education and Prevention Program (NAEPP). Guidelines for the diagnosis and management of asthma. Expert Panel Report 3. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); August 2007.
3. Walford HH, Doherty TA. Diagnosis and management of eosinophilic asthma: a US perspective. J Asthma Allergy. 2014; 7: 53–65.

Last Reviewed: 1/12/22, 1/11/23, 5/10/23, 5/8/24
Effective Date: 3/1/22, 6/15/23, 6/15/24

4. Goldman M, Hirsch I, Zangrilli JG, et al. The association between blood eosinophil count and benralizumab efficacy for patients with severe, uncontrolled asthma: subanalyses of the Phase III SIROCCO and CALIMA studies. Curr Med Res Opin. 2017 Sep;33(9):1605-1613. doi:10.1080/03007995.2017.1347091. Epub 2017 Jul 19.
5. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS Guidelines on Definition, Evaluation, and Treatment of Severe Asthma. Eur Respir J 2014; 43: 343-373.
6. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. Eur Respir J 2020; 55: 1900588 [https://doi.org/10.1183/13993003.00588-2019].
7. National Asthma Education and Prevention Program (NAEPP). 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); December 2020.
8. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2021 Update. Available from: http://www.ginasthma.org. Accessed December 2021.

OHSU Health Services

Filspari (sparsentan)
Prior Authorization Guidelines

Affected Medication(s)

- Filspari (sparsentan) oral tablet

FDA Approved Indication(s)

- To reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression

Dosing

- 200 mg once daily for 14 days, then increase to the recommended dose of 400 mg daily if tolerated

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Filspari (sparsentan) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is Filspari (sparsentan) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member 18 years of age or older? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have documentation of primary immunoglobulin A nephropathy as proven by biopsy? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the patient have documentation of estimated glomerular filtration rate (eGFR) of 30 mL/min/1.73m^2 or greater? (Provide supporting documentation)

Last Reviewed: 5/10/23, 5/8/24
Effective Date: 6/15/23, 6/15/24

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

7. Does the patient have documentation of a total urine protein greater than or equal to 1 gram/day? (Provide supporting documentation)

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

8. Has the member previously trialed the following classes of medications at maximally indicated doses unless intolerance or contraindication is present? (Provide supporting documentation)

    - Angiotensin-converting enzyme inhibitor (i.e. lisinopril, benazepril, enalapril); OR
    - Angiotensin receptor blocker (i.e. irbesartan, losartan); AND
    - Sodium-glucose Cotransporter-2 inhibitor (i.e. Farxiga)

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

9. Is Filspari (sparsentan) being prescribed by, or in consult with, a nephrologist?

    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 or major compendia supported indication? (Provide supporting documentation)

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

2. Were updated chart notes (within past year) provided with documentation of significant clinical response to prior therapy received? (i.e. reduction in UPCR or UACR, increased or stable eGFR) (Provide supporting documentation)

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

3. Is Filspari (sparsentan) being prescribed by, or in consult with, a nephrologist?

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

Note:

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

References:

1. Filspari (sparsentan) tablets, [package insert]. San Diego, CA: Travere Therapeutics, Inc; 2023.

2. Drugs@FDA: FDA Approved Drug Products. 2023. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 22 Mar. 2023].

3. KDIGO Glomerular Diseases Work Group. 2021. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney International Supplements. 2021;11(2):1-221.

4. Wheeler, D. C., Toto, R. D., Stefansson, B. V., Jongs, N., Chertow, G. M., Greene, T., & Committees, D. C. T. (2021). A pre-specified analysis of the DAPA-CKD trial demonstrates the effects of dapagliflozin on major adverse kidney events in patients with IgA nephropathy. Kidney International, 100(1), 215-224.

Last Reviewed: 5/10/23, 5/8/24
Effective Date: 6/15/23, 6/15/24

Fintepla® (fenfluramine)
Prior Authorization Guidelines

Affected Medication(s)

- Fintepla oral solution

FDA Approved Indication(s)

- Treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome in patients 2 years of age and older

Dosing

- Initial starting dose: 0.1 mg/kg twice daily, which can be increased weekly based on efficacy and tolerability
- Patients not on concomitant Diacomit (stiripentol): The maximum daily maintenance dosage of Fintepla is 0.35 mg/kg twice daily (maximum daily dosage of 26 mg)
- Patients taking concomitant Diacomit (stiripentol) plus clobazam: The maximum daily maintenance dosage of Fintepla for patients taking these medications is 0.2 mg/kg twice daily (maximum daily dosage of 17 mg)

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request a renewal of a previously approved Fintepla (fenfluramine) prior authorization and indication is for the same as previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member age 2 years or older?
    a. If yes, continue to #5
    b. If no, clinical review required

Last Reviewed: 9/9/20, 9/8/21, 5/11/22, 5/10/23, 5/8/24
Effective Date: 11/1/20, 11/1/21, 7/1/22, 6/15/23, 6/15/24

OHSUHealth Services

5. What is the indication for which this medication is being requested?
    a. Dravet syndrome, continue to #6
    b. Lennox-Gastaut syndrome, continue to #9
6. Has the member previously trialed valproate and clobazam (unless intolerance or contraindication provided) and continued to have 4 or more convulsive seizures per month despite optimized therapy? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Has the member previously had an inadequate response, intolerance, or contraindication to Diacomit in combination with clobazam? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Will the member continue therapy with at least one other antiepileptic drug or antiepileptic treatment (i.e. vagal nerve stimulation or ketogenic diet) in combination with Fintepla? (Provide treatment regimen)
    a. If yes, continue to #11
    b. If no, clinical review required
9. Has the member previously trialed at least TWO of the following adjunctive treatments with an inadequate response, intolerance, or contraindication: lamotrigine, felbamate, topiramate, clobazam, or rufinamide? (Provide supporting documentation)
    a. If yes, continue to #10
    b. If no, clinical review required
10. Will the member continue therapy with at least one other antiepileptic drug in combination with Fintepla (fenfluramine)? (Provide supporting documentation)
    a. If yes, continue to #11
    b. b. If no, clinical review required
11. Is the treatment being 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 documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
    a. If yes, continue to #2

OHSUHealth Services

b. If no, clinical review required

2. Were updated chart notes (within the past 6 months) with documentation of at least a 50% decrease in the frequency of convulsive seizures compared to pre-therapy baseline?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Has the member continued therapy with at least one other antiepileptic drug or antiepileptic treatment (i.e. vagal nerve stimulation or ketogenic diet) in combination with Fintepla? (Provide treatment regimen)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the treatment being prescribed by or in consultation with a neurologist?
    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

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

References:

1. FINTEPLA® (fenfluramine) oral solution [package insert]. Emeryville, CA: Zogenix, Inc; March 2022.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 27 July. 2020].
3. Lagae, Lieven, et al. "Fenfluramine hydrochloride for the treatment of seizures in Dravet syndrome: a randomised, double-blind, placebo-controlled trial." The Lancet 394.10216 (2019): 2243-2254.
4. Nabbout, Rima, et al. "Fenfluramine for treatment-resistant seizures in patients with Dravet syndrome receiving stiripentol-inclusive regimens: a randomized clinical trial." JAMA neurology 77.3 (2020): 300-308.
5. National Institute for Health and Care Excellence; Epilepsies: Diagnosis and Management Clinical Guidelines. NICE Guideline. May 2021. Available at: https://www.nice.org.uk/guidance/cg137
6. Wilmhurst JM, Gaillard WD, Vinayan KP, et al. Summary of recommendations for the management of infantile seizures: Task force report for the ILAE commission of pediatrics. Epilepsia. 2015; 56(8):1185-1197
7. Wirrell, Elaine C., et al. "Optimizing the diagnosis and management of Dravet syndrome: recommendations from a North American consensus panel." Pediatric neurology 68 (2017): 18-34.

Last Reviewed: 9/9/20, 9/8/21, 5/11/22, 5/10/23, 5/8/24
Effective Date: 11/1/20, 11/1/21, 7/1/22, 6/15/23, 6/15/24

8. Kim HJ, Kim SH, MD, Kang HC, et al. Adjunctive Levetiracetam Treatment in Pediatric Lennox-Gastaut Syndrome. Pediatr Neurol. 2014 Oct;51(4):527-31. doi: 10.1016/j.pediatrneurol.2014.06.004. Epub 2014 Jun 25. https://www.ncbi.nlm.nih.gov/pubmed/25266616
9. Asadi-Pooya AA. Lennox-Gastaut syndrome: a comprehensive review. Neurol Sci. 2018 Mar;39(3):403-414. doi: 10.1007/s10072-017-3188-y. Epub 2017 Nov 9. https://www.ncbi.nlm.nih.gov/pubmed/29124439
10. Wirrell, EC, Hood, V, Knupp, KG, Meskis, MA, Nabbout, R, Scheffer, IE, et al. International consensus on diagnosis and management of Dravet syndrome. Epilepsia. 2022; 63: 1761– 1777.

OHSU Health Services

Fluticasone Propionate Nasal Spray
Prior Authorization Guidelines

Affected Medication(s)

- Fluticasone propionate nasal spray

FDA Approved Indication(s)

- Allergic rhinitis and non-allergic rhinitis in adult and pediatric patients ages 4 years and older

Dosing

- One to two sprays per nostril once daily depending on age

Initial Authorization Criteria

1. Is the medication being requested for FDA approved or major compendia supported indication?

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

2. Does the member have one of the following co-morbid conditions?

    a. Acute sinusitis, go to question #4
    b. Chronic Sinusitis, go to question #4
    c. Sleep Apnea, go to question #4
    d. Asthma, go to question #3
    e. None of the above, clinical review required

3. Is there a claim for the treatment of asthma or reactive airway disease in the past 90 days?

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

4. Is there evidence to support that treatment with fluticasone nasal spray will likely improve the control of the funded condition?

    a. If yes, approved for 12 months (Exception: Acute sinusitis approved for 1 month)
    b. If no, clinical review required

Last Reviewed: 9/9/20, 3/10/21, 3/9/22, 11/9/22, 11/8/23
Effective Date: 6/1/18, 11/1/20, 5/1/21

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. Flonase (fluticasone propionate) Nasal Spray, 50 mcg [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline. January 2015. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/020121s044lbl.pdf. Accessed June 1, 2018.

2. Oregon Medicaid PA criteria, May 1, 2018. Available at: http://www.oregon.gov/oha/HSD/OHP/Pages/Policy-Pharmacy.aspx. Accessed August 24, 2020.

Last Reviewed: 9/9/20, 3/10/21, 3/9/22, 11/9/22, 11/8/23
Effective Date: 6/1/18, 11/1/20, 5/1/21

OHSU Health Services

Galafold (migalastat hydrochloride)
Prior Authorization Guidelines

Affected Medication(s)

- Galafold (migalastat hydrochloride) oral capsule

FDA Approved Indication(s)

- Treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data

Dosing

- 123 mg orally once every other day

Initial Authorization Criteria

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

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

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

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

5. Does the member have a diagnosis of Fabry disease that is confirmed by biochemical and/or molecular genetic testing? (i.e. kidney interstitial capillary cell globotriaosylceramide (KIC GL-3)) (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 5/28/19, 3/11/20, 9/8/21, 9/14/22, 9/13/23
Effective Date: 7/15/19, 1/1/20, 11/1/21

OHSUHealth Services

6. Does the member have a GLA variant based on in vitro assay that is considered amenable? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required

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

8. Does the member have documented clinical manifestations of Fabry disease? (Examples include: severe neuropathic/limb pain, telangiectasias, angiokeratomas, abdominal pain, nausea, vomiting, diarrhea, constipation, corneal opacities, proteinuria, polyuria, and polydipsia) (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, clinical review required

9. Will Galafold (migalastat hydrochloride) be used in combination with other enzyme replacement therapy (ERT) for treatment of Fabry disease? (i.e. fabrazyme)
    a. If yes, clinical review required
    b. If no, continue to #10

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

Reauthorization Criteria

1. Is the documented indication FDA approved or supported by major compendia?
    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 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

Last Reviewed: 5/28/19, 3/11/20, 9/8/21, 9/14/22, 9/13/23
Effective Date: 7/15/19, 1/1/20, 11/1/21

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. Galafold [Product Information], Amicus Therapeutics U.S., Inc. Cranbury, NJ. December 2021.

2. Germain DP, Hughes DA, Nicholls K, et al.: Treatment of Fabry's Disease with the Pharmacologic Chaperone Migalastat. NEJM 2016; 375:545-555.

3. Desnick RJ, Brady R, Barranger J, et al. Fabry disease, an Under-Recognized Multisystemic Disorder: Expert Recommendations for Diagnosis, Management, and Enzyme Replacement Therapy. Ann Intern Med. 2003; 138(4):338-46.

Last Reviewed: 5/28/19, 3/11/20, 9/8/21, 9/14/22, 9/13/23
Effective Date: 7/15/19, 1/1/20, 11/1/21

OHSU Health Services

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

Affected Medication(s)

- Nivestym (filgrastim-aafi) injectable syringe
- Nivestym (filgrastim-aafi) injectable vial solution
- Releuko (filgrastim-ayow) injectable syringe
- Releuko (filgrastim-ayow) injectable vial solution
- Udenyca (pegfilgrastim-cbqv) injectable syringe
- Fylnetra (pegfilgrastim-pbbk) injectable syringe

FDA Approved Indication(s)

Nivestym/Releuko:

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

Udenyca/Fylnetra:

- 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
- To increase survival in patients acutely exposed to myelosuppressive doses of radiation (Udenyca only)

Dosing

- Indication-specific weight-based dosing, refer to package insert for details

Initial Authorization Criteria

Last Reviewed: 3/5/19, 7/23/19, 3/11/20, 11/10/21, 1/11/23, 9/13/23
Effective Date: 3/5/19, 9/15/19, 1/1/20, 3/15/23, 11/1/23

OHSUHealth Services

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

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

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

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

5. Does the member have a documented trial with insufficient response, intolerance, or contraindication to Releuko or Fylnetra? (NOTE: Peripheral blood progenitor cell (PBPC) mobilization and acute exposure to myelosuppressive doses of radiation are not FDA approved uses for Releuko or Fylnetra)
    a. If yes, continue to #6
    b. If no, clinical review required

6. What is the medication being requested for? (Provide supporting documentation)
    a. Bone Marrow Transplantation, approve for 4 months unless otherwise specified
    b. Peripheral Blood Progenitor cell (PBPC) mobilization, approve for 4 months unless otherwise specified (Nivestym only)
    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 (Udenyca only)
    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

OHSUHealth Services

Prophylaxis of febrile neutropenia in patients with non-myeloid malignancy

1. Does the planned chemotherapy regimen have a high risk (greater than 20% risk) of febrile neutropenia? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, continue to #5

2. Is the planned chemotherapy regimen for curative treatment intent? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, continue to #3

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

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

5. Does the member have at least one of the following risk factors for febrile neutropenia? (Provide supporting documentation)

        - 65 years or older and receiving full chemotherapy dose intensity
        - Prior chemotherapy or radiotherapy
        - Persistent neutropenia
        - Tumor involvement in the bone marrow
        - Recent surgery and/or open wounds
        - Renal dysfunction (creatinine clearance <50)
        - Liver dysfunction (bilirubin >2.0)

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

6. Does the planned chemotherapy regimen have an intermediate risk (10 to 20% risk) of febrile neutropenia? (Provide supporting documentation)
    a. If yes, continue to #7

b. If no, deny. Clinical criteria not met

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

Treatment of chemotherapy-induced febrile neutropenia

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

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

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

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

Severe chronic neutropenia

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

2. Does the member have a diagnosis of one of the following? (Provide supporting documentation)

    - Congenital neutropenia
    - Cyclic neutropenia
    - Idiopathic neutropenia

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

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

Other Indication

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

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

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. Fylnetra® subcutaneous injection [prescribing information]. Piscataway, NJ: Kashiv; May 2022
2. Udenyca [package insert]. Redwood City, CA; Coherus BioSciences, Inc; November 2022.
3. Nivestym [package insert]. Lake Forest, IL; Hospira, Inc., a Pfizer Company; March 2019. Accessed July 2019.
4. Releuko Prescribing Information. Kashiv BioSciences, LLC. Piscataway, NJ. June 2023.

Last Reviewed: 3/5/19, 7/23/19, 3/11/20, 11/10/21, 1/11/23, 9/13/23
Effective Date: 3/5/19, 9/15/19, 1/1/20, 3/15/23, 11/1/23

5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Hematopoietic Growth Factors. Version 1.2022. National Comprehensive Cancer Network, 2022. Accessed November 2022.
6. Smith TJ, Bohlke K, Lyman GH, Carson KR, Crawford J, Cross SJ, Goldberg JM, Khatcheressian JL, Leighl NB, Perkins CL, Somlo G, Wade JL, Wozniak AJ, Armitage JO. Recommendations for the use of WBC growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2015 Jul 13. pii: JCO.2015.62.3488. [Epub ahead of print]
7. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Human Granulocyte/Macrophage Colony Stimulating Factors (L34699). Centers for Medicare & Medicaid Services, Inc. Updated on 1/23/2018 with effective date 02/1/2018. Accessed March 2018.
8. First Coast Service Options, Inc. Local Coverage Determination (LCD): G-CSF (Neupogen®, Granix™, Zarxio™) (L34002). Centers for Medicare & Medicaid Services, Inc. Updated on 6/10/2016 with effective date 7/5/2016. Accessed March 2018.
9. National Government Services, Inc. Local Coverage Article: Filgrastim, Pegfilgrastim, Tbofilgrastim, Filgrastim-sndz (e.g., Neupogen®, Neulasta™, Granix™, Zarxio™) - Related to LCD L33394 (A52408). Centers for Medicare & Medicaid Services, Inc. Updated on 9/23/2016 with effective date 10/1/2016. Accessed March 2018.
10. Palmetto GBA. Local Coverage Determination: White Cell Colony Stimulating Factors (L37176).Centers for Medicare & Medicaid Services, Inc. Updated on 12/7/2017 with effective date 2/26/2018. Accessed March 2018.

OHSU Health Services

Glucagon-Like Peptide-1 (GLP-1) Analogs
Prior Authorization Guidelines

Affected Medication(s)

- Ozempic (semaglutide) injection solution
- Trulicity (dulaglutide) injection solution
- Victoza (liraglutide) injection

FDA Approved Indication(s)

Ozempic:

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
- To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease

Trulicity:

- As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus
- To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors

Victoza:

- As an adjunct to diet and exercise to improve glycemic control in patients 10 years of age and older with type 2 diabetes mellitus
- To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease

Note: Trulicity and Victoza are not substitutes for insulin and should not be used in patients with type 1 DM or for the treatment of ketoacidosis. Concurrent use of Victoza and prandial insulin has not been studied.

Dosing

- Refer indication specific compendia supported dosing

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)

Last Reviewed: 5/15/18, 11/26/19, 5/13/20, 1/13/21, 1/12/22, 9/14/22, 9/13/23
Effective Date: 6/1/18, 1/15/20, 7/1/20, 3/1/22, 11/15/22, 10/15/23

OHSUHealth Services

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

2. Is the request for renewal of a previously approved GLP-1 prior authorization with the same indication?

   a. If yes, continue to Reauthorization
   b. If no, continue to #3

3. Is GLP-1 being requested for an FDA approved indication? (Verify dosing with package insert)

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

4. Was a baseline HbA1c level provided along with documentation that this member's condition remains uncontrolled (i.e. HbA1c >7%)? (Provide supporting documentation)

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

5. Did the member have an inadequate response to metformin?

   a. If yes, continue to #7
   b. If no, continue to #6

6. Did the member have an intolerance to metformin despite proper dose titration OR a contraindication to metformin? (Document intolerance and/or contraindication. Metformin ER must be tried if intolerance due to GI side effects)

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

7. Did the member have an inadequate response or contraindication to one of the following Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors - Steglatro, Jardiance, or Farxiga? (Document contraindication if applicable)

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

Reauthorization Criteria

1. Is the documented indication FDA approved or supported by major compendia? (Verify dosing with package insert)

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

Last Reviewed: 5/15/18, 11/26/19, 5/13/20, 1/13/21, 1/12/22, 9/14/22, 9/13/23
Effective Date: 6/1/18, 1/15/20, 7/1/20, 3/1/22, 11/15/22, 10/15/23

OHSUHealth Services

2. Were updated HbA1c and chart notes (within 1 year) provided with documentation of significant clinical response?

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

Note:

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

References:

1. Ozempic (semaglutide) [Prescribing Information]. Plainsboro, NJ: Novo Nordisk, Inc. January 2020.
2. Ozempic. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com.
3. Trulicity ((liraglutide) [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. March 2023.
4. Trulicity. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com.
5. Victoza (liraglutide) [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc. July 2023.
6. Victoza. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com.
7. Standards of Medical Care in Diabetes – 2021. Diabetes Care 2021. Jan;44(Supplement 1). Available at: https://care.diabetesjournals.org/content/44/Supplement_1. Accessed December 2, 2021.
8. Das SR, Everett BM, Birtcher KK, Brown JM, Januzzi JL Jr, Kalyani RR, Kosiborod M, Magwire M, Morris PB, Neumiller JJ, Sperling LS. 2020 Expert Consensus Decision Pathway on Novel Therapies for Cardiovascular Risk Reduction in Patients With Type 2 Diabetes: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2020 Sep 1;76(9):1117-1145. doi: 10.1016/j.jacc.2020.05.037. Epub 2020 Aug 5. PMID: 32771263; PMCID: PMC7545583.

Last Reviewed: 5/15/18, 11/26/19, 5/13/20, 1/13/21, 1/12/22, 9/14/22, 9/13/23
Effective Date: 6/1/18, 1/15/20, 7/1/20, 3/1/22, 11/15/22, 10/15/23

OHSU Health Services

Growth Hormone
Prior Authorization Guidelines

Affected Medication(s)

- Nutropin AQ subcutaneous pen
- Humatrope subcutaneous solution
- Norditropin Flexpro subcutaneous pen (Non-Formulary)

FDA Approved Indication(s)

Norditropin, Nutropin AQ, and Humatrope:

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

Additional indications for Norditropin:

- Treatment of short stature associated with Noonan syndrome in pediatric patients
- Treatment of growth failure due to Prader-Willi syndrome (PWS) in pediatric patients

Dosing

- Refer to package insert for specific dosing recommendations
  -

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the request a renewal of a previously approved prior authorization for the same drug and indication as the previous approval?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3

Last Reviewed: 7/23/19, 3/11/20, 3/9/22, 1/11/23, 11/8/23
Effective Date: 9/15/19, 1/1/20, 5/1/22, 3/15/23, 1/1/24

OHSUHealth Services

3. Is the requested drug Nutropin AQ or Humatrope?
    a. If yes, continue to #5
    b. If no, continue to #4
4. Does the member have a previous trial with inadequate response, intolerance, or contraindication to Nutropin AQ and Humatrope? (NOTE: Norditropin is indicated for use in Prader-Willi and Noonan syndromes) (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the requested medication being prescribed by, or in consultation with, and endocrinologist?
    a. If yes, continue to #6
    b. If no, clinical review required
6. What is the diagnosis that the requested drug is being used for? (Provide supporting documentation)
    a. Short stature with growth failure due to growth hormone deficiency (GHD) in pediatrics, continue to corresponding criteria
    b. Growth failure due to Prader-Willi Syndrome (PWS) in pediatrics, continue to corresponding criteria
    c. Short stature associated with Turner's Syndrome (TS) in pediatrics, continue to corresponding criteria
    d. Short stature associated with Noonan Syndrome (NS) in pediatrics, continue to corresponding criteria
    e. Adult with growth hormone deficiency, continue to corresponding criteria

<u>Growth hormone deficiency (GHD) in pediatrics</u>

1. Does the member have auxologic evidence of short stature by one of the following? (Provide supporting documentation)
    - "Severe" short stature (height more than 2.5SD below mean for age)
    - Height more than 2 SD below mid-parental height (average of mother's/father's heights)
    - Height more than2 SD below mean for bone age AND a 1-year height velocity more than1 SD below the mean for chronologic age or (in children 2 years of age or older) a 1-year decrease of more than 0.5 SD in height
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a diagnosis of GHD confirmed by any of the following? (Provide supporting documentation)

- Insulin-like growth factor 1 (IGF-1) and insulin-like growth factor binding protein-3 (IGFBP-3) are more than 2 SD below normal with delayed bone age
- Positive for PROP1 or POU1F1 mutation
- When newborn, history of hypoglycemia, serum GH concentration <5 mcg/L, and deficiency of at least 1 other pituitary hormone or classical imaging triad (ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk
- Known pituitary abnormality (e.g. congenital anomaly, tumor, irradiation) and deficiency of at least 1 other pituitary hormone

a. If yes, continue to #5
b. If no, continue to #3

3. Has the member completed GH stimulation testing? (Provide supporting documentation)

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

4. Upon provocative testing, was GH < 10 mcg/L for two different stimuli? (Provide supporting documentation)

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

5. Have other causes of short stature or growth failure been ruled out? (i.e. hypothyroidism, chronic systemic disease, and/or skeletal disorders) (Provide supporting documentation)

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

6. Is there documentation of open epiphyses? (Provide supporting documentation)

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

Prader-Willi Syndrome (PWS) in pediatrics

1. Does the member have a diagnosis of PWS confirmed by genetic testing? (Provide supporting documentation)

    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 more than 2 SD below mid-parental height (average of mother's/father's heights)
    - Height more than 2 SD below mean of same gender and chronological age
    - Height velocity more than 2 SD below mean over 1 year OR more than1.5 SD below mean over 2 years

    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

<u>Turner's Syndrome (TS) in pediatrics</u>

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 there documentation of open epiphyses? (Provide supporting documentation)

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

<u>Noonan Syndrome in pediatrics</u>

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 evidence of short stature or growth failure as defined as any of the following? (Provide supporting documentation)
    - Height more than 2 SD below mid-parental height (average of mother's/father's heights)
    - Height more than 2 SD below mean of same gender and chronological age

- Height velocity more than 2 SD below mean over 1 year OR more than1.5 SD below mean over 2 years

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

3. Has severe hypertrophic cardiomyopathy been ruled out? (Examples of probable HCM include an abnormal electrocardiogram, an echocardiography showing left ventricle hypertrophy or systolic anterior motion of the mitral valve, or abnormal exercise testing) (Provide supporting documentation)

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

4. Has the member been screened for thyroid abnormalities? (Examples include autoimmune thyroiditis with presence of thyroid autoantibodies) (Provide supporting documentation)

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

5. Is there documentation of open epiphyses? (Provide supporting documentation)

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

<u>Adult with Growth Hormone Deficiency</u>

1. Was the diagnosis of growth hormone deficiency confirmed by one of the following? (Provide supporting documentation)

- Negative response to a growth hormone stimulation test (e.g. serum GH levels of <5 ng/mL on stimulation testing with either glucagon or insulin)
- Member has had pituitary gland removed, destroyed, or has had panhypopituitarism since birth

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

2. Will the requested medication be used for anti-aging therapy, to enhance athletic ability, or for body building purposes? (Provide supporting documentation)

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

Reauthorization Criteria

OHSUHealth Services

1. Is the requested drug being used for one of the following conditions? (Provide supporting documentation)
    - Short stature due to growth failure due to growth hormone deficiency (GHD) in pediatrics
    - Growth failure due to Prader-Willi Syndrome (PWS) in pediatrics
    - Short stature associated with Turner's Syndrome (TS) in pediatrics
    - Short stature associated with Noonan Syndrome (NS) in pediatrics

    a. If yes, continue to #5
    b. If no, continue to #2
2. Is the request for an adult member with growth hormone deficiency?

    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the adult member's IGF-1 concentration within the age-specific range of normal? (Provide supporting documentation)

    a. If yes, continue to #4
    b. If no, clinical review required
4. Is there documentation the member is benefiting from growth hormone therapy (e.g. increase quality of life, cardiovascular risk markers, etc.)? (Provide supporting documentation)

    a. If yes, continue to #9
    b. If no, clinical review required
5. Is there documentation of the member responding to therapy (i.e. growth velocity $\geq$ 2.5 cm/year)? (Provide supporting documentation)

    a. If yes, continue to #6
    b. If no, clinical review required
6. 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 #7
    b. If no, clinical review required
7. Is the member's IGF-I level maintained between 0 to +2 SD for age? (Provide supporting documentation)

    a. If yes, continue to #8
    b. If no, clinical review required
8. Is there documentation of open epiphyses? (Provide supporting documentation)

    a. If yes, continue to #9

b. If no, clinical review required

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

Note:

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

References:

1. Norditropin (somatropin) [Prescribing Information]. Plainsboro, New Jersey: Novo Nordisk Inc. February 2018.
2. Humatrope (somatropin) [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. June 2023.
3. Nutropin (somatropin). [Prescribing Information]. South San Francisco, CA: Genentech, Inc. December 2021.
4. Stanley T. Diagnosis of growth hormone deficiency in childhood. *Curr Opin Endocrinol Diabetes Obes*. 2012;19(1):47-52.
5. Goldstone AP, Holland AJ, Hauffa BP et al. Recommendations for the Diagnosis and Management of Prader-Willi Syndrome. Recommendations for the diagnosis and management of Prader-Willi syndrome. J Clin Endocrinol Metab 2008; 93:4183.
6. Grimberg A, DiVall SA, Polychronakos C et al. Guidelines for growth hormone and insulin-like growth factor-I treatment in children and adolescents: growth hormone deficiency, idiopathic short stature, and primary insulin-like growth factor-I deficiency. Horm. Res. Paediatr. 86, 361–397 (2016).
7. Consensus guidelines for the diagnosis and treatment of growth hormone (GH) deficiency in childhood and adolescence: summary statement of the GH Research Society. GH Research Society. J Clin Endocrinol Metab. 2000;85(11):3990–3993.
8. MacFarland CE, Brown DC, Johnston LB, et al. Growth Hormone Therapy and Growth in Children with Noonan's Syndrome: Results of 3 Years' Follow-Up. JCEM. 2011;86(5): 1953-1956.
9. Giacomozzi C, Deodati A, Shaikh M, G, et al. The Impact of Growth Hormone Therapy on Adult Height in Noonan Syndrome: A Systematic Review. Horm Res Paediatr 2015;83:167-176. doi: 10.1159/000371635

10. Fleseriu M, Hashim IA, Karavitaki N, et al. Hormonal Replacement in Hypopituitarism in Adults: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab 2016; 101:3888.

OHSU Health Services

Hereditary Angioedema (HAE) Acute Treatment
Prior Authorization Guidelines

Affected Medication(s)

- Icatibant acetate subcutaneous solution
- Berinert (human c-1 esterase inhibitor) intravenous solution
- Kalbitor (ecallantide) subcutaneous solution
- Ruconest (c1-esterase inhibitor, recombinant) intravenous solution

FDA Approved Indication(s)

Icatibant acetate
- Treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older

Berinert
- Treatment of acute attacks of hereditary angioedema (HAE) in patients 6 years of age and older

Kalbitor
- Treatment of acute attacks of hereditary angioedema (HAE) in patients 12 years of age and older

Ruconest
- Treatment of acute attacks of hereditary angioedema (HAE) in patients 13 years of age and older

Dosing

Icatibant acetate
- 30 mg administered by subcutaneous (SC) injection in the abdominal area
- Additional doses may be administered at intervals of at least 6 hours if response is inadequate or if symptoms recur. No more than 3 doses may be administered in any 24 hour period
- Patients may self-administer upon recognition of an HAE attack

Berinert
- 20 units/kg given intravenously

Kalbitor
- 30mg administered subcutaneously. An additional 30mg dose may be administered within a 24 hour period if the attack persists

Ruconest
- 50 units/kg given intravenously. May repeat dose one time if symptoms persist. Max 8400 units per 24 hours

Initial Authorization Criteria

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

Last Reviewed: 3/10/21, 5/11/22, 5/10/23, 5/8/24
Effective Date: 5/1/21, 6/15/23, 6/15/24

OHSUHealth Services

2. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    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, continue to #5
    b. If no, clinical review required
5. Does the member have one of the following clinical presentations consistent with HAE subtype I or II? (Provide supporting documentation)
        i. For HAE I (C1-inhibitor deficiency):
            1. 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
            2. Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); AND
            3. Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); AND
                a. Patient has a family history of HAE OR
                b. Normal C1q level
        ii. For HAE II (C1-inhibitor dysfunction):
            1. Normal to elevated C1-INH antigenic level; AND
            2. Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); AND
            3. 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 #6
    b. If no, clinical review required
6. Is the member avoiding possible triggers for HAE attacks? Possible triggers include:
        i. Systemic estrogen products
        ii. Antihypertensive agents containing ACE inhibitors
        iii. Dipeptidyl peptidase IV (DPP-IV) inhibitors (e.g., sitagliptin)
        iv. Neprilysin inhibitors (e.g., sacubitril)
    a. If yes, continue to #7

OHSUHealth Services

b. If no, clinical review required

7. Does the member have a history of attacks that impact normal daily living with the presence of subcutaneous angioedema, abdominal pain, or laryngeal edema? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Is the requested medication icatibant?
    a. If yes, continue to #10
    b. If no, continue to #9
9. Has this member had a documented trial with inadequate response, intolerance or contraindication to the use of icatibant OR is the member less than 18 years of age? (Provide supporting documentation)
    a. If yes, continue to #10
    b. If no, clinical review required
10. Is the requested medication indicated for use for this member's age?
    - Icatibant: 18 years of age and older
    - Berinert: 6 year of age and older
    - Kalbitor: 12 years of age and older
    - Ruconest: 13 years of age and older

    a. If yes, continue to #11
    b. If no, clinical review required
11. Is the dose requested appropriate for this patient's weight (icatibant and Kalbitor are not weight based)?
    a. If yes, continue to #12
    b. If no, clinical review required
12. Is the requested medication intended for use in combination with any other acute HAE treatments?
    a. If yes, clinical review required
    b. If no, approve for 3 months

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member demonstrated a clinically significant response to the medication (e.g. reduction in severity or duration of attack)? (Provide supporting documentation)

OHSUHealth Services

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

3. Has the member followed-up with their provider post-attack? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the dose requested appropriate for this patient's age and weight?
    a. If yes, go to question #5
    b. If no, clinical review required
5. Does the medication continue to be prescribed in the absence of any other acute HAE treatments?
    a. If yes, continue to #6
    b. If no, clinical review required
6. 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
    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. Icatibant acetate [Prescribing Information]. Tainan City 71243, Taiwan. Nang Kuang Pharmaceutical Co., Ltd. Dec 2020.
2. Kalbitor (ecallantide) [Prescribing Information]. Lexington, MA. Takeda Pharmaceutical Company Ltd. Jan 2021.
3. Firazyr (icatibant) [Prescribing Information]. Lexington, MA. Takeda Pharmaceutical Company Ltd. Sep 2020.
4. Berimert (C1 esterase inhibitor) [Prescribing Information]. Marburg, Germany. CSL Behring GmbH. Aug 2020.
5. Ruconest (C1 esterase inhibitor, recombinant) [Prescribing Information]. Bridgewater, NJ. Pharming Americas B.V. Oct 2019.
6. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract. 2021;9(1):132-150.e3.

7. Betschel, Stephen, et al. "The International/Canadian hereditary angioedema guideline." Allergy, Asthma & Clinical Immunology 15 (2019): 1-29.

OHSU Health Services

Hereditary Angioedema (HAE) Prophylactic Treatment
Prior Authorization Guidelines

Affected Medication(s)

- Cinryze (C1 esterase inhibitor)
- Haegarda (C1 esterase inhibitor)
- Orladeyo (berotralstat)
- Takhzyro (lanadelumab-flyo)

FDA Approved Indication(s)

Cinryze
- Routine prophylaxis against angioedema attacks in adults, adolescents and pediatric patients 6 years of age and older with HAE

Haegarda
- Routine prophylaxis to prevent HAE attacks in patients 6 years of age and older

Orladeyo
- Prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older

Takhzyro
- Prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 2 years and older

Dosing

- Refer to package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of previously approved therapy for the same drug and indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (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?

Last Reviewed: 3/10/21, 5/11/22, 5/10/23, 5/8/24
Effective Date: 5/1/21, 6/15/24

OHSUHealth Services

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

5. Does the member have one of the following clinical presentations consistent with HAE subtype? (Provide supporting documentation)

    i. For HAE I (C1-inhibitor deficiency):
        1. 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
        2. Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); AND
        3. Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); AND
            a. Patient has a family history of HAE OR
            b. Normal C1q level
    ii. For HAE II (C1-inhibitor dysfunction):
        1. Normal to elevated C1-INH antigenic level; AND
        2. Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); AND
        3. 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 #6
    b. If no, clinical review required

6. Is the member avoiding possible triggers for HAE attacks? Possible triggers include:

    i. Systemic estrogen products
    ii. Antihypertensive agents containing ACE inhibitors
    iii. Dipeptidyl peptidase IV (DPP-IV) inhibitors (e.g., sitagliptin)
    iv. Neprilysin inhibitors (e.g., sacubitril)

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

7. Does the member have a history of 2 or more attacks per month that are moderate to severe cutaneous or abdominal attacks OR mild to severe airway swelling attacks of HAE? (i.e. debilitating cutaneous/gastrointestinal symptoms OR laryngeal/pharyngeal/tongue swelling) (Provide supporting documentation)

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

8. Is the request for Haegarda or Takhzyro?

    a. If yes, continue to #10
    b. If no, continue to #9

9. Has this member had a documented trial with inadequate response, intolerance or contraindication to the use of both Haegarda and Takhzyro? (Provide supporting documentation)

OHSUHealth Services

a. If yes, continue to #10
b. If no, clinical review required

10. Is the requested medication approved for use for this member's age?

- Haegarda: 6 years of age and older
- Takhzyro: 2 year of age and older
- Cinryze: 6 years of age and older
- Orladeyo: 12 years of age and older

a. If yes, continue to #11
b. If no, clinical review required

11. Is the dose requested appropriate for this patient's weight (Orladeyo and Takhzyro are not weight based)?

a. If yes, continue to #12
b. If no, clinical review required

12. Is the requested medication intended for use in combination with any other prophylactic HAE treatments?

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

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)

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

2. Has the member demonstrated a clinically significant response to the medication (e.g. reduction in number of attacks or severity of attacks)? (Provide supporting documentation)

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

3. Is the request for Takhzyro?

a. If yes, continue to #4
b. If no, continue to #6

4. Has the member been attack free for greater than 6 months? (Provide supporting documentation)

a. If yes, continue to #5
b. If no, continue to #6

5. Is the request for dosing every 4 weeks or has clinical rationale been provided to medically justify remaining on every 2 week dosing?

OHSUHealth Services

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

6. Does the medication continue to be prescribed in the absence of any other prophylactic HAE treatments?
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the medication continued to be 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:

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. Cinryze (C1 esterase inhibitor) [Prescribing Information]. Lexington, MA. ViroPharma Biologics LLC. Jan 2021.
2. Haegarda (C1 esterase inhibitor) [Prescribing Information]. Marburg, Germany. CSL Behring GmbH. Oct 2020.
3. Orladeyo (berotralstat HCL) [Prescribing Information]. Durham, NC. BioCryst Pharmaceuticals Inc. Dec 2020.
4. Takhzyro (lanadelumab-flyo) [Prescribing Information]. Lexington, MA. Dyax Corp. Dec 2019.
5. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract. 2021;9(1):132-150.e3.
6. Zuraw B, Lumry WR, Johnston DT, et al. Oral once-daily berotralstat for the prevention of hereditary angioedema attacks: A randomized, double-blind, placebo-controlled phase 3 trial [published online ahead of print, 2020 Oct 21]. *J Allergy Clin Immunol.* 2020;S0091-6749(20)31484-6.
7. Bygum A, Andersen KE, Mikkelsen CS. Self-administration of intravenous C1-inhibitor therapy for hereditary angioedema and associated quality of life benefits. *Eur J Dermatol.* Mar-Apr 2009;19(2):147-151.
8. Bowen T, Cicardi M, Farkas H, et al. 2010 International consensus algorithm for the diagnosis, therapy and management of hereditary angioedema. *Allergy Asthma Clin Immunol.* 2010;6(1):24.
9. Craig T, Aygören-Pürsün E, Bork K, et al. WAO Guideline for the Management of Hereditary Angioedema. *World Allergy Organ J.* 2012 Dec;5(12):182-99.
10. Gompels MM, Lock RJ, Abinun M, et al. C1 inhibitor deficiency: consensus document. *Clin Exp Immunol.* 2005;139(3):379.
11. Bowen T, Cicardi M, Farkas H, et al. Canadian 2003 International Consensus Algorithm For the Diagnosis, Therapy, and Management of Hereditary Angioedema. *J Allergy Clin Immunol.* 2004 Sep;114(3):629-37.

12. Betschel S, Badiou J, Binkley K, et al. Canadian hereditary angioedema guideline. *Asthma Clin Immunol*. 2014 Oct 24;10(1):50.
13. Zuraw BL, Bernstein JA, Lang DM, et al. A focused parameter update: hereditary angioedema, acquired C1 inhibitor deficiency, and angiotensin-converting enzyme inhibitor-associated angioedema. *J Allergy Clin Immunol*. 2013 Jun;131(6):1491-3.
14. Betschel, Stephen, et al. "The International/Canadian hereditary angioedema guideline." Allergy, Asthma & Clinical Immunology 15 (2019): 1-29.

OHSU Health Services

Hepatitis C Agents
Prior Authorization Guidelines

Affected Medication(s)

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

FDA Approved Indication(s)

Epclusa: For the treatment of adult and pediatric patients 3 years and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis. For use in combination with ribavirin for decompensated cirrhosis

Mavyret: 1. For treatment of adult and pediatric patients 3 years and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). 2. For treatment of adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both

Vosevi: For treatment of adult patients with chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have 1. Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor. 2. Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor. Additional benefit of Vosevi over Epclusa was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with Sovaldi without a Ns5A inhibitor

Dosing

Adults:

- **Epclusa:** One tablet (sofosbuvir 400mg/velpatasvir 100mg) once daily
- **Mavyret:** Three tablets (glecaprevir 100 mg/pibrentasvir 40mg) once daily
- **Vosevi:** One tablet (sofosbuvir 400 mg/velpatasvir 100 mg/ voxilaprevir 100mg) once daily

Pediatric:

- Refer to corresponding package insert for recommended dosage

NOTE: See recommended treatment regimen table below for regimen details and treatment duration

Initial Authorization Criteria

1. Is the request for treatment of chronic Hepatitis C infection? (defined by positive HCV RNA detection in a patient with no suspicion of transmission in the previous 6 months OR persistent HCV detection

Last Reviewed: 1/22/19, 11/27/18, 3/20/18, 11/26/19, 9/9/20, 11/10/21, 11/9/22, 11/8/23
Effective Date: 1/1/18, 1/1/20, 11/1/20, 1/1/22, 1/1/23, 12/15/23

for ≥6 months OR diagnosis of chronic viral hepatitis C (B18.2) for ≥6 months, OR positive HCV RNA with evidence of clinically significant fibrosis [≥F1]) (Provide supporting documentation)

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

2. Have **ALL** of the following pre-treatment testing been documented (provide supporting documentation):

   - Genotype testing in past 3 years for patients with decompensated cirrhosis, patients with any prior treatment experience, and for regimens which are not pan-genotypic
   - History of previous HCV treatment including viral load after treatment and outcome if treatment experienced

   a. If yes, record results of each test and go to #3
   b. If no, clinical review required

3. Has the member been treated with a Direct Acting Antiviral (DAA) agent previously? (Provide treatment status)

   a. If yes, continue to #4
   b. If no, continue to #6

4. Did the member achieve a sustained virologic response (SVR) at week 12 or longer following the completion of their last DAA regimen? (Provide supporting documentation)

   a. If yes, continue to #5
   b. If no, document as treatment failure and continue to #6

5. Is the requested regimen being requested for treatment of HCV reinfection, as indicated by at least one of the following? (Provide supporting documentation)

   - Patient has ongoing risk factors for hepatitis C reinfection (e.g. sexually active men who have sex with men, persons who inject drugs)
   - Prior Hepatitis C infection was a different genotype than current infection

   a. If yes, document as reinfection and continue to #6
   b. If no, document as treatment failure and continue to #6

6. Is the drug being requested one of the following agents?
   - Elbasvir/grazoprevir for genotype 1a infection
   - Ledipasvir/sofosbuvir for genotype 1a infection in a treatment experienced member
   - Sofosbuvir/velpatasvir for genotype 3 infection in a cirrhotic or treatment-experienced member

a. If yes, continue to #7
b. If no, continue to #8

7. Has the member had a baseline NS5a resistance test that documents the presence of a resistant variant to the requested regimen? (Provide supporting documentation)

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

8. Is the prescribed drug regimen a recommended regimen based on the patient's genotype, age, treatment status (retreatment or treatment naïve) and cirrhosis status? (Provide supporting documentation)

    a. If yes, approve for appropriate duration
    b. If no, clinical review required

Table 1: Recommended Treatment Regimens for Adults, and Adolescents 12 years of age and older with Hepatitis C virus

Treatment History	Cirrhosis Status	Recommended Regimen
Treatment Naïve (Genotype 1-6)		
Treatment naïve, confirmed reinfection or prior treatment with PEG/RBV	Non-cirrhotic or compensated cirrhosis	• SOF/VEL x 12 weeks • G/P x 8 weeks
	Compensated cirrhosis	• G/P x 8 weeks • SOF/VEL x 12 weeks (baseline resistance testing recommended for GT3)
	Decompensated Cirrhosis	• SOF/VEL + RBV x 12 weeks • SOF/VEL x 24 weeks (if ribavirin ineligible*)
Treatment Experienced (Genotype 1-6)		
Sofosbuvir based regimen treatment failures, including: Sofosbuvir + ribavirin	Non-cirrhotic or compensated cirrhosis	• SOF/VEL/VOX x12 weeks • G/P x 16 weeks (except GT3)

Ledipasvir/sofosbuvir Velpatasvir/sofosbuvir		
Elbasvir/grazoprevir treatment failures	Non-cirrhotic or compensated cirrhosis	• SOF/VEL/VOX x 12 weeks
Glecaprevir/pibrentasvir treatment failures	Non-cirrhotic or compensated cirrhosis	• G/P + SOF + RBV x 16 weeks • SOF/VEL/VOX x 12 weeks (plus RBV if compensated cirrhosis)
Multiple DAA Treatment Failures, including: sofosbuvir/velpatasvir/voxilaprevir glecaprevir/pibrentasvir + sofosbuvir	Non-cirrhotic or compensated cirrhosis	• G/P + SOF + RBV x 16-24 weeks • SOF/VEL/VOX x 24 weeks
Abbreviations: DAA = direct acting antiviral; EBV/GZR = elbasvir/grazoprevir; G/P = glecaprevir and pibrentasvir; PEG= pegylated interferon; RAV = resistance-associated variant; RBV = ribavirin; SOF = sofosbuvir; SOF/VEL = sofosbuvir/velpatasvir; SOF/VEL/VOX = sofosbuvir/velpatasvir/voxilaprevir * Ribavirin ineligible/intolerance may include: 1) neutrophils < 750 mm3, 2) hemoglobin < 10 g/dl, 3) platelets <50,000 cells/mm3, autoimmune hepatitis or other autoimmune condition, hypersensitivity or allergy to ribavirin		
^ Rarely, genotyping assays may indicate the presence of a mixed infection (e.g., genotypes 1a and 2). Treatment data for mixed genotypes with direct-acting antivirals are limited. However, in these cases, a pangenotypic regimen is appropriate.		
Ribavirin-containing regimens are absolutely contraindicated in pregnant women and in the male partners of women who are pregnant. Documented use of two forms of birth control in patients and sex partners for whom a ribavirin containing regimen is chosen is required.		
All regimens containing a protease inhibitor (elbasvir, glecaprevir, simeprevir, paritaprevir, voxilaprevir) should not be used in patients with moderate to severe hepatic impairment (CTP B and C).		
There is limited data supporting DAA regimens in treatment- experienced patients with decompensated cirrhosis. These patients should be handled on a case by case basis with the patient, prescriber, and CCO or FFS medical director.		
Definitions of Treatment Candidates • Treatment-naïve: Patients without prior HCV treatment. • Treat as treatment- naïve: Patients who discontinued HCV DAA therapy within 4 weeks of initiation or have confirmed reinfection after achieving SVR following HCV treatment. • Treatment-experienced: Patients who received more than 4 weeks of HCV DAA therapy.		

Table 2: Recommended Treatment Regimens for children ages 3 - 12 years of age with Hepatitis C virus

Treatment History	Cirrhosis Status	Recommended Regimen
Treatment Naïve Genotype 1-6		
Treatment naïve, confirmed reinfection or prior treatment with PEG/RBV	Non-cirrhotic or compensated cirrhosis	• SOF/VEL x 12 weeks • G/P x 8 weeks
	Decompensated Cirrhosis	• SOF/VEL + RBV x 12 weeks
Treatment Experienced with DAA regimen		
Note: Efficacy and safety extremely limited in treatment experienced to other DAAs in this population. Can consider recommended treatment regimens in adults if FDA approved for pediatric use. Recommend consulting with hepatologist.		
Abbreviations: DAA = direct acting antiviral; G/P = glecaprevir and pibrentasvir; RBV = ribavirin; SOF = sofosbuvir; SOF/VEL = sofosbuvir/velpatasvir • All regimens containing a protease inhibitor (elbasvir, glecaprevir, simeprevir, paritaprevir, voxilaprevir) should not be used in patients with moderate to severe hepatic impairment (CTP B and C). • There is limited data supporting DAA regimens in treatment- experienced patients with decompensated cirrhosis. These patients should be handled on a case by case basis with the patient, prescriber, and CCO or FFS medical director.		

Table 3: Recommended dosage of sofosbuvir/velpatasvir in pediatric patients 3 years of age and older:

Body Weight	Dosing of sofosbuvir/velpatasvir
Less than 17 kg	One 150 mg/37.5 mg pellet packet once daily
17 kg to less than 30 kg	One 200 mg50 mg pellet packet OR tablet once daily
At least 30 kg	Two 200 mg/50 mg pellet packets once daily OR one 400 mg/100 mg tablet once daily

Table 4: Recommended dosage of glecaprevir/pibrentasvir in pediatric patients 3 years of age and older:

Body Weight	Dosing of sofosbuvir/velpatasvir
Less than 20 kg	Three 50mg/20 mg pellet packets once daily
20 kg to less than 30 kg	Four 50 mg/20 mg pellet packets once daily

30 kg to less than 45 kg	Five 50 mg/20 mg pellet packets once daily
45 kg and greater OR 12 years of age and older	Three 100mg/40 mg tablets once daily

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. Epclusa (velpatasvir and sofosbuvir tablet, film coated) [Prescribing Information]. Foster City, CA: Gilead Sciences Inc. June 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7f30631a-ee3b-4cfe-866b-964df3f0a44f. Accessed October 12, 2021
2. Mavyret (glecaprevir and pibrentasvir tablet, film coated) [Prescribing Information]. North Chicago, IL: AbbVie Inc. June 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7bf99777-0401-9095-8645-16c6e907fcc0. Accessed October 12, 2021
3. Vosevi (sofosbuvir, velpatasvir, and voxilaprevir tablet, film coated) [Prescribing Information]. Foster City, CA: Gilead Sciences Inc. November 2019. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=17ffc094-8ca7-45d2-80d8-fd043bc9a221. Accessed October 12, 2021
4. Zepatier (elbasvir and grazoprevir tablet, film coated) [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc. February, 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=164dc02a-9180-426a-b8b5-04ab39d2bbd4. Accessed May 11, 2018
5. Oregon Medicaid PA Criteria, September 1, 2021. Available at: http://www.oregon.gov/oha/HSD/OHP/Pages/Policy-Pharmacy.aspx. Accessed November 1, 2021
6. Oregon Health Authority. Drug Class Update: Hepatitis C Direct-Acting Antivirals. September 2019. Available at: https://www.orpdl.org/durm/meetings/meetingdocs/2019_09_26/finals/2019_09_26_PnT_Complete.pdf Accessed October 28, 2019.
7. Oregon Health Authority. P&T Meetings: Complete Agenda Packet 09/26/2019. Hepatitis C Policy Discussion. Available at:

https://www.oregon.gov/oha/HSD/OHP/Therapeutics/OHA%20Recommendations%2C%20approved%2010-03-2019.pdf

8. American Association for the Study of Liver Diseases (AASLD), Infectious Diseases Society of America (IDSA). HCV guidance: recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org/. Updated August 27, 2020. Accessed October 12, 2021.

OHSU Health Services

Icosapent ethyl
Prior Authorization Guidelines

Affected Medication(s)

- Icosapent ethyl capsule

FDA Approved Indication(s)

- As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels and:
  - Established cardiovascular disease OR
  - Diabetes mellitus and 2 or more additional risk factors for cardiovascular disease
- As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia

Dosing

- 2 grams orally twice daily with meals

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

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

3. Is icosapent ethyl being requested for an FDA approved indication?
   a. If yes, continue to #4
   b. If no, clinical review required

4. What is the requested drug being used for? (Provide documentation of diagnosis)
   a. Hypertriglyceridemia, continue to #5
   b. Atherosclerotic cardiovascular disease prevention, continue to #7
   c. Other indication, clinical review required

Last Reviewed: 5/11/22, 11/9/22, 7/12/23
Effective Date: 7/1/22, 1/1/23

OHSUHealth Services

5. Does the member have a triglyceride level of greater than 500 mg/dL confirmed by labs within 6 months? (Provide lab for review)

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

6. Did the member have a trial with inadequate response, intolerance, or a contraindication to both fibrates AND omega-3-acid ethyl esters (minimum 12-week trial)? (Provide supporting documentation)

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

7. Does the member have established cardiovascular disease confirmed by at least one of the following? (Provide supporting documentation)

    - Documented coronary artery disease (greater than or equal to 50% stenosis in at least two major epicardial coronary arteries, prior myocardial infarction, or prior hospitalization for high-risk non-ST-segment elevation acute coronary syndrome)
    - Documented cerebrovascular or carotid disease
    - History of carotid revascularization
    - Documented peripheral arterial disease

    a. If yes, continue to #10
    b. If no, continue to #8

8. Does the member have diabetes mellitus? (Provide supporting documentation)

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

9. Does the member have at least two (2) of the following risk factors? (Provide supporting documentation)

    - Men 55 years of age or older; women 65 years of age or older
    - Cigarette smoker
    - With Hypertension or on antihypertensive medication
    - HDL-C ≤40 mg/dL for men or ≤50 mg/dL for women
    - High-density CRP (hs-CRP) >3.00 mg/L (0.3 mg/dL)
    - Renal dysfunction (CrCL>30mL/min and <60mL/min)
    - Retinopathy
    - Microalbuminuria or macroalbuminuria
    - ABI <0.9 without symptoms of intermittent claudication

    a. If yes, continue to #10

b. If no, clinical review required

10. Does the member have a triglyceride level between 135 mg/dL and 500 mg/dL within 6 months? (Provide lab for review)
    a. If yes, continue to #11
    b. If no, clinical review required
11. Is the member currently receiving a maximally tolerated statin AND ezetimibe for at least four (4) consecutive weeks and will continue with therapy unless intolerance or contraindication present OR low-density lipoprotein (LDL) cholesterol level is at goal? (Provide supporting documentation)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has this member been seen within the past 12 months for treatment of hypertriglyceridemia or prevention of atherosclerotic cardiovascular disease? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the request for hypertriglyceridemia?
    a. If yes, continue to #4
    b. If no, approve for 12 months unless otherwise specified
4. Is documentation of a significant clinical response to therapy provided? (Provide lab for review)
    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:

Last Reviewed: 5/11/22, 11/9/22, 7/12/23
Effective Date: 7/1/22, 1/1/23

1. Vascepa (icosapent ethyl) [Prescribing Information]. Bridgewater, NJ: Amarin Pharma, Inc. April 2023.
2. Bhatt DL, Steg PG, Miler M, et al. Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia. New England Journal of Medicine. 2019;380(1):11-22.
3. Orringer, CE, Jacobson, TA, Maki, KC. National Lipid Association Scientific Statement on the use of icosapent ethyl in statin-treated patients with elevated triglycerides and high or very-high ASCVD risk. J Clin Lipidol. 2019;13(6):860-72.
4. Grundy, Scott M., et al. "2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines." Journal of the American College of Cardiology 73.24 (2019): e285-e350.
5. Virani, Salim S., et al. "2021 ACC expert consensus decision pathway on the management of ASCVD risk reduction in patients with persistent hypertriglyceridemia: a report of the American College of Cardiology Solution Set Oversight Committee." Journal of the American College of Cardiology 78.9 (2021): 960-993.

OHSU Health Services

Inbrija (levodopa)
Prior Authorization Guidelines

Affected Medication(s)

- Inbrija inhalation powder

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

- 84mg (contents of two capsules) inhaled, as needed, for OFF symptoms up to five times a day
- Maximum dose per OFF period is 84mg, not to exceed 420mg per day

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation with the Inbrija (levodopa) for the same diagnosis?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have Parkinson's disease and experiencing at least 2 hours of "off" time daily? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Has the member previously trialed at least one medication from each of the following classes unless an intolerance or contraindication is present? (Provide supporting documentation)
    - COMT inhibitors (entacapone, opicapone, tolcapone)
    - MAO-B inhibitors (rasagiline, safinamide, selegiline)
    - Dopamine agonists (ropinirole, pramipexole, rotigotine)

Last Reviewed: 1/10/24
Effective Date: 2/15/24

OHSUHealth Services

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

6. Is the treatment 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 or major compendia supported indication? (Provide documentation of diagnosis)

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

2. Has the member experienced a documented positive response to therapy defined by a reduction in frequency of "off" episodes? (Provide supporting documentation)
(Note: For subsequent renewals documented maintenance of initial response is required)

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

3. Is the treatment prescribed by or in consultation with a neurologist?

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

Note:

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

References:

1. INBRIJA (levodopa inhalation powder) inhalation powder [package insert]. Ardsley, NY: Acorda Therapeutics, Inc.; January 2023.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 07 Dec. 2023].
3. Fox, Susan H., et al. "International Parkinson and movement disorder society evidence-based medicine review: Update on treatments for the motor symptoms of Parkinson's disease." Movement Disorders 33.8 (2018): 1248-1266.

OHSU Health Services

Increlex (mecasermin)
Prior Authorization Guidelines

Affected Medication(s)

- Increlex (mecasermin) subcutaneous vial solution

FDA Approved Indication(s)

Children ≥ 2 years old and adolescents:

- Treatment of growth failure 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/dose twice daily
- Maximum dose: 0.12 mg/kg/dose twice daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request a renewal of a previously approved Increlex (mecasermin) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved indication?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have documentation of open epiphyses demonstrated on bone radiograph? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have any of the following secondary forms of IGF-1 deficiency? (Provide supporting documentation)
    - Growth Hormone deficiency (GHD)

Last Reviewed: 3/5/19, 3/11/20, 7/14/21, 7/13/22, 7/12/23
Effective Date: 3/5/19, 1/1/20

- Malnutrition
- Hypothyroidism
- Chronic treatment with pharmacologic doses of steroidal anti-inflammatories

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

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

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

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

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

<u>Severe IGF-1 Deficiency</u>

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

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

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

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

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

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

<u>Growth hormone (GH) Gene Deletion</u>

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

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

2. Does the member have a presence of neutralizing antibodies to GH as confirmed by serum testing or genetic testing? (Provide supporting documentation)

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

OHSUHealth Services

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a positive clinical response to therapy as defined by a height velocity of at least 2cm per year? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Has the member met their expected adult height goal? (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, approve for 12 months unless otherwise specified

Note:

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. Increlex (mecasermin [rDNA origin] injection) [Product Information], Tercica, Inc. Brisbane, CA. August 2005.
2. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Growth Hormone Use in Adults and Children – 2003 Update. Endocrine Practice 2003; 64-76.

Last Reviewed: 3/5/19, 3/11/20, 7/14/21, 7/13/22, 7/12/23
Effective Date: 3/5/19, 1/1/20

OHSU Health Services

Injectable CGRP Antagonists
Prior Authorization Guidelines

Affected Medication(s)

- Aimovig (erenumab) subcutaneously solution
- Emgality (galcanezumab) subcutaneous solution

FDA Approved Indication(s)

- Aimovig:
  - Preventive treatment of migraines in adults
- Emgality:
  - Preventive treatment of migraines in adults
  - Treatment of episodic cluster headache in adults

Dosing

- Aimovig: 70mg to 140mg subcutaneously once monthly
- Emgality:
  - Migraine: 240mg subcutaneously once as loading dose followed by 120mg subcutaneously once monthly
  - Episodic cluster headache: 300mg at onset of cluster period and then monthly until the end of the cluster period

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the request for continuation with the same CGRP antagonist?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3
3. Is the member 18 years of age or older?
   a. If yes, continue to #4
   b. If no, clinical review required
4. Is the treatment prescribed by or in consultation with a neurologist or headache specialist?
   a. If yes, continue to #5

Last Reviewed: 11/11/20, 11/10/21, 11/9/22, 11/8/23
Effective Date: 1/1/21, 1/15/23

OHSUHealth Services

b. If no, clinical review required

5. Have overuse headaches been ruled out as the cause or a contributing factor to this member's migraine or cluster headaches? (Provide supporting documentation)

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

6. What indication is the requested CGRP inhibitor intended to treat? (Provide documentation of diagnosis)

    a. Migraine, continue to #7
    b. Episodic Cluster Headache, continue to #9
    c. Other, clinical review required

7. Over the last three (3) months, has this member experienced 15 or more headache days per month, which, on at least 8 days per month, have the features of a migraine headache? (Provide supporting documentation)

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

8. Has the member had a documented trial and failure (≥8 weeks), intolerance or contraindication to at least one migraine prophylactic drug from each of the following drug groups? (Provide supporting documentation)

        - Group 1: topiramate or divalproex sodium
        - Group 2: amitriptyline or venlafaxine extended-release
        - Group 3: metoprolol, propranolol, timolol

    a. If yes, continue to #12
    b. If no, clinical review required

9. Does this member have documentation of at least two cluster periods lasting at least seven days to one year with at least five attacks? (Provide supporting documentation)

    a. If yes, continue to #10
    b. If no, clinical review required

10. Are this member's cluster periods separated by at least three (3) months of pain-free remission?

    a. If yes, continue to #11
    b. If no, clinical review required

OHSUHealth Services

11. Has the member had a documented trial and failure, intolerance to at least three (3) of the following treatments for episodic cluster headache or a contraindication to ALL? (Provide supporting documentation)

    - Verapamil immediate release (minimum 320mg/day)
    - Lithium
    - Topiramate

    a. If yes, continue to #12
    b. If no, clinical review required

12. Does the documentation submitted attest that the member has not received botulinum toxin for headache prevention in the previous two months AND the treatment does not include a CGRP antagonist to be used concurrently with botulinum toxin?

    a. If yes, continue to #13
    b. If no, clinical review required

13. Will the requested CGRP antagonist be used in combination with another CGRP antagonist (injectable or oral)?

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

Reauthorization Criteria

1. Does the requested CGRP antagonist continue to be used without concurrent botulinum toxin?

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

2. Will the requested CGRP antagonist be used in combination with another CGRP antagonist (injectable or oral)?

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

3. What indication is the requested CGRP inhibitor intended to treat? (Provide documentation of diagnosis)

    a. Migraine, continue to #4
    b. Episodic Cluster Headache, continue to #5
    c. Other, clinical review required

4. Has the member experienced a documented positive response to therapy defined by a reduction in migraine frequency or intensity? Note: For subsequent renewals, documented maintenance of initial response is required. (Provide supporting documentation)

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

5. Has the member experienced a documented positive response to therapy defined by a reduction of five (5) or more weekly cluster headache attacks? (Provide supporting documentation)

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

6. Has the provider attested that the member continues to require therapy for episodic cluster headaches (cluster period has not resolved)?

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

Note:

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

References:

1. Loder E, Burch R, Rizzoli P. The 2012 AHS/AAN guidelines for prevention of episodic migraine: a summary and comparison with other recent clinical practice guidelines. Headache. 2012;52:930-945.
2. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults. Neurology. 2012;78:1337-1345.
3. Ellis A, Otuonye I, Kumar, V, et al. Calcitonin gene-related peptide (CGRP) inhibitors as preventive treatments for patients with episodic or chronic migraines: effectiveness and value. 2018. Available at: https://icer-review.org/wp-content/uploads/2017/11/ICER_Migraine_Final_Evidence_Report_070318.pdf. Accessed September 29, 2020.
4. Robbins MS, Starling AJ, Pringsheim TM, et al. Treatment of cluster headache: The American Headache Society evidence-based guidelines. Headache. 2016;56:1093-1106.
5. Becker W. Cluster headache: conventional pharmacological management. Headache. 2013;53:1191-1196.
6. Wei DY, Khalil M, Goadsby PJ. Managing cluster headache. Pract Neurol. 2019;19:521-528.

Last Reviewed: 11/11/20, 11/10/21, 11/9/22, 11/8/23
Effective Date: 1/1/21, 1/15/23

7. Aimovig (erenumab) [Prescribing Information]. Thousand Oaks, CA. Amgen Inc. April 2020.
8. Emgality (galcanezumab) [Prescribing Information]. Indianapolis, IN. Eli Lilly and Company. December 2019.
9. Goadsby PJ, Reuter U, Hallström Y, et al. A controlled trial of erenumab for episodic migraine. N Engl J Med. 2017. 377;2123-2132.
10. Dodick DW, Ashina M, Brandes JL, et al. ARISE: a phase 3 randomized trial of erenumab for episodic migraine. Cephalgia. 2018;38:1026-1037.
11. Reuter U, Goadsby PJ, Lanteri-Minet M, et al. Efficacy and tolerability of erenumab in patients with episodic migraine in whom two-to-four previous preventive treatments were unsuccessful: a randomized, double-blind, placebo-controlled, phase 3b study. Lancet. 2018;392:2280-2287.
12. Tepper S, Ashina M, Reuter U, et al. Safety and efficacy of erenumab for preventive treatment of chronic migraine: a randomized, double-blind, placebo-controlled phase 2 trial. Lancet Neurol. 2017;16:425-434.
13. Stauffer VL, Dodick DW, Zhang Q, et al. Evaluation of galcanezumab for the prevention of episodic migraine: the EVOLVE-1 randomized clinical trial. JAMA Neurol. 2018;75:1080-1088.
14. Skljarevski V, Matharu M, Millen BA, et al. Efficacy and safety of galcanezumab for the prevention of episodic migraine: results of the EVOLVE-2 phase 3 randomized controlled clinical trial. Cephalgia. 2018;38:1442-1454.
15. Detke HC, Goadsby PJ, Wang S, et al. Galcanezumab in chronic migraine: the randomized, double-blind, placebo-controlled REGAIN study. Neurology. 2018;91:e2211-2221.
16. Ailani, Jessica, et al. "The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice." Headache: The Journal of Head and Face Pain 61.7 (2021): 1021-1039.
17. International Headache Society. Third edition of the International Classification of Headache Disorder (ICHD-3). Available at: https://ichd-3.org/. Published 2018. Accessed on October 13, 2022.

OHSUHealth Services

Inqovi® (decitabine and cedazuridine), Onureg® (azacitidine) Prior Authorization Guidelines

Affected Medication(s)

- Inqovi oral tablet
- Onureg oral tablet

FDA Approved Indication(s)

- Inqovi:
  - Treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.
- Onureg:
  - Continued treatment of adult patients with acute myeloid leukemia (AML) who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy

Dosing

- Inqovi:
  - One tablet (35mg decitabine and 100mg cedazuridine) by mouth one time daily on Days 1 through 5 of each 28-day cycle
- Onureg:
  - 300mg orally once time daily on days 1 through 14 of each 28-day cycle

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)

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

2. Is the request for continuation of therapy with the same anti-cancer medication?

   a. If yes, continue to Reauthorization
   b. If no, continue to #3

Last Reviewed: 1/13/21, 1/12/22, 1/11/23, 1/10/24
Effective Date: 3/1/21

OHSUHealth Services

3. Is the medication being requested for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, continue to #4
4. Is the medication being requested for an indication supported by the National Comprehensive Cancer Network (NCCN) recommendation with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is there medical rationale why the member cannot use generic IV formulation? (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?
    a. If yes, approve for 4 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by NCCN recommendation with an evidence level of 2A or higher? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Example include reduction in tumor size, objective response, delay in progression, partial response, etc.) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with an oncologist?

OHSUHealth Services

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

Note:

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

References:

1. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 05 Oct. 2020].
2. INQOVI® (decitabine and cedazuridine) tablets, [package insert]. Princeton, NJ: Taiho Oncology, Inc; 2020.
3. ONUREG (azacitidine) tablets, [package insert]. Summit, NJ: Celegene Corp.; 2020.
4. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Myelodysplastic Syndromes. Version 2.2022 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed December 7, 2021.
5. Garcia-Manero, Guillermo, et al. "Oral cedazuridine/decitabine: a phase 2, pharmacokinetic/pharmacodynamic, randomized, crossover study in MDS and CMML." Blood (2020).
6. Wei, Andrew H., et al. "The QUAZAR AML-001 Maintenance Trial: results of a phase III international, randomized, double-blind, placebo-controlled study of CC-486 (oral formulation of azacitidine) in patients with acute myeloid leukemia (AML) in first remission." (2019): LBA-3.
7. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Acute Myeloid Leukemia. Version 1.2022 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed December 7, 2021.

OHSU Health Services

Isturisa (osilodrostat)
Prior Authorization Guidelines

Affected Medication(s)

- Isturisa (osilodrostat) oral tablet

FDA Approved Indication(s)

- Adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

Dosing

- Initiate dosage at 2 mg orally twice daily. Titrate dosage by 1 to 2 mg twice daily no more frequently than every 2 weeks based on rate of cortisol changes, individual tolerability and improvement in signs and symptoms. Maximum recommended dosage is 30 mg twice daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation with the Isturisa for the same diagnosis?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the treatment prescribed by or in consultation with an endocrinologist?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Has the member been diagnosed with endogenous Cushing's Disease and has either failed pituitary surgery or is not a candidate for surgery? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a 24-hour mean urinary free cortisol level greater than 1.5 times the upper limit of normal? (Above 67 µg/24 hours) (Provide supporting lab values)
    a. If yes, continue to #6

Last Reviewed: 11/11/20, 11/10/21, 11/9/22, 7/12/23
Effective Date: 1/1/21, 12/15/22

b. If no, clinical review required

6. Does the member have a previous trial with inadequate response, intolerance, or contraindication to ketoconazole? (Provide supporting documentation)

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

Reauthorization Criteria

1. Is the treatment prescribed by or in consultation with an endocrinologist?

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

2. Has the member been diagnosed with endogenous Cushing's Disease and has either failed pituitary surgery or is not a candidate for surgery? (Provide supporting documentation)

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

3. Has the member experienced a documented positive response to therapy defined by a reduction in 24-hour urinary free cortisol levels to normal levels and/or improvement in signs or symptoms? (Provide supporting documentation) Note: For subsequent renewals documented maintenance of initial response is required

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

Note:

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

References:

1. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 27 July. 2020].
2. ISTURISA (osilodrostat) oral tablet [package insert]. Lebanon, NJ: Recordati Rare Disease, Inc; 2020.
3. Pivonello, Rosario, et al. "Efficacy and safety of osilodrostat in patients with Cushing's disease (LINC 3): a multicentre phase III study with a double-blind, randomised withdrawal phase." The Lancet Diabetes & Endocrinology 8.9 (2020): 748-761.
4. Lynnette K. Nieman, Beverly M. K. Biller, James W. Findling, M. Hassan Murad, John Newell-Price, Martin O. Savage, Antoine Tabarin, Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice

Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 100, Issue 8, 1 August 2015, Pages 2807–2831, https://doi.org/10.1210/jc.2015-1818

5. Fleseriu, Maria, et al. "Consensus on diagnosis and management of Cushing's disease: a guideline update." The lancet Diabetes & endocrinology 9.12 (2021): 847-875.

OHSUHealth Services

Iwilfin (eflornithine)
Prior Authorization Guidelines

Affected Medication(s)

- Iwilfin (eflornithine) oral tablet

FDA Approved Indication(s)

- To reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma (HRNB) who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy

Dosing

- 0.75 to 1.5 m^2: 576 mg by mouth twice daily
- Greater than 1.5 m^2: 768 mg by mouth twice daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the medication being requested for an indication supported by the National Comprehensive Cancer Network (NCCN) recommendation with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)
    a. If yes, continue to #6

Last Reviewed: 5/8/24
Effective Date: 6/15/24

OHSUHealth Services

b. If no, clinical review required

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

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by NCCN recommendation with an evidence level of 2A or higher? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Example include reduction in tumor size, objective response, delay in progression, partial response, etc.) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with an oncologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. IWILFIN™ (eflornithine) tablets [package insert]. Louisville, KY: USWM, LLC 2024.
2. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Neuroblastoma. Version 1.2024 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/pdf/neuroblastoma.pdf. [Accessed February 8, 2024.]
3. Oesterheld J, Ferguson W, Kraveka JM, et al. Eflornithine as Postimmunotherapy Maintenance in High-Risk Neuroblastoma: Externally Controlled, Propensity Score-Matched Survival Outcome Comparisons. J Clin Oncol. 2024;42(1):90-102.

OHSU Health Services

Joenja® (leniolisib)
Prior Authorization Guidelines

Affected Medication(s)

- Joenja (leniolisib) oral tablet

FDA Approved Indication(s)

- Treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome in adult and pediatric patients 12 years of age and older

Dosing

- 70 mg orally twice daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is Joenja® (leniolisib) being requested for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member 12 years of age or older?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have confirmed APDS-associated PI3Kδ mutation with a documented variant in PIK3CD or PIK3R1? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 7/12/23
Effective Date: 8/15/23

OHSU Health Services

6. Does the member have nodal and/or extranodal lymphoproliferation with measurable index lesions? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Does the member have clinical findings and manifestations compatible with APDS such as recurrent sinopulmonary infections, intermittent herpesvirus viremia, and/or organ dysfunction? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Will Joenja be used in combination with immunosuppressive medications, PI3Kδ inhibitors, or B-cell depleters such as rituximab? (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, continue to #9
9. Is the treatment being prescribed by, or in consultation with, an immunologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of clinical response to prior therapy received (ex. decrease in size of index lesions, decrease in infections)?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, an immunologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and

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

References:

1. Joenja (leniolisib) tablets, [package insert]. Saint Quentin Fallavier, France: Skypharma Production SAS for Pharming Technologies B.V.; 2023
2. Drugs@FDA: FDA Approved Drug Products. 2023. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 17 Apr. 2023]
3. Rao VK, Webster S, Šedivá A, et al. A randomized, placebo-controlled phase 3 trial of the PI3Kδ inhibitor leniolisib for activated PI3Kδ syndrome. Blood. 2023;141(9):971-983.
4. Coulter TI, Cant AJ. The Treatment of Activated PI3Kδ Syndrome. Front Immunol. 2018 Sep 7;9:2043.

OHSU Health Services

Jynarque (tolvaptan)
Prior Authorization Guidelines

Affected Medication(s)

- Jynarque (tolvaptan) oral tablet

FDA Approved Indication(s)

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

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

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for use to treat an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the request a renewal of a previously approved Jynarque (tolvaptan) prior authorization and the indication is for the same as previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #4
4. Is the member 18 years of age or older?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a diagnosis of autosomal dominant polycystic kidney disease confirmed by ultrasonography/ MRI/CT scan with at least two unilateral or bilateral cysts in patients with a family history of ADPKD, at least three unilateral or bilateral cysts in members with an unknown family history, AND/OR positive genetic testing? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 4/2/19, 3/11/20, 9/8/21, 9/14/22, 9/13/23
Effective Date: 5/1/19, 1/1/20

OHSUHealth Services

6. Is the member at risk of rapidly-progressing autosomal dominant polycystic kidney disease (ADPKD) defined by any of the following? (Provide supporting documentation)
    - MAYO class 1C, 1D, or 1E
    - Total kidney volume (TKV) >750 mL
    - An ultrasound determined kidney length of > 16.5 cm
    - PROPKD score >6
    - Age of < 55 with CKD stage 3

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

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

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

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

Reauthorization Criteria

1. Has the member had a positive clinical response to therapy as defined by a slowing in the decline in kidney function and/or an improvement in kidney pain? (Provide supporting documentation)

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

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

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

Note:

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

References:

1. Jynarque [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; October 2018.
2. Chapman AB, Devuyst O, Eckardt KU, et al. Autosomal Dominant Polycystic Kidney Disease (ADPKD): Report from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. 2/2017.
3. Srivastava A, Patel N. Autosomal dominant polycystic kidney disease. American Academy of Family Physician. 2014;90(5):303-307
4. Torres VE, Chapman AB, Devuyst O, et al. Tolvaptan in patients with autosomal dominant polycystic kidney disease. The New England Journal of Medicine. 2012;367:2407-18.

Last Reviewed: 4/2/19, 3/11/20, 9/8/21, 9/14/22. 9/13/23
Effective Date: 5/1/19, 1/1/20

OHSU Health Services

Kalydeco (ivacaftor)
Prior Authorization Guidelines

Affected Medication(s)

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

FDA Approved Indication(s)

- Treatment of cystic fibrosis (CF) in patients age 1 month 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

- Refer to package insert for specific dosing recommendation

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Kalydeco (ivacaftor) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is Kalydeco (ivacaftor) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have documentation of a cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation that is responsive to ivacaftor based on in vitro data and/or clinical data? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the patient have documentation of baseline FEV1, ALT, and AST? (Provide supporting documentation)
    a. If yes, continue to #6

Last Reviewed: 10/18/18, 7/23/19, 3/11/20, 7/14/21, 7/13/22, 7/12/23, 5/8/24
Effective Date: 11/15/18, 9/15/19, 1/1/20, 9/1/21, 8/15/23, 6/15/24

b. If no, clinical review required

6. Is the patient at least 1 month of age?
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is Kalydeco (ivacaftor) being prescribed by, or in consult with, a pulmonologist or a specialist experienced in treating cystic fibrosis patient?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

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

Note:

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. Kalydeco® (ivacaftor) [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc. May 2023.
2. Kalydeco®. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed July 1, 2019.
3. Simon, MD. Cystic fibrosis: Overview of the treatment of lung disease. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed August 31, 2018

Last Reviewed: 10/18/18, 7/23/19, 3/11/20, 7/14/21, 7/13/22, 7/12/23, 5/8/24
Effective Date: 11/15/19, 9/15/19, 1/1/20, 9/1/21, 8/15/23, 6/15/24

OHSU Health Services

Koselugo® (selumetinib)
Prior Authorization Guidelines

Affected Medication(s)

- Koselugo oral capsule

FDA Approved Indication(s)

- Treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).

Dosing

- Refer to corresponding package insert for dosing recommendations

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request a renewal of a previously approved Koselugo (selumetinib) prior authorization and indication is for the same as previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member currently have a diagnosis of neurofibromatosis type 1 confirmed through genetic testing or 2 or more of the following diagnostic criteria? (Provide supporting documentation)
        i. 6 or more café-au-lait macules (greater than or equal to 0.5 cm in prepubertal subjects or greater than or equal to 1.5 cm in post pubertal subjects)
        ii. Two or more neurofibromas of any type or one plexiform neurofibroma
        iii. Freckling in the axillary or inguinal region
        iv. Optic glioma
        v. Two or more Lisch nodules (iris hamartomas)

Last Reviewed: 9/9/20, 9/8/21, 11/9/22, 11/8/23
Effective Date: 11/1/20, 11/1/21, 1/15/23, 12/15/23

OHSUHealth Services

vi. A distinctive osseous lesion such as sphenoid dysplasia or thinning of long bone cortex with or without pseudarthrosis
vii. A heterozygous pathogenic *NF1* variant with a variant allele fraction of 50% in apparently normal tissue such as white blood cells
viii. A first-degree relative (parent, sibling, or offspring) with NF-1 by the above criteria

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

5. Does the member have at least one measurable (at least 3cm in one dimension) plexiform neurofibroma that is inoperable? (Provide supporting documentation)

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

6. Is the member's plexiform neurofibroma symptomatic, disfiguring, or growing in size? (Provide supporting documentation)

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

7. Is the treatment being prescribed by, or in consultation with, an oncologist or neurologist?

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

Reauthorization Criteria

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

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

2. Were updated chart notes (within the past 6 months) provided with documentation of a clinical positive response defined as a decrease in or maintenance of plexiform neurofibroma volume compared to pre-therapy 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 an oncologist or neurologist?

a. If yes, approve for 12 months reauthorization
b. If no, clinical review required

Last Reviewed: 9/9/20, 9/8/21, 11/9/22, 11/8/23
Effective Date: 11/1/20, 11/1/21, 1/15/23, 12/15/23

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. Koselugo [selumetinib] capsules. AstraZeneca Pharmaceuticals, LP. Wilmington, DE; December 2021.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 26 May. 2020].
3. Widemann, Brigitte C., et al. "Phase I study of the MEK1/2 inhibitor selumetinib (AZD6244) hydrogen sulfate in children and young adults with neurofibromatosis type 1 (NF1) and inoperable plexiform neurofibromas (PNs)." (2014): 10018-10018.
4. Gross AM, Wolters P, Baldwin A et al. SPRINT: Phase II study of the MEK ½ inhibitor selumetinib (AZD6244, ARRY142886) in children with neurofibromatosis type 1 (NF1) and inoperable plexiform neurofibromas (PN). Journal of Clinical Oncology. 2018; 36(15): 10503. Available from: http://ascopubs.org/doi/abs/10.1200/JCO.2018.36.15_suppl.10503. Accessed August 12, 2020.
5. Miller DT, Freedenberg D, Schorry E, et al. Health Supervision for Children With Neurofibromatosis Type 1. Pediatrics. 2019;143(5):e20190660
6. Dombi E, Baldwin A, Marcus L, et al. Activity of selumetinib in neurofibromatosis type-1 related plexiform neurofibromas. N Engl J Med. 2016; 375(26): 2550-2560.
7. Ferner, Rosalie E., et al. "Guidelines for the diagnosis and management of individuals with neurofibromatosis 1." Journal of medical genetics 44.2 (2007): 81-88.
8. National Institutes of Health Consensus Development Conference Statement: neurofibromatosis. Bethesda, Md., USA, July 13-15, 1987. Neurofibromatosis 1:172-178,1988
9. Legius E, Messiaen L, Wolkenstein P, et al. Revised diagnostic criteria for neurofibromatosis type 1 and Legius syndrome: An international consensus recommendation. Genet Med 2021; 23:1506.

Last Reviewed: 9/9/20, 9/8/21, 11/9/22, 11/8/23
Effective Date: 11/1/20, 11/1/21, 1/15/23, 12/15/23

OHSUHealth Services

Long-Acting Opioids
Prior Authorization Guidelines

Affected Medication(s)

- All long-acting opioids

FDA Approved Indication(s)

- Pain, chronic (severe), in patients requiring a long-term daily around-the-clock opioid analgesic

Dosing

- Variable based on drug entity

Authorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the requested drug a formulary long-acting opioid?
    a. If yes, continue to #4
    b. If no, continue to #3
3. Has the patient had an insufficient clinical response to a trial of two (2) or more formulary long-acting opioids? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does this patient have pain related to one of the following conditions: active malignancy, palliative care, hospice or sickle cell disease? (Provide supporting documentation)
    a. If yes, approve for 12 months
    b. If no, continue to #5
5. Is the request for continuation of opioid therapy in which this patient has been established on long-acting opioid therapy or has been on short-acting opioids for at least 90 days either by a previously approved opioid request, claims history or documentation submitted by the provider? (Note: If transitioning care from specialist to PCP, including supporting documentation of transition notes)
    a. If yes, continue to #10
    b. If no, continue to #6

Last Reviewed: 5/13/20, 11/11/20, 1/12/22, 1/11/23, 1/10/24, 5/8/24
Effective Date: 6/1/20, 1/1/21, 3/1/22, 2/15/24, 6/15/24

OHSUHealth Services

6. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (NOTE: Acute or subacute (<90 days) management of pain associated with back or spine conditions with long-acting opioids is not funded; management of opioid dependence is funded) (Provide documentation of diagnosis)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the requested medication being used for the treatment of migraines or other headaches?
    a. If yes, clinical review required
    b. If no, continue to #8
8. Is the member concurrently on other short-acting or long-acting opioids (coverage is limited to one opioid product regardless of formulation)? (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, continue to #9
9. Does this patient have a signed pain management agreement with their provider inclusive of random urine drug screens AND monitoring of the Oregon Prescription Drug Monitoring Program (PDMP) AND patient is compliant with agreement requirements? (Note: Members residing in a long-term care facility are exempt from this requirement)
    a. If yes, approve up to 3 months
    b. If no, clinical review required
10. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #11
    b. If no, clinical review required
11. Does this patient have a signed pain management agreement with their provider inclusive of random urine drug screens AND monitoring of the Oregon Prescription Drug Monitoring Program (OR PDMP) AND patient is compliant with agreement requirements? (Note: Members residing in a long-term care facility are exempt from this requirement)
    a. If yes, continue to #12
    b. If no, clinical review required
12. Has the provider documented that the benefits of chronic opioid treatment outweigh the risks in this patient?
    a. If yes, continue to #13
    b. If no, clinical review required

OHSUHealth Services

13. Has this patient been referred to non-pharmacologic treatment for the management of pain (e.g. physical therapy, occupational therapy) or has non-pharmacologic treatment been documented to be not tolerated or ineffective? (Provide supporting documentation)

    a. If yes, continue to #14
    b. If no, clinical review required

14. Does this patient have a documented trial with inadequate response to non-opioid treatment for their condition and will opioids be continued in conjunction with non-opioid treatment if appropriate (e.g. NSAIDs, gabapentin, pregabalin, duloxetine, tri-cyclic antidepressants)? (Provide supporting documentation)

    a. If yes, continue to #15
    b. If no, clinical review required

15. Have improvements in the patient's functional goals or quality of life been documented from baseline as a result of opioid treatment? (Provide supporting documentation)

    a. If yes, continue to #16
    b. If no, clinical review required

16. Is the requested total daily morphine equivalent dose less than 50?

    a. If yes, approve for 12 months
    b. If no, continue to question #17

17. Does this patient have an active order of naloxone prescribed within the past 12 months?

    a. If yes, continue to #18
    b. If no, clinical review required

18. Does this patient have an active taper plan or has rationale been provided for avoidance of a taper at this time? (Provide supporting documentation)

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

Note:

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

References:

1. Opioid Risk Tool: https://www.drugabuse.gov/sites/default/files/opioidrisktool.pdf

Last Reviewed: 05/13/20, 11/11/20, 1/12/22, 1/11/23, 1/10/24, 5/8/24
Effective Date: 6/1/20, 1/1/21, 3/1/22, 2/15/24, 6/15/24

OHSU Health Services

Mesnex® (mesna)
Prior Authorization Guidelines

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

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member currently receiving or planning to receive ifosfamide containing chemotherapy regimen? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. 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 #5
    b. If no, clinical review required
5. 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

Note:

Last Reviewed: 1/11/23, 1/10/24
Effective Date: 3/15/23

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. Mesnex (mesna) [Prescribing Information]. Deerfield, IL: Baxter Healthcare Corporation. December 2021.

Last Reviewed: 1/11/23, 1/10/24
Effective Date: 3/15/23

OHSU Health Services

MS Agents
Prior Authorization Guidelines

Affected Medication(s)

- Bafiertam (monomethyl fumarate) oral capsule
- Dimethyl fumarate oral capsule
- Extavia (interferon beta-1b) subcutaneous solution
- Fingolimod oral capsule
- Glatiramer acetate subcutaneous solution
- Glatopa (glatiramer acetate) subcutaneous solution
- Kesimpta (ofatumumab) injection solution
- Teriflunomide oral tablet

FDA Approved Indication(s)

- Bafiertam: For the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- Dimethyl fumarate: For the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults
- Extavia: For the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- Fingolimod: For treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older
- Glatiramer acetate/ Glatopa: For treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- Kesimpta: For the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- Teriflunomide: For the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults

Dosing

- Refer to corresponding package insert for dosing recommendations

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)

    a. If yes, continue to #2

Last Reviewed: 11/27/18, 11/26/19, 3/11/20, 7/14/21, 9/14/22, 11/6/22, 7/12/23
Effective Date: 1/15/19, 1/1/20, 9/1/21, 1/1/23, 8/15/23

OHSUHealth Services

b. If no, clinical review required

2. Is the request for renewal of a previously approved prior authorization for the same medication with the same indication?

    a. If yes, continue to Reauthorization
    b. If no, continue to #3

3. Is the medication being requested for an FDA approved indication? (Provide supporting documentation)

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

4. Is an MRI result consistent with multiple sclerosis provided? (Provide supporting documentation)

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

5. Is the member 18 years of age or older? (Note: fingolimod is indicated for 10 years of age and older)

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

6. Is the request for glatiramer, dimethyl fumarate, fingolimod, or teriflunomide?

    a. If yes, continue to #8
    b. If no, continue to #7

7. Did the member have a sufficient trial with an inadequate response, intolerance, or contraindication to at least TWO of the following: glatiramer, dimethyl fumarate, fingolimod, or teriflunomide? (Provide supporting documentation)

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

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

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

9. Is the medication being prescribed by, or in consultation with, a neurologist?

    a. If yes, approve for 12 months

b. If no, clinical review required

Reauthorization Criteria

1. Is the medication being requested for an FDA approved indication? (Provide supporting documentation)
    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? (Examples include: Lemtrada (alemtuzumab), Aubagio (teriflunomide), Tecfidera (dimethyl fumarate), Gilenya (fingolimod), Glatopa (glatiramer acetate), interferon beta preparations, Tysabri (natalizumab), Ocrevus (ocrelizumab), etc.) (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, continue to #3
3. Is clinical documentation confirming responsiveness to therapy provided? (Confirm stable disease with slowed progression compared to pretreatment or no treatment) (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the medication being prescribed by or in consultation with a neurologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. Bafiertam Prescribing Information. High Point, NC: Banner Life Sciences LLC; April 2020.
2. Extavia Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2020.
3. Kesimpta Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2022.

Last Reviewed: 11/27/18, 11/26/19, 3/11/20, 7/14/21, 9/14/22, 11/6/22, 7/12/23
Effective Date: 1/15/19, 1/1/20, 9/1/21, 1/1/23, 8/15/23

4. Gilenya (fingolimod) Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporations; April 2023.
5. Copaxone Prescribing Information. Overland Park, KS: Teva Neuroscience, Inc.; August 2019.
6. Tecfidera Prescribing Information. Cambridge, MA: Biogen Inc.; July 2019.
7. Aubagio (teriflunomide) [Prescribing Information]. Cambridge, MA: Genzyme Corporation, A Sanofi Company. January 2023.Rae-Grand A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Neurology. 2018;90(17):777-788. Available at: http://n.neurology.org/content/neurology/90/17/777.full.pdf. Accessed June 16, 2021.

Last Reviewed: 11/27/18, 11/26/19, 3/11/20, 7/14/21, 9/14/22, 11/6/22, 7/12/23
Effective Date: 1/15/19, 1/1/20, 9/1/21, 1/1/23, 8/15/23

OHSU Health Services

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 ursodiol in adults with an inadequate response to ursodiol, or as monotherapy in adults unable to tolerate ursodiol

Dosing

- Refer to package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Ocaliva (obeticholic acid) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Did the member have a previous trial with insufficient response to ursodiol as defined by one of the following? (Provide supporting documentation)
    - ALP greater than 1.67 times the upper normal limit (UNL)
    - Total bilirubin greater than one time the ULN but less than two times the ULN with at least 12 months of ursodiol at a dose of ≥ 13 mg/kg/day

    a. If yes, continue to #6
    b. If no, continue to #5

OHSUHealth Services

5. Does the member have an intolerance or contraindication to ursodiol? (Provide supporting documentation of intolerance or contraindication)
    a. If yes, continue to #6
    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 requested dose appropriate based on liver function?
    a. If yes, continue to #8
    b. If no, clinical review required
8. Is the treatment being prescribed by, or in consult with, a hepatologist or another related specialist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is Ocaliva (obeticholic acid) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there evidence of improvement of primary biliary cholangitis, defined as all of the following? (Provide supporting documentation)
    - ALP <1.67-times the ULN
    - Decrease of ALP >15% from baseline
    - Normal total bilirubin level

    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the requested dose appropriate based on liver function?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the treatment being prescribed by, or in consult with, a hepatologist or another related specialist?
    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. Ocaliva Prescribing Information. New York, NY: Intercept Pharmaceuticals, Inc.; October 2022. Available at https://ocaliva.com/.
2. Lindor, KD, Gershwin ME, Poupon R et al. AASLD Practice Guidelines: Primary biliary cirrhosis. Hepatology. 2009; 50(1): 291-308.
3. European Association for the Study of the Liver (EASL). EASL clinical practice guidelines: the diagnosis and management of patients with primary biliary cholangitis. J Hepatology. 2017;67:145-72.
4. Lindor, Keith D., et al. "Primary biliary cholangitis: 2018 practice guidance from the American Association for the Study of Liver Diseases." Hepatology 69.1 (2019): 394-419.

Last Reviewed: 1/10/24
Effective Date: 2/15/24

OHSUHealth Services

Ogsiveo (nirogacestat hydrobromide)
Prior Authorization Guidelines

Affected Medication(s)

- Ogsiveo oral tablet

FDA Approved Indication(s)

- Treatment of adult patients with progressing desmoid tumors who require systemic treatment

Dosing

- 150 mg orally twice daily until disease progression or unacceptable toxicity

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of therapy with same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the medication being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, continue to #4
4. Is the medication being requested for an indication supported by the National Comprehensive Cancer Network (NCCN) recommendation with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 1/10/24
Effective Date: 2/15/24

OHSUHealth Services

6. Does the member have a previous trial with inadequate response, intolerance or contraindication to at least TWO of the following: imatinib, pazopanib or sorafenib? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
7. Is the medication being prescribed by, or in consultation with, an oncologist?
    a. If yes, approve for 4 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by NCCN recommendation with an evidence level of 2A or higher? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Example include reduction in tumor size, objective response, delay in progression, partial response, etc.) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with an oncologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. OGSIVEO (nirogacestat) tablets, [package insert]. Stamford, CT: SpringWorks Therapeutics, Inc.; 2023.
2. Drugs@FDA: FDA Approved Drug Products. 2023. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 11 Dec. 2023].

3. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Soft Tissue Sarcoma. Version 3.2023 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed December 14, 2023.
4. Gounder M, Ratan R, Alcindor T, et al. Nirogacestat, a γ-Secretase Inhibitor for Desmoid Tumors. N Engl J Med. 2023;388(10):898-912.

OHSUHealth Services

Ojjaara (momelotinib)
Prior Authorization Guidelines

Affected Medication(s)

- Ojjaara oral tablet

FDA Approved Indication(s)

- Treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF (post-polycythemia vera (PV) and post-essential thrombocythemia (ET)) in adults with anemia

Dosing

- 200 mg orally once daily until disease progression or unacceptable toxicity

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #5
    b. If no, continue to #4
4. Is the medication being requested for an indication supported by the National Comprehensive Cancer Network (NCCN) recommendation with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 5/8/24
Effective Date: 6/15/24

OHSUHealth Services

6. Does the member have a previous trial with inadequate response, intolerance or contraindication to either Jakafi or Inrebic? (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?
    a. If yes, approve for 4 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by NCCN recommendation with an evidence level of 2A or higher? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Example include reduction in tumor size, objective response, delay in progression, partial response, etc.) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with an oncologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. OJJAARA (momelotinib) tablets [package insert]. Durham, NC: GlaxoSmithKline, LLC; 2023.
2. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Myeloproliferative Neoplasms. Version 3.2023 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf. [Accessed December 12, 2023.]

3. Verstovsek S, Gerds AT, Vannucchi AM, et al. Momelotinib versus danazol in symptomatic patients with anaemia and myelofibrosis (MOMENTUM): results from an international, double-blind, randomised, controlled, phase 3 study [published correction appears in Lancet. 2023 Apr 29;401(10386):1426]. Lancet. 2023;401(10373):269-280.
4. Mesa RA, Kiladjian JJ, Catalano JV, et al. SIMPLIFY-1: A Phase III Randomized Trial of Momelotinib Versus Ruxolitinib in Janus Kinase Inhibitor-Naïve Patients With Myelofibrosis. J Clin Oncol. 2017;35(34):3844-3850.

OHSU Health Services

Omnipod Insulin Pump
Prior Authorization Guidelines

Affected Medication(s)

- Omnipod

FDA Approved Indication(s)

- For the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin

Initial Authorization Criteria

1. Is the request for use in a member with type 1 diabetes and meets one of the following? (Provide documentation of diagnosis)

    i. C-peptide testing requirement
    - The C-peptide level is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method; OR
    - For a client with renal insufficiency and a creatinine clearance (actual or calculated from age, weight, and serum creatinine) less than or equal to 50 ml/minute, a fasting C-peptide level is less than or equal to 200 percent of the lower limit of normal of the laboratory's measurement method; AND
    - A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225 mg/dl.

    ii. Beta cell autoantibody test is positive

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

2. Is the member currently on an insulin pump?

    a. If yes, continue to #3
    b. If no, continue to #4

3. Does the member meet all of the following criteria? (Provide supporting documentation)

    i. Documented frequency of glucose self-testing with an average of at least four times per day during the month prior to medical assistance program enrollment; AND
    ii. Has a plan to be seen and evaluated by the treating physician at least every three months; AND

Last Reviewed: 9/14/22, 9/13/23
Effective Date: 11/15/22

iii. The external insulin infusion pump is ordered by with follow-up care rendered by a physician who manages patients on continuous subcutaneous insulin infusion therapy and who works closely with a team including nurses, diabetic educators, and dieticians who are knowledgeable in the use of continuous subcutaneous insulin infusion therapy

a. If yes, approve
b. If no, clinical review required

4. Does the member meet all of the following criteria? (Provide supporting documentation)
   i. Completed a comprehensive diabetes education program; AND
   ii. Been on a program of multiple daily injections of insulin (i.e., at least three injections per day) with frequent self-adjustments of insulin dose for at least six months prior to initiation of the insulin pump; AND
   iii. Documented frequency of glucose self-testing an average of at least four times per day during the two months prior to initiation of the insulin pump and meets one or more of the following criteria while on the multiple injection regimen:
      1. Glycosylated hemoglobin level (HbA1C) greater than 7 percent
      2. History of recurring hypoglycemia
      3. Wide fluctuations in blood glucose before mealtime
      4. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
      5. History of severe glycemic excursions

   a. If yes, approve
   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. Omnipod 5 ACE Pump®. Acton, MA: Insulet Corporation; 2022.
2. Health System Division: Medical Assistance Programs – Chapter 410 Division 122 DURABLE MEDICAL EQUIPMENT, PROSTHETIC ORTHOTICS AND SUPPLIES (DMEPOS). (410-122-0525). Oregon Health Authority. Available at: https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=84246

Last Reviewed: 9/14/22, 9/13/23
Effective Date: 11/15/22

OHSUHealth Services

Oncology Policy
Prior Authorization Guidelines

Affected Medication(s)

- Abiraterone acetate tablet
- Akeega (niraparib-abiraterone tablet)
- Alecensa (alectinib oral capsule)
- Alunbrig (brigatinib oral tablet)
- Augtyro (repotrectinib oral capsule)
- Ayvakit (avapritinib tablet)
- Balversa (erdafitinib tablet)
- Bexarotene capsule
- Bosulif (bosutinib oral tablet)
- Braftovi (encorafenib capsule)
- Brukinsa (zanubrutinib capsule)
- Cabometyx (cabozantinib oral tablet)
- Calquence (acalabrutinib oral tablet)
- Caprelsa (vandetanib oral tablet)
- Cometriq (cabozantinib oral capsule)
- Copiktra (duvelisib oral capsule)
- Cotellic (cobimetinib tablet)
- Daurismo (glasdegib tablet)
- Emcyt (estramustine capsule)
- Erivedge (vismodegib capsule)
- Erleada (apalutamide tablet)
- Erlotinib tablet
- Everolimus tablet and tablet for suspension
- Exkivity (mobocertinib capsule)
- Fruzaqla (fruquintinib capsule)
- Fotivda (tivozanib capsule)
- Gavreto (pralsetinib capsule)
- Gefitinib tablet
- Gilotrif (afatinib dimaleate tablet)
- Gleostine (lomustine capsule)
- Ibrance (palbociclib capsule and tablet)
- Iclusig (ponatinib hydrochloride tablet)
- Idhifa (enasidenib tablet)
- Imatinib mesylate tablet
- Imbruvica (ibrutinib tablet, capsule, and suspension)
- Inlyta (axitinib tablet)
- Myleran (busulfan tablet)
- Nerlynx (neratinib tablet)
- Nilutamide tablet
- Ninlaro (ixazomib capsule)
- Nubeqa (darolutamide tablet)
- Odomzo (sonidegib capsule)
- Orserdu (elacestrant tablet)
- Pazopanib tablet
- Pemazyre (pemigatinib tablet)
- Piqray (alpelisib daily dose tablet)
- Pomalyst (pomalidomide capsule)
- Qinlock (ripretinib tablet)
- Retevmo (selpercatinib capsule)
- Rezlidhia (olutasidenib tablet)
- Rozlytrek (entrectinib capsule and oral pellets)
- Rubraca (rucaparib tablet)
- Rydapt (midostaurin capsule)
- Sorafenib tablet
- Sprycel (dasatinib tablet)
- Stivarga (regorafenib tablet)
- Sunitinib malate capsule
- Tabloid (thioguanine tablet)
- Tabrecta (capmatinib tablet)
- Tafinlar (dabrafenib mesylate capsule and tablet for suspension)
- Tagrisso (osimertinib tablet)
- Talzenna (talazoparib capsule)
- Tasigna (nilotinib hydrochloride capsule)
- Tavalisse (fostamatinib disodium hexahydrate tablet)
- Tazverik (tazemetostat tablet)
- Temozolomide capsule
- Tepmetko (tepotinib tablet)
- Thalomid (thalidomide capsule)
- Tibsovo (ivosidenib tablet)
- Toremifene tablet

Last Reviewed: 11/26/19, 7/8/20, 1/13/21, 3/10/21, 5/12/21, 7/14/21, 9/8/21, 11/10/21, 5/11/22, 1/11/23, 5/10/23, 9/13/23, 11/8/23, 1/10/24, 5/8/24
Effective Date: 1/1/20, 9/1/20, 3/1/21, 5/1/21, 7/1/21, 9/1/21, 11/1/21, 1/1/22, 7/11/22, 3/15/23, 6/15/23, 12/15/23, 10/15/23, 2/15/24, 6/15/24

- Inrebic (fedratinib capsule)
- Jakafi (ruxolitinib tablet)
- Jaypirca (pirtobrutinib tablet)
- Kisqali (ribociclib tablet)
- Krazati (adagrasib tablet)
- Lapatinib ditosylate tablet
- Lenalidomide capsule
- Lenvima (lenvatinib capsule)
- Leukeran (chlorambucil tablet)
- Lonsurf (trifluridine/tipiracil tablet)
- Lorbrena (lorlatinib tablet)
- Lumakras (sotorasib tablet)
- Lynparza (olaparib tablet)
- Lytgobi (futibatinib tablet)
- Matulane (procarbazine tablet)
- Mekinist (trametinib dimethyl sulfoxide tablet and oral solution)
- Mektovi (binimetinib tablet)
- Tukysa (tucatinib tablet)
- Turalio (pexidartinib capsule)
- Vanflyta (quizartinib tablet)
- Venclexta (venetoclax tablet)
- Verzenio (abemaciclib tablet)
- Vitrakvi (larotrectinib capsule and oral solution)
- Vizimpro (dacomitinib tablet)
- Vonjo (pacritinib citrate capsule)
- Welireg (belzutifan tablet)
- Xalkori (crizotinib capsule)
- Xospata (gilteritinib tablet)
- Xpovio (selinexor tablet)
- Xtandi (enzalutamide capsule)
- Zejula (niraparib tablet)
- Zelboraf (vemurafenib tablet)
- Zolinza (vorinostat capsule)
- Zydelig (idelalisib tablet)
- Zykadia (ceritinib tablet)

FDA Approved Indication(s)

- Refer to major compendia for supported use

Dosing

- Refer indication specific compendia supported dosing

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of therapy with the same anti-cancer medication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the medication being requested for an FDA approved indication? (Provide supporting documentation)

OHSUHealth Services

a. If yes, continue to #5
b. If no, continue to #4

4. Is the medication being requested for an indication supported by the National Comprehensive Cancer Network (NCCN) recommendation with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)

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

5. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)

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

6. Is the medication being prescribed by, or in consultation with, an oncologist?

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

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by NCCN recommendation with an evidence level of 2A or higher? (Provide supporting documentation)

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

2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Example include reduction in tumor size, objective response, delay in progression, partial response, etc.) (Provide supporting documentation)

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

3. Is the medication being prescribed by or in consultation with an oncologist?

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

Note:

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

Last Reviewed: 11/26/19, 7/8/20, 1/13/21, 3/10/21, 5/12/21, 7/14/21, 9/8/21, 11/10/21, 5/11/22, 1/11/23, 5/10/23, 9/13/23, 11/8/23, 1/10/24, 5/8/24
Effective Date: 1/1/20, 9/1/20, 3/1/21, 5/1/21, 7/1/21, 9/1/21, 11/1/21, 1/1/22, 7/11/22, 3/15/23, 6/15/23, 10/15/23, 12/15/23, 2/15/24, 6/15/24

References:

1. National Comprehensive Cancer Network. NCCN – NCCN Guidelines. Available at: https://www.nccn.org.

OHSU Health Services

Opzelura (ruxolitinib)
Prior Authorization Guidelines

Affected Medication(s)

- Opzelura topical cream

FDA Approved Indication(s)

- Topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in immunocompetent patients ≥12 years of age whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
- Topical treatment of non-segmental vitiligo in patients ≥12 years of age

Dosing

- Atopic dermatitis: Apply a thin layer to the affected skin twice daily; area should not exceed 20% BSA
- Vitiligo: Apply a thin layer to affected area(s) twice daily; application area should not exceed 10% BSA

Initial Authorization Criteria

1. Is the submitted diagnosis provided and covered by Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 12 years old or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member currently have severe inflammatory skin disease defined as having functional impairment (e.g. inability to use hands or feet or actives of daily living, or significant facial involvement preventing normal social interaction AND one or more of the following: At least 10% of body surface area involved AND/OR Hand, face, foot or mucous membrane involvement? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required

Last Reviewed: 1/11/23, 1/10/24
Effective Date: 3/15/23, 2/15/24

OHSUHealth Services

5. Has the member had 2 or more unsuccessful treatments with moderate to high potency topical corticosteroids? (E.g. betamethasone ointment/augmented cream, triamcinolone ointment, halobetasol, fluocinonide ointment/cream, etc.) (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, continue to #6
6. Does the member have a contraindication or clinical rationale for avoiding moderate to high potency topical corticosteroids? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Has the member had a previous trial with inadequate response, intolerance, or contraindication to a topical calcineurin inhibitor (i.e. tacrolimus)? (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, continue to #8
8. Does the member have a contraindication or clinical rationale for avoiding a topical calcineurin inhibitor? (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, clinical review required
9. Is the requested treatment dose appropriate and is the member's application area (BSA %) within FDA approved limits?
    a. If yes, continue to #10
    b. If no, clinical review required
10. Is the treatment being prescribed by, or in consultation with, an appropriate specialist?
    a. If yes, continue to #11
    b. If no, clinical review required
11. What is the diagnosis that the medication is being requested for?
    a. Atopic dermatitis, continue to #12
    b. Vitiligo, approve for 3 months
12. Has the member an inadequate response, intolerance, or contraindication to at least two of the following therapies: cyclosporine, methotrexate, azathioprine, mycophenolate mofetil, oral corticosteroids, or phototherapy? (Provide supporting documentation)
    a. If yes, approve for 3 months
    b. If no, clinical review required

Note:

Last Reviewed: 1/11/23, 1/10/24
Effective Date: 3/15/23, 2/15/24

OHSUHealth Services

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. Opzelura (ruxolitinib) [prescribing information]. Wilmington, DE: Incyte Corporation; July 2022.
2. Opzelura. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed October 13, 2022.
3. Opzelura. Lexicomp Online, Pediatric and Neonatal Lexi-Drugs Online, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2022. Available at: http://online.lexi.com/lco/action/home. Accessed October 13, 2022.
4. Oregon Health Plan. Prioritized List of Health Services. January 1, 2024. Available at: https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx. Accessed December 28, 2023.
5. Grimes MD. Vitiligo: Management and prognosis. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com. Accessed October 13, 2022.
6. Weston MD, Howe MD. Treatment of atopic dermatitis (eczema). Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed October 13, 2022.
7. Arora CJ, Rafiq M, Shumack S, Gupta M. The efficacy and safety of tacrolimus as mono- and adjunctive therapy for vitiligo: A systematic review of randomised clinical trials. Australas J Dermatol 2020; 61:e1.
8. Dong Y, Yang Q, Guo B, et al. The effects of tacrolimus plus phototherapy in the treatment of vitiligo: a meta-analysis. Arch Dermatol Res 2021; 313:461.

Last Reviewed: 1/11/23, 1/10/24
Effective Date: 3/15/23, 2/15/24

OHSU Health Services

Oral and Nasal CGRP Antagonists
Prior Authorization Guidelines

Affected Medication(s)

- Ubrelvy (ubrogepant) oral tablet
- Nurtec (rimegepant) oral disintegrating tablet
- Zavzpret (zavegepant) nasal spray

FDA Approved Indication(s)

- Ubrelvy: Treatment of migraines with or without aura in adults
- Nurtec ODT:
  - Acute treatment of migraines with or without aura in adults
  - Preventive treatment of migraines in adults
- Zavzpret: Treatment of migraine with or without aura in adults

Dosing

- Refer to package insert for recommended dosing for corresponding diagnosis

Initial Authorization Criteria

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

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

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

4. What is the requested diagnosis?
   a. Management of acute migraine, continue to #5
   b. Migraine prophylaxis, continue to #7

5. Does the member have a previous trial with inadequate response to at least TWO triptan drugs (i.e. sumatriptan, rizatriptan, naratriptan, zolmitriptan, etc.)?

Last Reviewed: 5/10/23, 7/12/23
Effective Date: 6/15/23, 8/15/23

OHSUHealth Services

a. If yes, continue to #10
b. If no, continue to #6

6. Does the member have a contraindication to all triptan therapies? (Example of contraindications include: history of coronary artery disease, cardiac accessory conduction pathway disorders, history of stroke, transient ischemic attack, or hemiplegic or basilar migraine, peripheral vascular disease, ischemic bowel disease, uncontrolled hypertension, or severe hepatic impairment) (Provide supporting documentation)
    a. If yes, continue to #10
    b. If no, clinical review required

7. Over the last three (3) months, has this member experienced 15 or more headache days per month, which, on at least 8 days per month, have the features of a migraine headache? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required

8. Has the member had a documented trial and failure (≥8 weeks), intolerance or contraindication to at least one migraine prophylactic drug from each of the following drug groups? (Provide supporting documentation)
    - Group 1: topiramate or divalproex sodium
    - Group 2: amitriptyline or venlafaxine extended-release
    - Group 3: metoprolol, propranolol, timolol

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

9. Has the member had a documented trial, intolerance, or contraindication to BOTH Aimovig and Emgality? (Provide supporting documentation)
    a. If yes, continue to #10
    b. If no, clinical review required

10. Will the requested medication be used in combination with another oral or injectable CGRP antagonist?
    a. If yes, clinical review required
    b. If no, continue to #11

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

OHSU Health Services

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
    a. If yes, continue to #2
    b. If no, 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 migraine frequency compared to 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 neurologist?
    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

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

References:

1. Ubrelvy [prescribing information]. Allergan USA, Inc. Madison, NJ. March 2021.
2. Nurtec ODT [prescribing Information]. Biohaven Pharmaceuticals, Inc. New Haven, CT. January 2023.
3. ZAVZPRET spray [prescribing information]. Pfizer, New York, NY. March 2023.
4. Ailani J, Burch RC, Robbins MS, on behalf of the Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021;61(7):1021-1039.
5. International Headache Society. Third edition of the International Classification of Headache Disorder (ICHD-3). Available at: https://ichd-3.org/. Published 2018. Accessed on February 8, 2023.
6. Ellis A, Otuonye I, Kumar, V, et al. Calcitonin gene-related peptide (CGRP) inhibitors as preventive treatments for patients with episodic or chronic migraines: effectiveness and value. 2018. Available at: https://icer-review.org/wp-content/uploads/2017/11/ICER_Migraine_Final_Evidence_Report_070318.pdf. Accessed February 8, 2023.

Last Reviewed: 5/10/23, 7/12/23
Effective Date: 6/15/23, 8/15,23

OHSU Health Services

Oral Nutritional Supplements
Prior Authorization Guidelines

Affected Medication(s)

- All Formulary Oral Nutritional Supplements Products

Initial Authorization Criteria

1. Does the member have nutritional deficiency confirmed by ONE of the following? (Provide supporting documentation from within 6 months)

    - Low serum protein levels
    - Sufficient caloric or protein intake not obtainable through normal food (includes regular, liquefied, or pureed forms) intake confirmed by registered dietician assessment
    - Resident of home, nursing facility, or chronic home care facility with prolonged history of malnutrition, and diagnosis of symptoms of cachexia which would be futile and invasive

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

2. Does the member meet at least ONE of the following criteria? (Provide supporting documentation)

    - Increased metabolic needs due to severe trauma
    - Malabsorption caused by other medical condition(s) (i.e. short-gut syndrome, fistula, cystic fibrosis, renal dialysis, etc.)
    - Active medical condition(s) such as ongoing cancer treatment, advanced acquired immune deficiency syndrome (AIDS) or pulmonary insufficiency

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

3. Does the member have a recent unplanned weight loss of 10% or more? (Provide supporting documentation)

    a. If yes, approve for 6 months
    b. If no, continue to #4

4. Is the member's body weight already being maintained by oral nutritional supplementation?

    a. If yes, approve for 6 months
    b. If no, continued to #5

5. Is the member under 6 years of age?

    a. If yes, continue to #6

Last Reviewed: 05/13/20, 9/8/21, 11/9/22, 11/8/23
Effective Date: 6/1/20, 1/1/23

b. If no, clinical review required

6. Does the member have a diagnosis of "failure to thrive"?

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

Note:

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

References:

1. Health System Division: Medical Assistance Programs – Chapter 410 Division 148 Home Enteral/Parenteral Nutrition and IV Services. (410-146-260). Oregon Health Authority. Available at: https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=87829

Oral GnRH Antagonists
Prior Authorization Guidelines

Affected Medication(s)

- Myfembree (elagolix/estradiol/norethindrone) oral tablet
- Oriahnn (elagolix/estradiol/norethindrone) oral tablet
- Orilissa (elagolix) oral tablet

FDA Approved Indication(s)

Myfembree

- Management of moderate to severe pain associated with endometriosis in premenopausal patients
- Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal patients

Oriahnn

- Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in patients prior to menopause

Orilissa

- Management of moderate to severe pain associated with endometriosis

Dosing

- Refer to specific product package insert for dosing guidelines

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
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 a renewal of a previously approved prior authorization for the same drug and indication that it was previously approved?
    a. If yes, continue to Reauthorization

Last Reviewed: 7/12/23
Effective Date: 8/15/23

OHSUHealth Services

b. If no, continue to #4

4. Does the member have any of the following contraindications to therapy? (Provide supporting documentation)

    - Pregnancy
    - Osteoporosis or related bone-loss condition
    - Severe hepatic impairment (Child-Pugh class C)
    - Concomitant use of organic anion transporting polypeptide (OATP) 1B1 (Orilissa/Oriahnn only)

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

5. What is the indication for the requested drug?

    a. Pain associated with endometriosis, continue to #6
    b. Heavy menstrual bleeding associated with uterine fibroids (leiomyomas), continue to #7

6. Does the member have a previous 12-week trial with inadequate response, intolerance, or contraindication to both of the following? (Provide supporting documentation)

    - Two separate non-steroidal anti-inflammatory drugs (NSAIDs)
    - A combined hormonal contraceptive or progestin (oral, depot injection, or IUD)

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

7. Does the member have a previous 12-week trial with inadequate response, intolerance, or contraindication to at least two of the following? (Provide supporting documentation)

    - Hormone-releasing IUD
    - Continuous administration of combined hormonal contraceptive
    - Cyclic progestin
    - Tranexamic acid

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

OHSUHealth Services

Reauthorization Criteria

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

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

2. Does the member demonstrate positive clinical response to therapy such as reduced pain associated with endometriosis or at least a 50% reduction in menstrual blood loss from baseline? (Provide supporting documentation)

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

3. Has the member exceeded the FDA-approved cumulative treatment duration? (Provide supporting documentation)

    - Myfembree: 24 months
    - Oriahnn: 24 months
    - Orilissa 150mg: 24 months
    - Orilissa 200mg: 6 months

    a. If yes, clinical review required
    b. If no, approve for up to 18 months unless otherwise specified

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. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.; February 2021.
2. Oriahnn [package insert]. North Chicago, IL: AbbVie Inc.; August 2021
3. Myfembree [package insert]. Brisbane, CA: Myovant Sciences, Inc.; February 2023.
4. Taylor H, Giudice L, Lessey B, et al. Treatment of endometriosis-associated pain with elagolix, an oral GnRH antagonist. N Engl J Med 2017; 377:28-40.
5. The American College of Obstetricians and Gynecologists. Management of endometriosis. Practice Bulletin 114. July 2010 (Reaffirmed 2018).
6. Sabry, M, Al-Hendy, Ayman. Medical Treatment of Uterine Leiomyoma. Reprod Sci. 2012:19(4):339-53.

Last Reviewed: 7/12/23
Effective Date: 8/15/23

OHSUHealth Services

Orgovyx (relugolix)
Prior Authorization Guidelines

Affected Medication(s)

- Orgovyx (relugolix oral tablet)

FDA Approved Indication(s)

- Treatment of adults with advanced prostate cancer

Dosing

- Loading dose of 360mg on the first day of treatment followed by 120mg taken orally one time daily at approximately the same time each day

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the medication being requested for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, continue to #4
4. Is the medication being requested for an indication supported by the National Comprehensive Cancer Network (NCCN) recommendation with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 3/10/21, 3/9/22, 5/10/23, 5/8/24
Effective Date: 5/1/21, 6/15/23

OHSUHealth Services

6. Does the member have a previous trial with inadequate response, intolerance, or contraindication to leuprolide acetate? (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?
    a. If yes, approve for 4 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by NCCN recommendation with an evidence level of 2A or higher? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Example includes testosterone levels < 50ng/dL) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with an oncologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. ORGOVYX (relugolix) tablets, [package insert]. Brisbane, CA: Myovant Sciences, Inc.; 2021.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 26 Jan. 2021].
3. Shore, Neal D., et al. "Oral relugolix for androgen-deprivation therapy in advanced prostate cancer." New England Journal of Medicine 382.23 (2020): 2187-2196.
4. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Prostate Cancer. Version 3.2022 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed February 2, 2022.

Last Reviewed: 3/10/21, 3/9/22, 5/10/23, 5/8/24
Effective Date: 5/1/21, 6/15/23

OHSU Health Services

Orkambi® (lumacaftor/ivacaftor)
Prior Authorization Guidelines

Affected Medication(s)

- Orkambi (lumacaftor/ivacaftor) oral tablet
- Orkambi (lumacaftor/ivacaftor) oral granule packet

FDA Approved Indication(s)

- Treatment of cystic fibrosis (CF) in patients age 1 year and older who are homozygous for the F508del mutation in the CFTR gene

Dosing

- For patients less than 2 years old weighing 7 to less than 9 kg: One packet of Orkambi® (lumacaftor 75mg/ivacaftor 94mg) granules every 12 hours
- For patients less than 2 years old weighing 9 to less than 14 kg: One packet of Orkambi® (lumacaftor 100mg/ivacaftor 125mg) granules every 12 hours
- For patients less than 2 years old weighing 14kg or greater: One packet of Orkambi® (lumacaftor 150mg/ivacaftor 188mg) granules every 12 hours
- For patients 2-5 years old weighing less than 14 kg: One packet of Orkambi® (lumacaftor 100mg/ivacaftor 125mg) granules every 12 hours with fat-containing food
- For patients 2-5 years old weighing 14 kg or greater: One packet of Orkambi® (lumacaftor 150mg/ivacaftor 188mg) granules every 12 hours with fat-containing food
- For patients 6-11 years old: Two Orkambi® (lumacaftor 100mg/ivacaftor 125mg) tablets every 12 hours with fat containing food
- For patients 12 years and older: Two Orkambi® (lumacaftor 200mg/ivacaftor 125mg) tablets every 12 hours with fat containing food

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Orkambi (lumacaftor/ivacaftor) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3

Last Reviewed: 10/18/18, 3/11/20, 5/12/21, 5/11/22, 11/9/22, 11/8/23
Effective Date: 11/15/18, 1/1/20, 1/1/23

OHSUHealth Services

3. Is Orkambi (lumacaftor/ivacaftor) being requested for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the patient have a documentation of homozygous F508del mutation by an FDA-cleared CF mutation test? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the patient have documentation of baseline FEV1, ALT, and AST? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the patient at least 1 year of age?
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is Orkambi (lumacaftor/ivacaftor) being prescribed by, or in consult with, a pulmonologist or a specialist experienced in treating cystic fibrosis patient?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of significant clinical response to prior therapy received? (i.e. improvement of FEV1 from baseline) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Were updated chart notes (within past year) provided with documentation of follow up liver function tests? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required

Last Reviewed: 10/18/18, 3/11/20, 5/12/21, 5/11/22, 11/9/22, 11/8/23
Effective Date: 11/15/18, 1/1/20, 1/1/23

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

Note:

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

References:

1. Orkambi® (lumacaftor/ivacaftor) [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc. September 2022.
2. Orkambi®. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed August 31, 2018.
3. Simon, MD. Cystic fibrosis: Overview of the treatment of lung disease. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed April 18, 2022.

Last Reviewed: 10/18/18, 3/11/20, 5/12/21, 5/11/22, 11/9/22, 11/8/23
Effective Date: 11/15/18, 1/1/20, 1/1/23

OHSU Health Services

Oxervate (cenegermin-bkbj)
Prior Authorization Guidelines

Affected Medication(s)

- Oxervate (cenegermin-bkbj) eye drop solution

FDA Approved Indication(s)

- Treatment of neurotrophic keratitis

Dosing

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

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    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. Does the member have a diagnosis of neurotrophic keratitis (NK) stage 2 or stage 3? (Characterized as persistent corneal epithelial defect and/or corneal stroma involvement with presence corneal ulcer) (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Has the member trialed both preservative-free artificial tears and topical antibiotic eye drops with inadequate response? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Has the member previously been treated with a course of Oxervate for the same eye? (Note: Re-treatment with Oxervate is not supported)
    a. If yes, clinical review required
    b. If no, continue to #6x

Last Reviewed: 7/23/19, 3/11/20, 7/14/21, 7/13/22, 7/12/23
Effective Date: 9/15/19, 1/1/20

OHSUHealth Services

6. Is the medication being prescribed by, or in consultation with, and ophthalmologist? (Note: No more than 8 weeks per eye may be approved. Treatment beyond 8 weeks has not been studied)
    a. If yes, approve for 8 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:

1. Drugs@FDA: FDA Approved Drug Products. 2018. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 5 Dec. 2018].
2. OXERVATE (cenegermin-bkbj) ophthalmic solution [package insert]. Boston, MA: Dompe US, Inc.; 2017.
3. Sacchetti M, Lambiase A. Diagnosis and management of neurotrophic keratitis. Clin Ophthalmol. 2014;8:571–579. Published 2014 Mar 19. doi:10.2147/OPTH.S45921
4. Bonini S, Lambiase A, Rama P et al. Phase 2 randomized, double-masked, vehicle-controlled trial of recombinant human nerve growth factor for neurotrophic keratitis. Ophthalmology 2018;125:1332–1343.
5. Semeraro F, Forbice E, Romano V, et al. Neurotrophic Keratitis. Ophthalmologica 2014;231:191-197. doi: 10.1159/000354380
6. National Institute for Health and Care Excellence. Cenegermin for treating neurotrophic keratits. https://www.nice.org.uk/guidance/ta532. Published July, 2018. Accessed May 7, 2019.
7. Graham RH and Hendrix MA. Neurotrophic Keratitis Treatment and Management. Medscape. https://emedicine.medscape.com/article/1194889. Updated September 13, 2018. Accessed May 7, 2019.

Last Reviewed: 7/23/19, 3/11/20, 7/14/21, 7/13/22, 7/12/23
Effective Date: 9/15/19, 1/1/20

OHSU Health Services

Pulmonary Arterial Hypertension (PAH) Agents
Prior Authorization Guidelines

Affected Medication(s)

- Sildenafil 20 mg oral tablet
- Bosentan oral tablet
- Ambrisentan oral tablet

FDA Approved Indication(s)

- Sildenafil 20 mg oral tablet:
  - Treatment of pulmonary arterial hypertension (WHO Group 1) in adults to improve exercise ability and delay clinical worsening
  - Treatment of pulmonary hypertension (WHO Group 1) in pediatric patients 1 to 17 years old to improve exercise ability and in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underly improvements in exercise
- Bosentan:
  - Treatment of pulmonary arterial hypertension (WHO Group 1) in adults to improve exercise ability and to decrease clinical worsening.
  - Treatment of pulmonary arterial hypertension (WHO Group 1) in pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR)
- Ambrisentan oral tablet:
  - Treatment of pulmonary arterial hypertension (WHO Group 1) in adults to improve exercise ability and delay clinical worsening
  - Treatment of pulmonary arterial hypertension (WHO Group 1) in adults in combination with tadalafil to reduce the risk of disease progression and hospitalization for worsening PAH and to improve exercise ability

Dosing

- Sildenafil: 20 mg orally three times daily
- Bosentan: Weight based dosing taken orally twice daily. Refer to package insert for specific dosing information
- Ambrisentan: 5 mg orally once daily up to a maximum of 10 mg once daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)

   a. If yes, continue to #2

Last Reviewed: 4/2/19, 7/23/19, 3/11/20, 3/9/22, 9/14/22, 9/13/23
Effective Date: 5/1/19, 9/15/19, 1/1/120, 11/15/22, 10/15/23

OHSU Health Services

b. If no, clinical review required

2. Is the request for renewal of a previously approved authorization for use in pulmonary arterial hypertension?

    a. If yes, continue to Reauthorization
    b. If no, continue to #3

3. Is the medication being prescribed for an FDA approved indication? (Provide supporting documentation) (Note: sildenafil 20 mg is not FDA approved for erectile dysfunction)

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

4. Is the request for use to treat PAH World Health Organization (WHO) Group 1? (Provide supporting documentation)

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

5. Has the diagnosis been confirmed by right heart catheterization demonstrating mPAP ≥ 20 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? (Symptoms include shortness of breath and/or fatigue during moderate exertion or stress, shortness of breath and/or fatigue during minimal exertion, or an inability to carry out physical activity) (Provide supporting documentation)

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

7. Is the prescriber an appropriate specialist (i.e. pulmonologist or cardiologist)?

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

8. What is the requested medication?

    a. Sildenafil, continue to #9
    b. Bosentan, or Ambrisentan, continue to #11

OHSUHealth Services

9. Does the member currently take other organic nitrates in any form, regularly or intermittently? (Examples include isosorbide dinitrate, isosorbide mononitrate, and nitroglycerin) (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, continue to #10
10. Will the medication be used concomitantly with Adempas (riociguat)?
    a. If yes, clinical review required
    b. If no, approve for 6 months
11. Does the member have documentation of inadequate response, contraindication, or intolerance to a PDE5 inhibitor for treatment of PAH (e.g. sildenafil 20 mg)? (Provide supporting documentation)
    a. If yes, continue to #12
    b. If no, clinical review required
12. Does the member have preexisting moderate or severe hepatic impairment? (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, approve for 6 months

Reauthorization Criteria

1. Is the request for use to treat an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member demonstrated a positive clinical response to therapy? (Examples include improvement in 6-minute walking distance and/or stabilization or improvement in WHO functional class) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the prescriber a relevant specialist (i.e. pulmonologist or cardiologist)?
    a. If yes, approve for 12 months unless
    b. If no, clinical review required

Note:

OHSUHealth Services

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

References:

1. Revatio (sildenafil) [package insert]. NY, NY: Pfizer Labs; January 2023.
2. Tracleer (bosentan) [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US; May 2019
3. Letairis (ambrisentan) [package insert]. Foster City, CA: Gilead Sciences, Inc; 2020.
4. Taichman D.B., Ornelas J., Chung L., et al. (2014) Pharmacologic therapy for pulmonary arterial hypertension in adults: CHEST guideline and expert panel report. Chest 146:449–475.
5. Attridge RL, Moote R, Levine DJ. Chapter 17. Pulmonary Arterial Hypertension. In: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. Pharmacotherapy: A Pathophysiologic Approach, 9e New York, NY: McGraw-Hill; 2014.
6. Galiè N, Corris PA, Frost A, et al. Updated treatment algorithm of pulmonary arterial hypertension. J Am Coll Cardiol 2013; 62:D60.
7. Simonneau G, Robbins IM, Beghetti M, Channick RN, Delcroix M, Denton CP, et al. Updated clinical classification of pulmonary hypertension. J Am Coll Cardiol. 2009;54:S43–54
8. Badesch DB, Abman SH, Simonneau G, Rubin LJ, McLaughlin VV. Medical therapy for pulmonary arterial hypertension: Updated ACCP evidence-based clinical practice guidelines. Chest 2007;131:1917–1928.
9. The Criteria Committee of the New York Heart Association. Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels. 9th ed. Boston, Mass: Little, Brown & Co; 1994:253-256.
10. Simonneau, Gérald, et al. "Haemodynamic definitions and updated clinical classification of pulmonary hypertension." European Respiratory Journal 53.1 (2019).
11. Klinger, James R., et al. "Therapy for pulmonary arterial hypertension in adults: update of the CHEST guideline and expert panel report." Chest 155.3 (2019): 565-586.

Last Reviewed: 4/2/19, 7/23/19, 3/11/20, 3/9/22, 9/14/22, 9/13/23
Effective Date: 5/1/19, 9/15/19, 1/1/20, 11/15/22, 10/15/23

OHSU Health Services

Palynziq (pegvaliase-pqpz)
Prior Authorization Guidelines

Affected Medication(s)

- Palynziq (pegvaliase-pqpz) subcutaneous syringe

FDA Approved Indication(s)

- To reduce blood phenylalanine concentrations in adult patients with phenylketonuria who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management

Dosing

- Initial recommended dose: 2.5mg subcutaneously once weekly for four weeks.
- Titrate dosage in step-wise manner over at least five weeks to achieve a dosage of 20mg one time daily, based on tolerability (Maximum dose: 60 mg/day)

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request a renewal of a previously approved Palynziq (pegvaliase-pqpz) prior authorization and provided indication is the same as previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the member 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a blood phenylalanine concentration of 600 micromol/L or greater? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Has the member had a trial with inadequate response to a phenylalanine-restricted diet and does the treatment plan include continuation of a phenylalanine-restricted diet in combination with Palynziq

Last Reviewed: 1/22/19, 3/11/20, 7/14/21, 7/13/22, 7/12/23
Effective Date: 2/15/19, 1/1/20, 9/1/21

(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 sapropterin (Kuvan)? (Provide supporting documentation)

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

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

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

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

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

Reauthorization Criteria

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

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

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

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

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

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

Note:

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

References:

1. Palynziq (pegvaliase-pqpz) Injection [package insert]. Novato, CA: BioMarin Pharma, Inc; 2018.
2. Drugs@FDA: FDA Approved Drug Products. 2018. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 17 Sep. 2018].
3. Van Wegberg, A. M. J., et al. "The complete European guidelines on phenylketonuria: diagnosis and treatment." Orphanet journal of rare diseases 12.1 (2017): 162.

Last Reviewed: 1/22/19, 3/11/20, 7/14/21, 7/13/22, 7/12/23
Effective Date: 2/15/19, 1/1/20, 9/1/21

OHSU Health Services

Paroxysmal Nocturnal Hemoglobinuria (PNH) Agents
Prior Authorization Guidelines

Affected Medication(s)

- Empaveli (pegcetacoplan) subcutaneous solution
- Fabhalta (iptacopan) oral capsule

FDA Approved Indication(s)

- Treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH)

Dosing

- Empaveli: 1,080 mg subcutaneously twice weekly administered via an infusion pump or Empaveli on-body injector
- Fabhalta: 200 mg by mouth twice daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member 18 years of age or older? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as confirmed by detection of PNH clones of at least 10% by flow cytometry and the presence of at least 2 different glycosylphosphatidylinositol protein deficiencies within at least 2 different cell lines? (Provide supporting documentation of diagnosis)
    a. If yes, continue to #6

Last Reviewed: 5/8/24
Effective Date: 6/15/24

OHSUHealth Services

b. If no, clinical review required

6. Does the member have laboratory evidence of significant intravascular hemolysis (ex. LDH ≥ 1.5x upper limit of normal) with symptomatic disease and at least one other indication for therapy regardless of transfusion dependence? (Provide supporting documentation of diagnosis)

    - Patient has symptomatic anemia (i.e., hemoglobin < 7 g/dL or hemoglobin < 10 g/dL, in at least two independent measurements in a patient with cardiac symptoms)
    - Presence of a thrombotic event related to PNH
    - Presence of organ damage secondary to chronic hemolysis (ex. renal insufficiency, pulmonary insufficiency/hypertension)
    - Patient is pregnant and potential benefit outweighs potential fetal risk
    - Patient has disabling fatigue
    - Patient has abdominal pain (requiring admission or opioid analgesia), dysphagia, or erectile dysfunction

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

7. Has the member previously trialed Ultomiris or Soliris with inadequate response, intolerance, or contraindication? (Provide supporting documentation)

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

8. Is the request for Fabhalta?

    a. If yes, continue to #9
    b. If no, continue to #10

9. Has the member previously trialed Empaveli with inadequate response, intolerance, or contraindication? (Provide supporting documentation)

    a. If yes, continue to #10
    b. If no, clinical review required

10. Will the requested medication to be used with other complement inhibitor therapy?

    a. If yes, clinical review required
    b. If no, continue to #11

11. Is the medication being prescribed by, or in consult with, a hematologist?

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

OHSUHealth Services

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member developed a severe bone marrow failure syndrome, experienced spontaneous disease remission, or received a curative allogeneic stem cell transplant?
    a. If yes, clinical review required
    b. If no, continue to #3
3. Were updated chart notes (within past year) provided with documentation of significant clinical response to therapy received? (ex. decrease in serum LDH from baseline, stabilization or improvement in hemoglobin from baseline, decrease in transfusion requirement for baseline, reduction in thromboembolic events) (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Will the requested medication to be used with other complement inhibitor therapy?
    a. If yes, clinical review required
    b. If no, continue to #5
5. Is the medication being prescribed by, or in consult with, a hematologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. EMPAVELI (pegcetacoplan) injection solution [package insert]. Waltham, MA: Apellis Pharmaceuticals Inc; February 2024.
2. FABHALTA® (iptacopan) capsules [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; 2024.

Last Reviewed: 5/8/24
Effective Date: 6/15/24

3. Drugs@FDA: FDA Approved Drug Products. 2022. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 17 Jan. 2024].
4. Sahin F, Akay OM, Ayer M, et al. Pesg PNH diagnosis, follow-up and treatment guidelines. Am J Blood Res. 2016;6(2):19-27. Published 2016 Aug 5.
5. Peffault de Latour R, Roeth A, Kulasekararaj A, et al. Oral Monotherapy with Iptacopan, a Proximal Complement Inhibitor of Factor B, Has Superior Efficacy to Intravenous Terminal Complement Inhibition with Standard of Care Eculizumab or Ravulizumab and Favorable Safety in Patients with Paroxysmal Nocturnal Hemoglobinuria and Residual Anemia: Results from the Randomized, Active-Comparator-Controlled, Open-Label, Multicenter, Phase III Apply-PNH Study. Blood. 2022;140(Supplement 2):LBA-2-LBA-2.

OHSU Health Services

PCSK9 Inhibitor Agents
Prior Authorization Guidelines

Affected Medication(s)

- Praluent subcutaneous solution
- Repatha subcutaneous solution

FDA Approved Indication(s)

Praluent:

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

Repatha:

- To reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease
- As an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C)
- As adjunct to diet and other lipid-lowering therapies for the treatment of pediatric patients ≥10 years of age and adults with heterozygous familial hyperlipidemia to reduce LDL-C
- As an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of pediatric patients ≥10 years of age and adults 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 monthly

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)

    a. If yes, continue to #2

Last Reviewed: 5/28/19, 3/11/20, 11/10/21, 11/9/22, 7/12/23
Effective Date: 7/15/19, 1/1/20, 1/1/22, 8/15/23

b. If no, clinical review required

2. Is the request for a renewal of a previously approved PCSK9 inhibitor prior authorization for the same indication?

    a. If yes, continue to Reauthorization
    b. If no, continue to #3

3. Is the requested medication being used for an FDA-approved indication? (Provide supporting documentation)

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

4. Is the request for Praluent?

    a. If yes, continue to #5
    b. If no, continue to #6

5. Does the member have a previous trial with inadequate response, intolerance, or contraindication to treatment with Repatha? (Provide supporting documentation)

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

6. Are all of the following provided? (Provide supporting documentation)

    - Complete lipid panel performed within the last 3 months
    - Baseline LDL-C (untreated)
    - Documentation of dietary measures being undertaken to lower cholesterol

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

7. What is the diagnosis that the PCSK9 inhibitor is being requested for?

    a. Heterozygous or Homozygous familial hypercholesterolemia (HeFH/HoFH), continue to #8
    b. Hypercholesterolemia with history of clinical atherosclerotic cardiovascular disease (ASCVD), continue to #10

8. Is pre-treatment LDL-cholesterol received (within 3 months) with baseline LDL-C ≥100 mg/dL on a maximally tolerated lipid-lowering regimen? (Provide supporting documentation)

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

OHSUHealth Services

9. Does the member meet at least one of the following? (Provide supporting documentation)

    - Family History of myocardial infarction before age 60 years in first-degree relative
    - Family History of myocardial infarction before age 50 years in second-degree relative
    - Family History of LDL-C greater than 190 mg/dL in a first- or second-degree relative
    - Tendinous xanthomata and/or arcus cornealis in first-degree relative or documented during physical examination
    - Functional mutation of LDL receptor, apoB, OR PCSK9 gene confirmed by genetic testing

    a. If yes, continue to #12
    b. If no, clinical review required

10. Is pre-treatment LDL-cholesterol received (within 3 months) ≥70 mg/dL on a maximally tolerated lipid-lowering regimen? (Provide supporting documentation)

    a. If yes, continue to #11
    b. If no, clinical review required

11. Does the member have atherosclerotic cardiovascular disease (ASCVD) confirmed by at least one of the following? (Provide supporting documentation)

    - Acute coronary syndromes
    - History of myocardial infarction
    - Stable or unstable angina
    - Coronary or other arterial revascularization
    - Stroke
    - Transient ischemic attack
    - Peripheral arterial disease presumed to be of atherosclerotic origin

    a. If yes, continue to #12
    b. If no, clinical review required

12. Is the Member currently receiving high-intensity statin therapy for a consecutive 3 months and will continue with high-intensity statin therapy? (High-intensity statin therapy includes: atorvastatin 40-80 mg or rosuvastatin 20-40 mg) (Provide supporting documentation)

    a. If yes, continue to #17
    b. If no, continue to #13

13. What is the rationale provided for avoiding high-intensity statin therapy? (Provide supporting documentation)

    a. Statin intolerance due to myalgia or myopathy, continue to # 14

OHSUHealth Services

b. History of rhabdomyolysis with creatinine kinase (CK) levels greater than 10-times upper limit of normal (document date occurred), continue to #16
c. Labeled contraindication to all statins, continue to #16
d. All other rationale, deny. Clinical Review Required

14. Is the member currently receiving a maximally tolerated dose of a statin AND ezetimibe and will continue statin and ezetimibe with PCSK9? (Provide supporting documentation)

    a. If yes, continue to #17
    b. If no, continue to #15

15. Is documentation of persistent myalgia or myopathy on 2 separate 8-week trials with pravastatin, rosuvastatin, or fluvastatin provided?

    a. If yes, continue to #16
    b. If no, clinical review required

16. Has the member been on ezetimibe for 3 consecutive months and will continue concurrently with PCSK9? (Provide supporting documentation)

    a. If yes, continue to #17
    b. If no, clinical review required

17. Is the medication being prescribed by or in consultation with cardiologist, endocrinologist, or lipid specialist?

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

Reauthorization Criteria

1. Is the request for use to treat an FDA-approved indication? (Provide supporting documentation)

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

2. Is an updated lipid panel with confirmation of significant reduction in LDL defined as a decrease in LDL levels of at least 40% from pre-treatment levels provided OR is updated LDL-C less than 100mg/dL? (Provide supporting documentation)

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

3. Is the medication being prescribed by or in consultation with cardiologist, endocrinologist, or lipid specialist?

OHSUHealth Services

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. Praluent (alirocumab) [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC. April 2021.
2. Repatha (evolocumab) [Prescribing Information]. Thousand Oaks, CA: Amgen Inc. August 2022.
3. Praluent. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com.
4. Repatha. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com.
5. Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2014; June 24;129(25 Suupl 2):S1-45. Accessed July 31, 2018.
6. Rosenson RS, Durrington P. Familial hypercholesterolemia in adults: Overview. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. Available at: http://www.uptodate.com. Accessed July 31, 2018.
7. Grundy SM, Stone NJ, et al. 2018 ACC/AHA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Journal of the American College of Cardiology. 2019;73(24):e285-e350. Available at: https://www.onlinejacc.org/content/73/24/e285.

Last Reviewed: 5/28/19, 3/11/20, 11/10/21, 11/9/22, 7/12/23
Effective Date: 7/15/19, 1/1/20, 1/1/22, 8/15/23

OHSUHealth Services

Pegasys (peginterferon alfa-2a)
Prior Authorization Guidelines

Affected Medication(s)

- Pegasys (peginterferon alfa-2a subcutaneous injection solution)

FDA Approved Indication(s)

- Chronic Hepatitis C:
  - In adults as part of a combination regimen with other hepatitis C virus (HCV) antiviral drugs, is indicated for the treatment of adults with CHC and compensated liver disease.
  - In children 5 years of age or older in combination with ribavirin for the treatment of CHC and compensated liver disease.
- Chronic Hepatitis B:
  - In adults, with HBeAg-positive and HBeAg-negative CHB infection who have compensated liver disease and evidence of viral replication and liver inflammation.
  - In children 3 years of age and older with HBeAg-positive CHB, non-cirrhotic, with evidence of viral replication and elevations in serum alanine aminotransferase (ALT).
- Note: Compendia supported use for polycythemia vera and oncological conditions, refer to compendia for full list of supported use

Dosing

- Refer to package insert for weight-based dosing

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the request for continuation of therapy with the same medication for the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3
3. Is the documented indication approved by the FDA or supported by major compendia? (i.e. NCCN recommendation with an evidence level of 2A or higher) (Provide supporting documentation) (i.e. polycythemia vera, oncologic conditions)
   a. If yes, continue to #4
   b. If no, clinical review required

Last Reviewed: 3/9/22, 5/10/23, 5/8/24
Effective Date: 5/1/22

OHSUHealth Services

4. Is the use of Pegasys for the requested condition supported by current guidelines (i.e. hepatitis B or C)?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If N/A (requesting for non-oncological condition), continue to #6
    c. If no, clinical review required
6. Is the medication being prescribed by, or in consultation with, an oncologist, a hematologist or an appropriate specialist for the requested condition?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by major compendia? (i.e. NCCN recommendation with an evidence level of 2A or higher) (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the use of Pegasys for the requested condition supported by current guidelines (i.e. polycythemia vera)?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is there clinical documentation confirming positive response to therapy? (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, an oncologist, a hematologist, or an appropriate specialist for the requested condition?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. Pegasys (peginterferon alfa-2a) injection, [package insert]. Burlington, MA: PharmaEssentia Corp; 2021.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 01 Feb. 2022].
3. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Myeloproliferative Neoplasms. Version 2.2021 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf. Accessed Feb 23, 2022.

Last Reviewed: 3/9/22, 5/10/23, 5/8/24
Effective Date: 5/1/22

OHSU Health Services

Phenoxybenzamine
Prior Authorization Guidelines

Affected Medication(s)

- Phenoxybenzamine oral capsule

FDA Approved Indication(s)

- For the treatment of pheochromocytoma to control hypertension and sweating. Maybe necessary to use a beta-blocking agent concomitantly in excessive tachycardia

Dosing

- 20 to 40 mg twice to three times a day

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is phenoxybenzamine being requested for an FDA approved indication?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have confirmed pheochromocytoma by imaging? (Provide supporting documentation for review)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is phenoxybenzamine being requested as preoperative management? (Provide treatment plan/duration and planned surgical date)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is documentation with rationale to avoid other alpha-blockers received? (i.e. prazosin, terazosin, doxazosin)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the treatment being prescribed by or in consultation with an endocrinologist?
    a. If yes, approve for 1 month

Last Reviewed: 11/26/19, 7/14/21, 7/13/22, 7/12/23
Effective Date: 2/1/20, 9/1/21

OHSUHealth Services

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. Phenoxybenzamine [package insert]. Chestnut Ridge, NY: Par Pharma; November 2017.
2. Lenders JWM, Duh QY, Eisenhofer G, et al. Phenochromocytoma and paraganglioma: an endocrine society clinical practice guideline. The Journal of Clinical Endocrinology & Metabolism. 2014;6:1915-1942. Available at: https://doi.org/10.1210/jc.2014-1498.

OHSU Health Services

Posaconazole
Prior Authorization Guidelines

Affected Medication(s)

- Posaconazole tablet

FDA Approved Indication(s)

Oral Tablet:

- Invasive aspergillosis in patients 13 years of age and older
- Prophylaxis of invasive aspergillus and candida infections in patients 2 years of age and older who are at high risk of developing these infections due to being severely immunocompromised (i.e. hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy)

Dosing

- Refer to package insert for indication specific treatment dose and treatment duration

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved posaconazole prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
    a. If yes, continue to #5
    b. If no, continue to #4
4. Is the request for use to treat a major compendium supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the treatment being initiated by an infectious disease specialist?
    a. If yes, continue to #6

Last Reviewed: 9/14/22, 9/13/23
Effective Date: 11/15/22

b. If no, clinical review required

6. What is the requested medication being used for?

    a. Treatment of invasive aspergillosis, continue to corresponding criteria
    b. Prophylaxis of invasive aspergillus infection, continue to corresponding criteria
    c. Prophylaxis of invasive candida infection, continue to corresponding criteria
    d. Other indication, continue to corresponding criteria

Treatment of Invasive Aspergillosis

1. Does the member have a previous trial with inadequate response, intolerance, or contraindication to voriconazole? (Provide supporting documentation)

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

Prophylaxis of Invasive Aspergillus Infection

1. Has documentation been provided that the member is in a severely immunocompromised state? (i.e. hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy) (Provide supporting documentation)

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

2. Does the member have a previous trial with inadequate response, intolerance, or contraindication to voriconazole? (Provide supporting documentation)

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

Prophylaxis of Invasive Candida Infection

1. Has documentation been provided that the member is in a severely immunocompromised state? (i.e. hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy) (Provide supporting documentation)

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

2. Does the member have a previous trial with inadequate response, intolerance, or contraindication to the following?
    - Fluconazole or Itraconazole
    - Voriconazole

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

Other Indications

1. Does the member have a previous trial with inadequate response, intolerance, or contraindication to ALL standard treatment options for the requested indication? (Provide supporting documentation)

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

Reauthorization Criteria

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

2. Were updated chart notes (within 1 year) with documentation of significant clinical response to therapy or is the member still considered severely immunocompromised? (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, an infectious disease specialist?
    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

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

References:

1. Noxafil delayed-release tablets and oral suspension [prescribing information]. Whitehouse Station, NJ: Merck; May 2022.
2. Patterson TF, Thompson GR, Denning DW, et al. Practice guidelines for the diagnosis and management of aspergillosis: 2016 update by the Infectious Diseases Society of America. Clin Infect Dis. 2016;63(4):e1-e60.
3. Pappas PG, Kauffman CA, Andes DR, et al. Clinical practice guidelines for the management of candidiasis: 2016 update by the Infectious Diseases Society of America. Clin Infect Dis. 2016;62(4):e1-50.
4. The NCCN Prevention and Treatment of Cancer-Related Infections Clinical Practice Guidelines in Oncology (version 2.2022 – August 19, 2022). ©2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 29, 2022.

OHSU Health Services

Pregabalin
Prior Authorization Guidelines

Affected Medication(s)

- Pregabalin oral capsule

FDA Approved Indication(s)

- Management of neuropathic pain associated with diabetic peripheral neuropathy
- Management of postherpetic neuralgia
- Adjunctive therapy for treatment of partial onset seizures in patients 1 month and older
- Management of fibromyalgia
- Management of neuropathic pain associated with spinal cord injury

Dosing

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

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Lyrica (pregabalin) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is pregabalin being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Did the member have an inadequate response to a 3-month trial of gabapentin? (Provide supporting documentation)
    a. If yes, approve for 12 months

Last Reviewed: 7/17/18, 3/11/20, 3/10/21, 3/9/22, 5/10/23, 5/8/24
Effective Date: 8/15/18, 1/1/20, 5/1/21, 5/1/22

b. If no continue to #5

5. Does the member have a history of intolerance or contraindication to gabapentin? (Provide supporting documentation)

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

Reauthorization Criteria

1. Is pregabalin being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)

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

2. Were updated chart notes (within 1 year) with documentation of significant clinical response to prior therapy received? (Provide supporting documentation)

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

Note:

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

References:

1. Lyrica (pregabalin) [Prescribing Information]. New York, NY: Parke-Davis Div of Pfizer Inc. June 2020.
2. Lyrica. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed March 29, 2018.
3. Bajwa MD, Ortega, MD. Postherpetic neuralgia. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed June 25, 2018.
4. Feldman MD, PHD, McCulloch MD. Treatment of diabetic neuropathy. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed June 25, 2018.

Last Reviewed: 7/17/18, 3/11/20, 3/10/21, 3/9/22, 5/10/23, 5/8/24
Effective Date: 8/15/18, 1/1/20, 5/1/21, 5/1/22

OHSU Health Services

Prevymis
Prior Authorization Guidelines

Affected Medication(s)

- Prevymis oral tablet

FDA Approved Indication(s)

- Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
- Prophylaxis of CMV disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])

Dosing

- HSCT: 480 mg once daily through day 100 post-transplantation
- Kidney Transplant: 480 mg once daily through day 200 post-transplantation

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is Prevymis (letermovir) being requested for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Has documentation with rationale for avoidance or contraindication to both ganciclovir and valganciclovir been received? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Has the current medication list been reviewed by the care team confirming no major drug interaction with Prevymis? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required

Last Reviewed: 7/17/18, 3/11/20, 7/14/21, 9/14/22, 7/12/23
Effective Date: 8/15/18, 1/1/20, 9/1/21, 8/15/23

OHSUHealth Services

5. Is the treatment being prescribed by or in consultation with a hematologist/oncologist, transplant specialist, or infectious disease specialist?
    a. If yes, continue to #6
    b. If no, clinical review required
6. What indication is Prevymis (letermovir) being requested for?
    a. Prophylaxis of CMV in allogeneic HSCT recipients, continue to #7
    b. Prophylaxis of CMV in adult kidney transplant recipients, continue to #9
7. Is Prevymis (letermovir) being initiated within 100 days of transplant? (Provide documentation of transplant date)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Does the member meet one of the following criteria? 1) CMV-seropositive recipient 2) CMV-seronegative recipient receiving a graft from seropositive donor (CMV D+/R-) who received a T cell-depleted allograft, an HLA-1 mismatched allograft, an umbilical cord blood allograft, or alemtuzumab (Provide supporting documentation)
    a. If yes, approve for 4 months
    b. If no, clinical review required
9. Is Prevymis (letermovir) being initiated within 200 days of transplant? (Provide documentation of transplant date)
    a. If yes, continue to #10
    b. If no, clinical review required
10. Is the member CMV-seronegative and received a transplant from a CMV-positive donor?
    a. If yes, approve for 7 months or up to 200 days from date of transplant
    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. Letermovir (Prevymis) [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; 2023.

Last Reviewed: 7/17/18, 3/11/20, 7/14/21, 9/14/22, 7/12/23
Effective Date: 8/15/18, 1/1/20, 9/1/21, 8/15/23

2. Prevymis. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed July 25, 2021.
3. Wingard JR, Marr KA, Thorner AR. Prevention of viral infections in hematopoietic cell transplant recipients. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed July 25, 2021.

Last Reviewed: 7/17/18, 3/11/20, 7/14/21, 9/14/22, 7/12/23
Effective Date: 8/15/18, 1/1/20, 9/1/21, 8/15/23

OHSU Health Services

Promacta
Prior Authorization Guidelines

Affected Medication(s)

- Promacta oral tablet
- Promacta oral suspension packet

FDA Approved Indication(s)

- Treatment of thrombocytopenia in adult and pediatric patients 1 years and older with persistent or chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
- Treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy
- Treatment of adult patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy
- For first-line treatment of severe aplastic anemia, in combination with standard immunosuppressive therapy, in pediatric patients 2 years and older

Dosing

- Refer to package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Promacta (eltrombopag) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the documented indication approved by the FDA or supported by major compendia?
    a. If yes, continue to #4
    b. If no, clinical review required
4. What is the diagnosis that Promacta (eltrombopag) is being requested for?

Last Reviewed: 10/18/18, 3/11/20, 11/10/21, 11/9/22, 11/8/23
Effective Date: 11/15/18, 1/1/20, 1/1/22, 12/15/23

OHSUHealth Services

a. Persistent or chronic immune (idiopathic) thrombocytopenia (ITP), continue to corresponding criteria
b. Chronic hepatitis C-associated thrombocytopenia, continue to corresponding criteria
c. Severe aplastic anemia, continue to corresponding criteria
d. Other indications, continue to corresponding criteria

Persistent or Chronic Immune (idiopathic) Thrombocytopenia (ITP)

1. Is the patient's platelet count less than 30 x 10^9/L (30,000/mm)? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has patient previously tried and failed glucocorticoids AND splenectomy or rituximab (Failure defined as platelet count fails to reach greater than or equal to 50 x 10^9/L (50,000/mm))? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with a hematologist?
    a. If yes, approve for 3 months
    b. If no, clinical review required

Chronic Hepatitis C Associated Thrombocytopenia

1. Is the patient's platelet count less than 75 x 10^9/L (75,000/mm)? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there documentation of compensated liver disease (Defined as Child-Pugh Class A)? (Provide supported lab for review)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with a hepatologist or ID specialist?
    a. If yes, approve for 2 months
    b. If no, clinical review required

Aplastic Anemia

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

2. Has the patient tried and failed at least one prior immunosuppressive therapy (Example: cyclosporine)? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with a hematologist or appropriate specialist?
    a. If yes, approve for 4 months
    b. If no, clinical review required

Other 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?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the requested treatment dose appropriate? (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 an appropriate specialist?
    a. If yes, approve for 4 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by major compendia? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the medication being prescribed by or in consultation with an appropriate specialist?
    a. If yes, continue to #3
    b. If no, clinical review required
3. What is the diagnosis that Promacta (eltrombopag) is being requested for? (Record submitted diagnosis and review all criteria based on the submitted diagnosis)
    a. Persistent or chronic immune (idiopathic) thrombocytopenia (ITP), continue to #4
    b. Chronic hepatitis C-associated thrombocytopenia, continue to #5
    c. Severe aplastic anemia or other indication, continue to #6

4. Were updated chart notes (within previous 6 months) provided with documentation of significant clinical response to prior therapy received? (i.e. platelet count greater than or equal to 50 x 10^9/L (50,000/mm))? (Provide supporting documentation)

    a. If yes, approval for 12 months
    b. If no, clinical review required

5. Were updated chart notes (within previous 6 months) provided with documentation of significant clinical response to prior therapy received? (i.e. platelet count greater than or equal to 90 x 10^9/L (90,000/mm))? (Provide supporting documentation)

    a. If yes, approval for 12 months
    b. If no, clinical review required

6. Were updated chart notes (within previous 6 months) provided with documentation of significant clinical response to prior therapy received? (i.e. one of the following: platelet count increases to 20 x 10^9/L above baseline, stable platelet counts without transfusion for 8 or more weeks, hemoglobin increases by > 1.5 g/dL, ANC increases 100%, or ANC increase > 0.5 x10^9/L, decrease in bleeding events) (Provide supporting documentation)

    a. If yes, approval for 12 months
    b. If no, clinical review required

Note:

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

References:

1. Promacta® (eltrombopag) [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline LLC. August 2023.
2. Promacta®. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed August 28, 2018.
3. George, PhD, Arnold, MD. Immune thrombocytopenia (ITP) in adults: Second-line and subsequent therapies. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed August 28, 2018.
4. Afdhal NH, Dusheiko GM, Giannini EG, et al. Eltrombopag increases platelet numbers in thrombocytopenic patients with HCV infection and cirrhosis, allowing for effective antiviral therapy. Gastroenterology. 2014 Feb;146(2):442-52.e1.

Last Reviewed: 10/18/18, 3/11/20, 11/10/21, 11/9/22, 11/8/23
Effective Date: 11/15/18, 1/1/20, 1/1/22, 12/15/23

OHSU Health Services

Pyrukynd (mitapivat)
Prior Authorization Guidelines

Affected Medication(s)

- Pyrukynd (mitapivat) oral tablet

FDA Approved Indication(s)

- Treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency

Dosing

- Starting dose of 5mg twice daily; can be titrated up to 50mg by mouth two times daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Pyrukynd (mitapivat) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is Pyrukynd (mitapivat) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the patient 18 years of age or older?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have documentation of pyruvate kinase deficiency confirmed by biochemical (reduced PK activity in RBCs) or genetic testing (identifying a pathogenic PKLR gene mutation)? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have documentation of at least 2 variant alleles in the PKLR gene, of which at least 1 was a missense variant? (Provide supporting documentation)

Last Reviewed: 5/11/22, 5/10/23, 5/8/24
Effective Date: 7/1/22, 6/15/24

OHSUHealth Services

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

7. Is the member homozygous for the c.1436G>A (p.R479H) variant or have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene? (Provide supporting documentation)

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

8. Is the member's hemoglobin 10 g/dL or less? (Provide supporting documentation)

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

9. Has the member previously had 6 or more transfusions in the past year or has severe symptomatic anemia? (Provide supporting documentation)

   a. If yes, continue to #10
   b. If no, clinical review required

10. Is Pyrukynd (mitapivat) being prescribed by, or in consult with, a hematologist?

    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 or major compendia supported indication? (Provide supporting documentation)

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

2. Were updated chart notes (within past year) provided with documentation of significant clinical response to prior therapy received? (i.e. improvement in hemoglobin by at least 1.5 g/dL from baseline or reduction in RBC transfusions from baseline) (Provide supporting documentation)

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

3. Is Pyrukynd (mitapivat) being prescribed by, or in consult with, a hematologist?

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

Note:

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

References:

1. PYRUKYND® (mitapivat) tablets, [package insert]. Cambridge, MA: Agios Pharmaceuticals, Inc; 2022.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 29 Mar. 2022].
3. van Beers, Eduard J., et al. "Mitapivat (AG-348) in Adults with Pyruvate Kinase Deficiency Who Are Not Regularly Transfused: A Phase 3, Randomized, Multicenter, Double-Blind, Placebo-Controlled Study (ACTIVATE) in Progress." Blood 134 (2019): 4791.
4. Lynch, Megan, et al. "Mitapivat (AG-348) in adults with Pyruvate Kinase deficiency who are regularly transfused: a phase 3, open-label, multicenter, study (ACTIVATE-T) in progress." Blood 134 (2019): 3526.

Last Reviewed: 5/11/22, 5/10/23, 5/8/24
Effective Date: 7/1/22, 6/15/24

OHSU Health Services

Recorlev (levoketoconazole)
Prior Authorization Guidelines

Affected Medication(s)

- Recorlev (levoketoconazole) oral tablet

FDA Approved Indication(s)

- Treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative

Dosing

- Initial 150mg orally twice daily, titrated up to a max of 600mg twice daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Recorlev (levoketoconazole) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is Recorlev (levoketoconazole) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the patient 18 years of age or older?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have documentation of endogenous Cushing's syndrome with a mean Urinary Free Cortisol level (UFC) greater than or equal to 1.5x the upper limit of normal (normal range: 11 to 138 nmol/day or 4 to 50 µg/day)? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 5/11/22, 5/10/23, 5/8/24
Effective Date: 7/1/22, 6/15/23, 6/15/24

OHSUHealth Services

6. Has the member previously undergone pituitary surgery that was not curative or is the member not a candidate for surgery? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Has the member previously trialed a maximum tolerated dose of ketoconazole for at least 8 weeks with treatment failure or is there a documented intolerance or contraindication to ketoconazole? (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, continue to #8
8. Is Recorlev (levoketoconazole) being prescribed by, or in consult with, an endocrinologist?
    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 or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of significant clinical response to prior therapy received? (i.e. decrease in mUFC from baseline that is maintained within normal range) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is Recorlev (levoketoconazole) being prescribed by, or in consult with, an endocrinologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. RECORLEV (levoketoconazole) tablets, [package insert]. Chicago, IL: Xeris Pharmaceuticals, Inc; 2022.

Last Reviewed: 5/11/22, 5/10/23, 5/8/24
Effective Date: 7/1/22, 6/15/23, 6/15/24

2. DailyMed – Recorlev- levoketoconazole tablet. 2022. U.S. National Library of Medicine. National Institutes of Health. [online]
3. Lynnette K. Nieman, Beverly M. K. Biller, James W. Findling, M. Hassan Murad, John Newell-Price, Martin O. Savage, Antoine Tabarin, Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 100, Issue 8, 1 August 2015, Pages 2807–2831, https://doi.org/10.1210/jc.2015-1818
4. Fleseriu, Maria, et al. "Consensus on diagnosis and management of Cushing's disease: a guideline update." The Lancet Diabetes & Endocrinology 9.12 (2021): 847-875.
5. Fleseriu, Maria, et al. "Efficacy and safety of levoketoconazole in the treatment of endogenous Cushing's syndrome (SONICS): a phase 3, multicentre, open-label, single-arm trial." The Lancet Diabetes & Endocrinology 7.11 (2019): 855-865.
6. Zacharieva, Sabina Z., et al. "MON-332 Safety and Efficacy of Levoketoconazole in the Treatment of Endogenous Cushing's Syndrome (LOGICS): A Double-Blind, Placebo-Controlled, Withdrawal Study." Journal of the Endocrine Society 4.Supplement_1 (2020): MON-332.

OHSU Health Services

Retacrit (epoetin alfa-epbx)
Prior Authorization Guidelines

Affected Medication(s)

- Retacrit (epoetin alfa-epbx) subcutaneous solution

FDA Approved Indication(s)

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

Dosing

- Refer to package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Retacrit (epoetin alfa-epbx) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the medication being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required

Last Reviewed: 11/27/18, 3/11/20, 9/8/21, 11/9/22, 11/8/23
Effective Date: 1/15/19, 1/1/20, 11/1/21, 12/15/23

OHSUHealth Services

4. Have serum ferritin, transferrin saturation, hemoglobin (Hb), and hematocrit (Hct) labs been completed within 30 days of planned administration? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20%? (Review serum ferritin and transferrin saturation lab values) (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have a hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30%? (Review hemoglobin and/or hematocrit lab values) (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, continue to #7
7. Is the medication being requested to reduce allogeneic blood transfusions in elective, non-cardiac, non-vascular surgery? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Have other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) been ruled out? (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, clinical review required
9. Which indication is Retacrit (epoetin alfa-epbx) being requested for?
    a. Anemia secondary to myelodysplastic syndrome (MDS), continue to corresponding criteria
    b. Anemia secondary to Myeloproliferative Neoplasms (MPN) – Myelofibrosis, continue to corresponding criteria
    c. Anemia secondary to chemotherapy treatment, continue to corresponding criteria
    d. Anemia secondary to chronic kidney disease (non-dialysis patients), approve for 3 months unless otherwise specified
    e. Anemia secondary to zidovudine treated, HIV-infected patients, continue to corresponding criteria
    f. Reduction of allogeneic blood transfusions in elective, non-cardiac, non-vascular surgery, continue to corresponding criteria
    g. Other Indication, continue to corresponding criteria

<u>Anemia secondary to myelodysplastic syndrome (MDS)</u>

1. Does the member have symptomatic anemia? (Examples: exertional dyspnea, dyspnea at rest, fatigue, lethargy, confusion, etc.) (Provide supporting documentation)

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

2. Does the member have an endogenous serum erythropoietin level ≤ 500 mUnits/mL? (Provide supporting documentation)

    a. If yes, approve for 45 days unless otherwise specified
    b. If no, clinical review required

<u>Anemia secondary to Myeloproliferative Neoplasms (MPN) – Myelofibrosis</u>

1. Does the member have an endogenous serum erythropoietin level < 500 mUnits/mL? (Provide supporting documentation)

    a. If yes, approve for 45 days unless otherwise specified
    b. If no, clinical review required

<u>Anemia secondary to chemotherapy treatment</u>

1. Is the member receiving concurrent myelosuppressive chemotherapy for non-myeloid malignancies? (Provide supporting documentation)

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

2. Is the therapy intention of the chemotherapy curative? (Provide supporting documentation)

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

3. Are there two or more additional months of planned chemotherapy remaining? (Provide supporting documentation)

    a. If yes, approve for 6 months or until completion of chemotherapy course, whichever is less
    b. If no, clinical review required

<u>Anemia secondary to zidovudine treated, HIV-infected patients</u>

1. Does the member have an endogenous serum erythropoietin level ≤ 500 mUnits/mL AND is the member currently receiving zidovudine administered at ≤ 4200 mg/week? (Provide supporting documentation)

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

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

1. Does the member have a hemoglobin (Hb) level between 10 g/dL and 13 g/dL and/or is the hematocrit (Hct) between 30% and 39%? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the surgery high-risk for perioperative blood loss? (i.e. expected to lose >2 units of blood)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is patient unwilling to donate autologous blood pre-operatively?
    a. If yes, approve for 45 days unless otherwise specified
    b. If no, clinical review required

Other Indications

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

Reauthorization Criteria

1. Is Retacrit (epoetin alfa-epbx) being requested for an FDA approved or major compendia approved indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Was the last dose of Retacrit (epoetin alfa-epbx) less than 60 days ago? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Were updated chart notes (within 1 year) provided with documentation of significant clinical response to therapy? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is there documentation of an absence of unacceptable toxicity from the drug? (Examples include severe cardiovascular events (stroke, myocardial infarction, thromboembolism, uncontrolled

hypertension), tumor progression or recurrence in members with cancer, seizures, pure red cell aplasia, severe cutaneous reactions (erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis), "gasping syndrome" (central nervous system depression, metabolic acidosis, gasping respirations) due to benzyl alcohol preservative, etc.) (Provide supporting documentation)

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

5. Were lab values obtained within 30 days of the date of administration (unless otherwise indicated)? (Provide supporting documentation)

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

6. Does the member have adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% measured within the previous 3 months? (Provide supporting documentation)

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

7. Have other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) been ruled out? (Provide supporting documentation)

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

8. Does the member meet the clinical requirements for their corresponding diagnosis as defined below? (Provide supporting documentation)

   - Anemia secondary to myelodysplastic syndrome (MDS) with Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) < 36%
   - Anemia secondary to myeloproliferative neoplasms (MF, post-PV myelofibrosis, post-ET myelofibrosis) with Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30%
   - Reduction of allogeneic blood transfusions in elective, non-cardiac, non-vascular surgery with Hemoglobin (Hb) between 10 g/dL and 13 g/dL and/or Hematocrit (Hct) between 30% and 39%
   - Anemia secondary to palliative myelosuppressive chemotherapy for non-myeloid malignancies with Hemoglobin (Hb) <10 g/dL and/or Hematocrit (Hct) < 30% and requesting epoetin alfa to be used concurrently with chemotherapy with minimum two additional months of therapy remaining
   - Anemia secondary to zidovudine treated, HIV-infected patients with Hemoglobin (Hb) <12 g/dL and/or Hematocrit (Hct) < 36% AND receiving zidovudine administered at ≤4200 mg/week

- Anemia secondary to chronic kidney disease with hemoglobin (Hb) <12 g/dL and/or hematocrit (Hct) <36% in pediatric patients OR hemoglobin (Hb) <11 g/dL and/or hematocrit (Hct) <33% in adult patients
- Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) < 33% for all other indications
- Use supported by major compendia

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. Retacrit (epoetin alfa-epbx) [Prescribing Information]. Lake Forest, IL: Pfizer Laboratories. July 2022.
2. Retacrit®. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed October 19, 2018.
3. Peeters, HR, Jongen-Lavrencic, M, Vreugdenhil, G, Swaak, AJ. Effect of recombinant human erythropoietin on anaemia and disease activity in patients with rheumatoid arthritis and anaemia of chronic disease: a randomized placebo controlled double blind 52 weeks clinical trial. Ann Rheum Dis 1996; 55:739.
4. Pincus T, Olsen NJ, Russell IJ, et al. Multicenter study of recombinant human erythropoietin in correction of anemia in rheumatoid arthritis. Am J Med 1990; 89:161-8.
5. Saag, MS, Bowers, P, Leitz, GJ, Levine, AM. Once-weekly epoetin alfa improves quality of life and increases hemoglobin in anemic HIV+ patients. AIDS Res Hum Retroviruses 2004; 20:1037.
6. Grossman, HA, Goon, B, Bowers, P, Leitz, G. Once-weekly epoetin alfa dosing is as effective as three times weekly dosing in increasing hemoglobin levels and is associated with improved quality of life in anemic HIV infected patients. J Acquir Immune Defic Syndr 2003; 34:368.
7. Afdhal, NH, Dieterich, DT, Pockros, PJ, et al. Epoetin alfa maintains ribavirin dose in HCV-infected patients: a prospective, double-blind, randomized controlled study. Gastroenterology 2004; 126:1302.
8. Cervantes F, Alvarez-Laran A, Hernandez-Boluda JC, et al. Erythropoietin treatment of the anaemia of myelofibrosis with myeloid metaplasia: results in 20 patients and review of the literature. British Journal of Haematology, 127: 399–403. doi:10.1111/j.1365-2141.2004.05229.x
9. Shaffer CL, Ransom JL. Current and theoretical considerations of erythropoietin use in anemia of bronchopulmonary dysplasia. J of Pediatric Pharmacy Practice 1996; 1:23-29.
10. Reiter PD, Rosenberg AA, Valuck RJ. Factors associated with successful epoetin alfa therapy in premature infants. Ann Pharmacother 2000; 34:433-439.
11. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD):Erythropoiesis Stimulating Agents - Epoetin alfa, Epoetin beta, Darbepoetin alfa, Peginesatide (L34633). Centers for Medicare & Medicaid Services, Inc. Updated on 09/20/2017 with effective dates 10/1/2017.

12. CGS Administrators, Inc. Local Coverage Determination (LCD): Erythropoiesis Stimulating Agents (ESAs) (L34356). Centers for Medicare & Medicare Services. Updated on 02/26/2018 with effective dates 10/01/2017.
13. First Coast Service Options, Inc. Local Coverage Determination (LCD): Erythropoiesis Stimulating Agents (ESAs) (L36276). Centers for Medicare & Medicare Services. Updated on 02/22/2018 with effective dates 02/08/2018.
14. National Coverage Determination (NCD) for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21). Centers for Medicare & Medicare Services, Inc. Updated 12/3/2015 with an effective date 10/1/2015.

Last Reviewed: 11/27/18, 3/11/20, 9/8/21, 11/9/22, 11/8/23
Effective Date: 1/15/19, 1/1/20, 11/1/21, 12/15/23

OHSU Health Services

Rezurock® (belumosudil)
Prior Authorization Guidelines

Affected Medication(s)

- Rezurock oral tablet

FDA Approved Indication(s)

- Adult and pediatric patients 12 years and older with chronic graft-versus-host disease after failure of at least two prior lines of systemic therapy

Dosing

- 200mg orally once daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request a renewal of a previously approved Rezurock (belumosudil) prior authorization and provided indication is the same as previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a diagnosis of chronic graft vs host disease? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the member 12 years of age or older?
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 11/10/21, 1/11/23, 1/10/24
Effective Date: 1/1/22, 2/15/24

OHSUHealth Services

6. Does the member have a documented trial with inadequate response to systemic steroids? (Provide supporting documentation)
    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 at least TWO of the following: ruxolitinib, tacrolimus, cyclosporine, ibrutinib, imatinib, methotrexate, sirolimus, or mycophenolate mofetil? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Is the medication prescribed by, or in consultation with, a provider specializing in transplant or oncology?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within 1 year) with documentation of stability or improvement in chronic graft vs host disease? (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 provider specializing in transplant or an oncologist?
    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

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

Last Reviewed: 11/10/21, 1/11/23, 1/10/24
Effective Date: 1/1/22, 2/15/24

References:

1. REZUROCK (belumosudil) tablets. Warrendale, PA 15086; Kadmon Pharmaceuticals, LLC. 2021.
2. Drugs@FDA: FDA Approved Drug Products. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 24 August. 2021].
3. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Hematopoietic Cell Transplant. Version 3.2023 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Accessed November 28, 2023.
4. Cutler, Corey, et al. "Belumosudil for chronic graft-versus-host disease (cGVHD) after 2 or more prior lines of therapy: the ROCKstar Study." Blood (2021).

OHSU Health Services

Rivfloza™ (nedosiran)
Prior Authorization Guidelines

Affected Medication(s)

- Rivfloza (nedosiran) subcutaneous injection

FDA Approved Indication(s)

- To lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function

Dosing

- < 50 kg: 128 once monthly
- ≥ 50 kg: 160 mg once monthly

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a documented diagnosis of primary hyperoxaluria type 1 as confirmed by genetic testing or biopsy? (Provide supporting documentation of diagnosis)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the member 9 years of age or older? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 5/8/24
Effective Date: 6/15/24

6. Has the member had a liver transplant?
    a. If yes, clinical review required
    b. If no, continue to #7
7. Does the patient have documentation of estimated glomerular filtration rate (eGFR) of 30 mL/min/1.73m2 or greater? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Is Rivfloza (nedosiran) being prescribed by, or in consult with, a specialist in genetics, nephrology, or urology?
    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 or major compendia supported? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of significant clinical response to therapy received? (ex. decrease in urinary oxalate excretion from baseline, reduction in spot urinary oxalate: creatinine ratio from baseline, stabilization of GFR) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is Rivfloza (nedosiran) being prescribed by, or in consult with, a specialist in genetics, nephrology, or urology?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. RIVFLOZA (nedosiran) subcutaneous injection, [package insert]. Costa Mesa, CA: Pyramid Laboratories; 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2024. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 6 Feb. 2024].
3. Groothoff JW, Metry E, Deesker L, et al. Clinical practice recommendations for primary hyperoxaluria: an expert consensus statement from ERKNet and OxalEurope. Nat Rev Nephrol. 2023;19(3):194-211.
4. Baum MA, Langman C, Cochat P, et al. PHYOX2: a pivotal randomized study of nedosiran in primary hyperoxaluria type 1 or 2. Kidney Int. 2023;103(1):207-217.

OHSU Health Services

Roflumilast
Prior Authorization Guidelines

Affected Medication(s)

- Roflumilast 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

- 250 mcg once daily for 4 weeks, followed by 500 mcg once daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request a renewal of a previously approved roflumilast prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved indication?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have documentation of severe or very severe COPD (i.e. FEV1 of < 50% predicted) associated with chronic bronchitis? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a history of COPD exacerbations (i.e. one or more hospitalizations for an exacerbation within the past 12 months)? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 7/12/23
Effective Date: 8/15/23

6. Does the member have a previous trial (at least 8-weeks) with inadequate response, intolerance, or contraindication to ALL of the following? (NOTE: Use of inhaled corticosteroid (ICS) may be waived if eosinophil count is < 100 cells/µL)
    - Long-acting bronchodilator (LABA)
    - Long-acting muscarinic antagonist (LAMA)
    - Inhaled corticosteroid (ICS)

    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the medication being prescribed by, or in consultation with, a pulmonologist or other respiratory specialist?

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

Reauthorization Criteria

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

    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a positive clinical response to therapy (e.g., reduction in exacerbations, positive change from baseline in post-bronchodilator FEV1)? (Provide supporting documentation)

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

    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. Daliresp (roflumilast) [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP. March 2020.

Last Reviewed: 7/12/23
Effective Date: 8/15/23

2. Daliresp. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed June 14, 2023.
3. Ferguson MD, Make MD. Management of refractory chronic obstructive pulmonary disease. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed June 14, 2023.
4. Agustí, Alvar, et al. "Global initiative for chronic obstructive lung disease 2023 report: GOLD executive summary." American Journal of Respiratory and Critical Care Medicine 207.7 (2023): 819-837.

OHSU Health Services

Rufinamide
Prior Authorization Guidelines

Affected Medication(s)

- Rufinamide tablet
- Rufinamide 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 in two divided doses (Max: 3200 mg per day)

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved rufinamide prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is rufinamide being requested for an FDA approved indication? (Provide supporting documentation)
    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? (i.e. valproic acid, lamotrigine, topiramate, felbamate, cannabidiol) (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Will the member continue therapy with at least one other antiepileptic drug in combination with rufinamide?
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 7/17/18, 3/11/20, 7/14/21, 9/14/22, 9/13/23
Effective Date: 8/15/18, 1/1/20, 9/1/21

6. Does the member have familial short QT syndrome? (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, continue to #7
7. Is the treatment being prescribed by or in consultation with a neurologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is rufinamide being requested for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within 1 year) with documentation of significant clinical response to prior therapy received? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by or in consultation with a neurologist?
    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

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

References:

1. Banzel (rufinamide) [Prescribing Information]. Woodcliff Lake, NJ: Eisai Inc. June 2015.
2. Banzel. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed June 25, 2018.
3. National Institute for Health and Care Excellence (NICE): Epilepsies: diagnosis and management. National Institute for Health and Care Excellence (NICE). London, United Kingdom. Available at: https://www.nice.org.uk/guidance/cg137/resources/epilepsies-diagnosis-and-management-35109515407813. Accessed June 27, 2018.

Last Reviewed: 7/17/18, 3/11/20, 7/14/21, 9/14/22, 9/13/23
Effective Date: 8/15/18, 1/1/20, 9/1/21

4. National Institute of Neurological Disorders and Stroke. Lennox-Gastaut Syndrome Information Page. Available at: https://www.ninds.nih.gov/Disorders/All-Disorders/Lennox-Gastaut-Syndrome-Information-Page.
5. Debopam Samanta, Management of Lennox-Gastaut syndrome beyond childhood: A comprehensive review, Epilepsy & Behavior, Volume 114, Part A, 2021,107612, ISSN 1525-5050, https://doi.org/10.1016/j.yebeh.2020.107612.

Last Reviewed: 7/17/18, 3/11/20, 7/14/21, 9/14/22, 9/13/23
Effective Date: 8/15/18, 1/1/20, 9/1/21

OHSU Health Services

Rukobia® (fostemsavir tromethamine)
Prior Authorization Guidelines

Affected Medication(s)

- Rukobia oral tablet

FDA Approved Indication(s)

- Treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations

Dosing

- 600mg ER by mouth two times daily with or without food

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request a renewal of a previously approved Rukobia (fostemsavir tromethamine) prior authorization and indication is for the same as previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Does the member currently have documented resistance or contraindications to 3 or more different classes of antiretrovirals? (examples include: NRTIs, INSTIs, PIs, NNRTIs, CCR5 antagonist) (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Will Rukobia (fostemavir) be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral medications? (Provide treatment regimen)
    a. If yes, continue to #5
    b. If no, clinical review required

Last Reviewed: 9/9/20, 9/8/21, 9/14/22, 9/13/23
Effective Date: 11/1/20, 11/1/21

OHSUHealth Services

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

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within the past 6 months) provided with documentation of virologic suppression compared to pre-therapy baseline? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Will Rukobia (fostemavir) continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral medications? (Provide treatment regimen)
    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 or provider experienced in the treatment of HIV?
    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

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

References:

1. RUKOBIA (fostemsavir) oral extended-release tablet [package insert]. Triangle Park, NC: Viiv Healthcare; 2020.

Last Reviewed: 9/9/20, 9/8/21, 9/14/22, 9/13/23
Effective Date: 11/1/20, 11/1/21

2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 27 July. 2020].
3. US Department of Health and Human Services. "Guidelines for the use of antiretroviral agents in adults and adolescents with HIV." (2019).
4. World Health Organization. "Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy, July 2017." (2017).
5. Kozal M, Aberg J, Pialoux G, et al. Fostemsavir in Adults with Multidrug-Resistant HIV-1 Infection. N Engl J Med. 2020;382(13):1232-1243. doi:10.1056/NEJMoa1902493
6. Lagishetty C, Moore K, Ackerman P, Llamoso C, Magee M. Effects of Temsavir, Active Moiety of Antiretroviral Agent Fostemsavir, on QT Interval: Results From a Phase I Study and an Exposure-Response Analysis. Clin Transl Sci. 2020;13(4):769-776. doi:10.1111/cts.12763

Last Reviewed: 9/9/20, 9/8/21, 9/14/22, 9/13/23
Effective Date: 11/1/20, 11/1/21

OHSU Health Services

Sapropterin (Kuvan)
Prior Authorization Guidelines

Affected Medication(s)

- Sapropterin oral tablet
- Sapropterin oral powder

FDA Approved Indication(s)

- To reduce blood phenylalanine (Phe) levels in adult and pediatric patients ≥1 month of age with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4) responsive phenylketonuria (PKU) in conjunction with a PHE-restricted diet

Dosing

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

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request a renewal of a previously approved sapropterin (Kuvan) prior authorization and provided indication is for same as previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Will sapropterin (Kuvan) be used in conjunction with a phenylalanine-restricted diet (i.e. foods with high protein such as meat, fish, eggs, and milk products should be avoided)? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required

Last Reviewed: 1/22/19, 3/11/20, 7/14/21, 7/13/22, 7/12/23
Effective Date: 2/15/19, 1/1/20, 9/1/21, 9/1/22

OHSUHealth Services

5. Is the baseline phenylalanine level provided and does it exceed 360 µmol/L? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Will the member have a phenylalanine blood level measured after 1 week of therapy and then periodically for up to 1 month of therapy? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the treatment being prescribed by or in consultation with a specialist experienced in treatment of hyperphenylalaninemia?
    a. If yes, approve for 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 supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is sapropterin (Kuvan) being used in conjunction with a phenylalanine-restricted diet (i.e. foods with high protein such as meat, fish, eggs, and milk products should be avoided)? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Has the member demonstrated a positive clinical response to therapy as defined by a decrease in average blood Phenylalanine levels by at least 30% below pretreatment baseline? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Will the member's blood phenylalanine levels continue to be monitored throughout therapy? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the treatment being prescribed by or in consultation with a specialist experienced in treatment of hyperphenylalaninemia?
    a. If yes, approve for 12 months unless otherwise specified

b. If no, clinical review required

Note:

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. Drugs@FDA: FDA Approved Drug Products. 2018. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 17 Sep. 2018].
2. Kuvan (sapropterin dihydrochloride) [Prescribing Information]. Novato, CA: BioMarin Pharmaceutical, Inc. March 2020.
3. Vockley, Jerry, et al. "Phenylalanine hydroxylase deficiency: diagnosis and management guideline." Genetics in Medicine 16.2 (2014): 188.
4. Van Wegberg, A. M. J., et al. "The complete European guidelines on phenylketonuria: diagnosis and treatment." Orphanet journal of rare diseases 12.1 (2017): 162.

Last Reviewed: 1/22/19, 3/11/20, 7/14/21, 7/13/22, 7/12/23
Effective Date: 2/15/19, 1/1/20, 9/1/21, 9/1/22

OHSUHealth Services

Scemblix® (asciminib)
Prior Authorization Guidelines

Affected Medication(s)

- Scemblix oral tablet

FDA Approved Indication(s)

- Treatment of adults with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+CML) in chronic phase (CP) that meet one of the following:
  - Are previously treated with two or more tyrosine kinase inhibitors (TKIs)
  - Have the T315I mutation

Dosing

- For patients previously treated with two or more tyrosine kinase inhibitors (TKIs): 80mg by mouth once daily, or 40mg orally twice daily
- For patients with the T315I mutation: 200mg twice daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the request for continuation of therapy with the same anti-cancer medication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3
3. Is the medication being requested for an FDA approved indication? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, continue to #4
4. Is the medication being requested for an indication supported by the National Comprehensive Cancer Network (NCCN) recommendation with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
   a. If yes, continue to #5
   b. If no, clinical review required

Last Reviewed: 1/12/22, 1/11/23, 1/10/24
Effective Date: 3/1/22

OHSUHealth Services

5. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have T315I mutation? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, continue to #9
7. Has the member previously trialed Iclusig with an inadequate response or clinically significant adverse effect? (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, continue to #8
8. Does the member have a contraindication to treatment with Iclusig?
    a. If yes, continue to #9
    b. If no, clinical review required
9. Is the medication being prescribed by, or in consultation with, an oncologist?
    a. If yes, approve for 4 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by NCCN recommendation with an evidence level of 2A or higher? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Example: BCR-ABL1 ≤ 0.1%) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with an oncologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. SCEMBLIX (asciminib) tablets, [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; 2022.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 9 Dec. 2021].

Clinical Practice Guidelines in Oncology (NCCN Guidelines): Chronic Myeloid Leukemia. Version 1.2024 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed November 28, 2023.

OHSU Health Services

Short-Acting Opioids
Prior Authorization Guidelines

Affected Medication(s)

- All short-acting opioids

FDA Approved Indication(s)

- Pain (moderate to severe)

Dosing

- Variable based on drug entity

Authorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the requested drug a formulary short-acting opioid?
    a. If yes, go to question #4
    b. If no, continue to question #3
3. Has the patient had an insufficient clinical response to a trial of two (2) or more formulary short-acting opioids? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does this patient have pain related to one of the following conditions: active malignancy, palliative care, hospice or sickle cell disease? (Provide supporting documentation)
    a. If yes, approve for 12 months
    b. If no, continue to question #5
5. Is the request for continuation of opioid therapy in which this patient has been established on opioids for at least 90 days verified by a previously approved opioid request, claims history or documentation submitted by the provider? (Note: If transitioning care from specialist to PCP, including supporting documentation of transition notes)
    a. If yes, continue to question #13
    b. If no, continue to #6

Last Reviewed: 11/11/20, 1/12/22, 1/11/23, 1/10/24, 5/8/24
Effective Date: 1/1/21, 2/15/24, 6/15/24

OHSUHealth Services

6. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)

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

7. Which of the following applies to this patient?

    a. Acute use exceeding 90 morphine equivalents per day – continue to question #8
    b. Acute use requesting greater than two opioids prescriptions within 60 days – continue to question #10

8. Does the provider attest to reviewing the Oregon Prescription Drug Monitoring Program (OR PDMP) prior to prescribing opiate therapy?

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

9. Was this patient stable on the prescribed dose in an inpatient setting prior to discharge? (Provide supporting documentation)

    a. If yes, approve for 14 days
    b. If no, clinical review required

10. Does this patient have a documented trial with inadequate response, intolerance or contraindication to non-steroidal anti-inflammatories (NSAIDs) or acetaminophen? (Provide supporting documentation)

    a. If yes, continue to #11
    b. If no, clinical review required

11. Does the provider attest to reviewing the Oregon Prescription Drug Monitoring Program (OR PDMP) prior to prescribing opiate therapy AND is the member compliant? (Note: Members residing in a long-term care facility are exempt from this requirement)

    a. If yes, continue to #12
    b. If no, clinical review required

12. Does this patient have an outlined treatment plan including functional goals? (Provide supporting documentation)

    a. If yes, approve for up to 3 months (limited to minimum duration of expected treatment)
    b. If no, clinical review required

13. Does this patient have a signed pain management agreement with the provider inclusive of random urine drug screens AND monitoring of the Oregon Prescription Drug Monitoring Program (PDMP)

AND patient is compliant with agreement requirements? (Note: Members residing in a long-term care facility are exempt from this requirement)

a. If yes, continue to #14
b. If no, clinical review required

14. Has the provider documented that the benefits of chronic opioid treatment outweigh the risks in this patient?

    a. If yes, continue to #15
    b. If no, clinical review required

15. Has this patient been referred to non-pharmacologic treatment for the management of pain (e.g. physical therapy, occupational therapy) or has non-pharmacologic treatment been documented to be not tolerated or ineffective? (Provide supporting documentation)

    a. If yes, continue to #16
    b. If no, clinical review required

16. Does this patient have a documented trial with inadequate response to non-opioid treatment for their condition and will opioids be continued in conjunction with non-opioid treatment if appropriate (e.g. NSAIDs, gabapentin, pregabalin, duloxetine, tri-cyclic antidepressants)? (Provide supporting documentation)

    a. If yes, continue to #17
    b. If no, clinical review required

17. Have improvements in the patient's functional goals or quality of life been documented from baseline as a result of opioid treatment? (Provide supporting documentation)

    a. If yes, continue to #18
    b. If no, clinical review required

18. Is the requested total daily morphine equivalent dose less than 50?

    a. If yes, approve for 12 months
    b. If no, continue to question #19

19. Does this patient have an active order of naloxone prescribed within the past 12 months?

    a. If yes, continue to #20
    b. If no, clinical review required

20. Does this patient have an active taper plan or has rationale been provided for avoidance of a taper at this time? (Provide supporting documentation)

    a. If yes, approve for 6 months

b. If no, clinical review required

Note:

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

References:

1. Opioid Risk Tool: https://www.drugabuse.gov/sites/default/files/opioidrisktool.pdf

OHSU Health Services

Sirturo (bedaquiline), Pretomanid
Prior Authorization Guidelines

Affected Medication(s)

- Sirturo (bedaquiline oral tablet)
- Pretomanid oral tablet

FDA Approved Indication(s)

- Sirturo: Part of combination therapy in the treatment of adult and pediatric patients (5 years and older and weighing at least 15 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Reserved for use when an effective treatment regimen cannot otherwise be provided.
- Pretomanid: Part of a combination regimen with bedaquiline and linezolid for the treatment of adults with pulmonary extensively drug resistant (XDR), treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB).

Dosing

- Refer to package insert for pediatric dosing
- Sirturo: 400mg orally one time daily for two weeks followed by 200mg 3 times per week
- Pretomanid 200mg tablet orally one time daily for 26 weeks (in combination with bedaquiline and linezolid)

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the medication being requested for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is tuberculosis treatment being managed through state funded tuberculosis program?
    a. If yes, deny. Medication funded through state program
    b. If no, continue to #4
4. Does the patient have documentation of resistance to, intolerance to, or contraindication to quad therapy with isoniazid, rifampin, ethambutol, pyrazinamide? (Provide supporting documentation)

Last Reviewed: 7/8/20, 11/10/21, 11/9/22, 11/8/23
Effective Date: 9/1/20, 1/1/22

OHSUHealth Services

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

5. Is the request for one of the following treatment regimens?
    - Pretomanid + Sirturo + linezolid
    - Sirturo + at least 3 additional antituberculotic agents active against member's *M. tuberculosis* isolate

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

6. Is the medication being prescribed by, or in consultation with, an infectious disease specialist or a specialist experienced in treating tuberculosis?

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

Note:

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

References:

1. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
2. DailyMed – Pretomanid tablet. 2019. U.S. National Library of Medicine. National Institutes of Health. [online] https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5e31a6a9-864f-4aba-8085-37ee1ddcd499
3. Pretomanid (pretomanid) oral tablet [package insert]. New York, NY: Mylan Laboratories; 2020.
4. Sirturo (bedaquiline) oral tablet [package insert]. Titusville, NJ: Janssen Products, LP; October 2021.
5. Nahid, Payam, et al. "Treatment of drug-resistant tuberculosis. An official ATS/CDC/ERS/IDSA clinical practice guideline." American journal of respiratory and critical care medicine 200.10 (2019): e93-e142.

Last Reviewed: 7/8/20, 11/10/21, 11/9/22, 11/8/23
Effective Date: 9/1/20, 1/1/22

OHSU Health Services

Skyclarys® (omaveloxolone)
Prior Authorization Guidelines

Affected Medication(s)

- Skyclarys (omaveloxolone) oral tablet

FDA Approved Indication(s)

- Treatment of Friedreich's ataxia (FA) in adults and adolescents aged 16 and older

Dosing

- 150 mg orally once daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is Skyclarys® (omaveloxolone) being requested for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member between ages 16 and 40?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have Friedreich's ataxia confirmed by genetic testing? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have a stable modified Friedreich's Ataxia Rating Scale (mFARS) score between 20 and 80? (Provide supporting documentation)

Last Reviewed: 7/12/23
Effective Date: 8/15/23

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

7. Does the member have a left ventricular ejection fraction of at least 40%? (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 clinical geneticist or neurologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of clinical response to prior therapy received?
    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 or neurologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. Skyclarys (omaveloxolone) capsules, [package insert]. Plano, TX: Reata Pharmaceuticals, Inc.; 2023.
2. Drugs@FDA: FDA Approved Drug Products. 2023. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 22 Mar. 2023].

3. Lynch, D. R., Chin, M. P., Delatycki, M. B., Subramony, S. H., Corti, M., Hoyle, J. C., Boesch, S., Nachbauer, W., Mariotti, C., Mathews, K. D., Giunti, P., Wilmot, G., Zesiewicz, T., Perlman, S., Goldsberry, A., O'Grady, M., & Meyer, C. J. (2021). Safety and Efficacy of Omaveloxolone in Friedreich Ataxia (MOXIe Study). Annals of neurology, 89(2), 212–225.
4. Lynch, D. R., Chin, M. P., Boesch, S., Delatycki, M. B., Giunti, P., Goldsberry, A., Hoyle, J. C., Mariotti, C., Mathews, K. D., Nachbauer, W., O'Grady, M., Perlman, S., Subramony, S. H., Wilmot, G., Zesiewicz, T., & Meyer, C. J. (2023). Efficacy of Omaveloxolone in Friedreich's Ataxia: Delayed-Start Analysis of the MOXIe Extension. Movement disorders : official journal of the Movement Disorder Society, 38(2), 313–320.
5. Corben, L. A., Collins, V., Milne, S., Farmer, J., Musheno, A., Lynch, D., Subramony, S., Pandolfo, M., Schulz, J. B., Lin, K., Delatycki, M. B., & Clinical Management Guidelines Writing Group (2022). Clinical management guidelines for Friedreich ataxia: best practice in rare diseases. Orphanet journal of rare diseases, 17(1), 415.

OHSU Health Services

Sohonos® (palovarotene)
Prior Authorization Guidelines

Affected Medication(s)

- Sohonos (palovarotene) oral capsule

FDA Approved Indication(s)

- For the reduction in volume of new heterotopic ossification (HO) in adults and pediatric patients aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP)

Dosing

- Refer to package insert for dosing recommendations

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is Sohonos® (palovorotene) being requested for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member at least 8 years of age for females or at least 10 years of age for males?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have documentation of FOP diagnosis, with the R206H ACVR1 mutation or other FOP variants reported to be associated with progressive heterotopic ossification? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 11/8/23
Effective Date: 12/15/23

OHSUHealth Services

6. Is the treatment dose appropriate?
    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 or appropriate specialist? (Provide supporting documentation)
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of clinical response to prior therapy received?
    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 or appropriate specialist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. SOHONOS (palovarotene) capsules [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; 2023.
2. Drugs@FDA: FDA Approved Drug Products. 2022. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 21 Sept. 2023].
3. Pignolo RJ, Hsiao EC, Al Mukaddam M, et al. Reduction of New Heterotopic Ossification (HO) in the Open-Label, Phase 3 MOVE Trial of Palovarotene for Fibrodysplasia Ossificans Progressiva (FOP). J Bone Miner Res. 2023;38(3):381-394.

Last Reviewed: 11/8/23
Effective Date: 12/15/23

4. Kaplan FS, et al. The medical management of fibrodysplasia ossificans progressiva: current treatment considerations. Proc Intl Clin Council FOP 2. 2022: 1-127.

OHSU Health Services

Symdeko (tezacaftor/ivacaftor)
Prior Authorization Guidelines

Affected Medication(s)

- Symdeko oral tablet

FDA Approved Indication(s)

- Treatment of patients with cystic fibrosis (CF) aged 6 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

- Patients age 6 to 11 years weighing less than 30 kg: Tezacaftor 50 mg/ivacaftor 75 mg orally in the morning and ivacaftor 75 mg orally in the evening, approximately 12 hours apart
- Patients age 6 to 11 years weighing 30 kg or greater: Tezacaftor 100 mg/ivacaftor 150 mg orally in the morning and ivacaftor 150 mg orally in the evening, approximately 12 hours apart.
- Patients age 12 and older: Tezacaftor 100 mg/ivacaftor 150 mg orally in the morning and ivacaftor 150 mg in the evening, approximately 12 hours apart

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Symdeko (tezacaftor/ivacaftor) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is Symdeko (tezacaftor/ivacaftor) being requested for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the patient have a documentation of homozygous F508del mutation by an FDA-cleared CF mutation test or at least one mutation in the cystic fibrosis transmembrane conductance regulator

Last Reviewed: 10/18/18, 3/11/20, 5/12/21, 7/13/22, 7/12/23
Effective Date: 11/15/18, 1/1/20, 7/1/21, 8/15/23

(CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical data? (Provide supporting documentation)

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

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

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

6. Is the patient at least 6 years of age?

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

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

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

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

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

Reauthorization Criteria

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

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

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

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

3. Were updated chart notes (within past year) provided with documentation of follow up liver function tests? (Provide supporting documentation)

   a. If yes, continue to #4

b. If no, clinical review required

4. Is Symdeko (tezacaftor/ivacaftor) being prescribed by, or in consult with, a pulmonologist or a provider at a cystic fibrosis center?

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

Note:

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. Symdeko (tezacaftor/ivacaftor) [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc. December 2022.
2. Symdeko. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed August 31, 2018.
3. Simon, MD. Cystic fibrosis: Overview of the treatment of lung disease. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed August 31, 2018.

Last Reviewed: 10/18/18, 3/11/20, 5/12/21, 7/13/22, 7/12/23
Effective Date: 11/15/18, 1/1/20, 7/1/21, 8/15/23

OHSU Health Services

Synagis (palivizumab)
Prior Authorization Guidelines

Affected Medication(s)

- Synagis intramuscular injection

FDA Approved Indication(s)

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

Dosing

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

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the request for a compendia supported indication? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the member's weight provided for review?
   a. If yes, continue to #4
   b. If no, clinical review required
4. Does the member have a history of hospitalization for RSV infection during the current RSV season? (Provide supporting documentation)
   a. If yes, clinical review required

Last Reviewed: 3/5/19, 3/11/20, 11/10/21, 11/9/22, 12/1/22, 9/13/23
Effective Date: 3/5/19, 1/1/20, 12/1/22, 10/15/23

b. If no, continue to #5

5. Has the member or birth mother of the member received other therapies (i.e. Beyfortus (nirsevimab) or Abrysvo) for the prevention of RSV during or prior to the RSV season? (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, continue to #6
6. 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

<u>Premature Birth</u>

1. Does the member have a history of premature birth defined as less than 29 weeks gestation? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member less than 12 months of age at the start of RSV season?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the treatment plan include 5 or less doses of Synagis? (Provide supporting documentation)
    a. If yes, approve for up to 5 doses during RSV season
    b. If no, clinical review required

<u>Chronic Lung Disease of Prematurity</u>

1. Does the member have a history of premature birth defined as gestational age of less than 32 weeks gestation? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a diagnosis of chronic lung disease as defined by a requirement for >21% oxygen for at least 28 days after birth? (Provide supporting documentation)

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

3. Is the member < 12 months old at the start of RSV season?

    a. If yes, approve for up to 5 doses
    b. If no, continue to #4

4. Is the member <24 months old at the start of RSV season?

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

5. Does the member have a continued requirement for medical support including chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen within 6 months of the start of RSV season? (Provide supporting documentation)

    a. If yes, approve for up to 5 doses during RSV season
    b. If no, clinical review required

<u>Hemodynamically Significant Congenital Heart Disease</u>

1. Is the member <12 months of age at onset of RSV season?

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

2. Does the member have a diagnosis of acyanotic heart disease and is receiving medication to control congestive heart failure and will require a cardiac surgical procedure? (Provide supporting documentation)

    a. If yes, approve for up to 6 doses
    b. If no, continue to #3

3. Does the member have a diagnosis of moderate to severe pulmonary hypertension? (Provide supporting documentation)

    a. If yes, approve for up to 5 doses during the RSV season
    b. If no, continue to #4

4. Does the member have a diagnosis of cyanotic heart defect and RSV prophylaxis is recommended by a pediatric cardiologist? (Provide supporting documentation)

    a. If yes, approve up to 5 doses during RSV season
    b. If no, clinical review required

5. Is the member <24 months of age at onset of RSV season?

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

6. Does the member have a history of cardiopulmonary bypass during the RSV season? (Provide supporting documentation)

    a. If yes, approve up to 6 doses during RSV season
    b. If no, clinical review required

Anatomic Pulmonary Abnormalities or Neuromuscular Disorder

1. Is the member <12 months of age at the onset of RSV season?

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

2. Does the member have a diagnosis of a neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway? (e.g. ineffective cough) (Provide supporting documentation)

    a. If yes, approve for up to 5 doses during RSV season
    b. If no, clinical review required

Immunocompromised

1. Is the member <24 months of age at the onset of RSV season?

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

2. Will the member continue to be profoundly immunocompromised during the RSV season? (Examples include: solid organ or hematopoietic stem cell transplantation, chemotherapy administration, or immunocompromising disease) (Provide supporting documentation)

    a. If yes, approve for up to 5 doses during RSV season
    b. If no, clinical review required

Cystic Fibrosis

1. Is the member <12 months of age at the onset of RSV season?

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

2. Does the member have CLD of prematurity (defined as gestational age <32 weeks and a requirement for >21% oxygen for at least 28 days after birth) and/or nutritional compromise (i.e. tube feeding requirement)? (Provide supporting documentation)

a. If yes, approve for up to 5 doses during RSV season
b. If no, clinical review required

3. Is the member <24 months of age at the onset of RSV season?

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

4. Does the member have manifestations of severe lung disease as defined by previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography/chest computed tomography that persist when member is not experiencing exacerbation? (Provide supporting documentation)

    a. If yes, approve for up to 5 doses during RSV season
    b. If no, continue to #5

5. Does the member have a weight for length that is < 10th percentile? (Provide supporting documentation)

    a. If yes, approve for up to 5 doses during RSV season
    b. If no, clinical review required

Note:

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. Synagis (palivizumab) [Prescribing Information]. Gaithersburg, MD: Med Immune, LLC. May 2017.
2. Committee on Infectious Diseases. "Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection." Pediatrics (2014): peds-2014. Available at: http://pediatrics.aappublications.org/content/pediatrics/134/2/415.full.pdf

Last Reviewed: 3/5/19, 3/11/20, 11/10/21, 11/9/22, 12/1/22, 9/13/23
Effective Date: 3/5/19, 1/1/20, 12/1/22, 10/15/23

OHSU Health Services

Tacrolimus ointment
Prior Authorization Guidelines

Affected Medication(s)

- Tacrolimus topical ointment

FDA Approved Indication(s)

- Atopic dermatitis: indicated for treatment of moderate to severe atopic dermatitis in immunocompetent patient not responsive to conventional therapy or when conventional therapy is not appropriate
- Other compendia supported uses:
  - Oral lichen planus
  - Psoriasis
  - Pyoderma gangrenosum
  - Vitiligo

Dosing

- 0.03% ointment for children 2 years of age and up; 0.1% ointment for adults only
- Atopic dermatitis: apply a thin layer to the affected skin twice daily
- Psoriasis: apply thin layer of 0.03% ointment twice daily
- Oral lichen planus: apply a thin layer of 0.1% ointment to affected area up to 4 times daily
- Pyoderma gangrenosum: apply thin layer of 0.1% or 0.3% ointment to affected area once daily
- Vitiligo: apply thin layer of 0.1% or 0.3% ointment to affected area twice daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is tacrolimus ointment being requested for one of the following conditions? (Provide supporting documentation)
   - Atopic dermatitis

Last Reviewed: 4/2/19 3/11/20, 11/10/21, 9/14/22, 7/12/23, 1/10/24
Effective Date: 5/1/19, 1/1/20, 8/15/23, 2/15/24

- Psoriasis
- Lichen planus
- Vitiligo

a. If yes, continue to #4
b. If no, continue to #7

4. Does the member currently have severe inflammatory skin disease defined as having functional impairment (e.g. inability to use hands or feet or actives of daily living, or significant facial involvement preventing normal social interaction AND one or more of the following: At least 10% of body surface area involved AND/OR hand, foot, face, or mucous membrane involvement? (Provide supporting documentation)

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

5. Has the member had 2 or more unsuccessful treatments with moderate to high potency corticosteroids? (E.g. betamethasone ointment/augmented cream, triamcinolone ointment, halobetasol, fluocinonide ointment/cream, etc.) (Provide supporting documentation)

    a. If yes, approve for 6 months
    b. If no, continue to #6

6. Does the member have a contraindication or clinical rationale for avoiding moderate to high potency corticosteroids? (Provide supporting documentation)

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

7. Has the member tried and had an inadequate response OR does the member have a contraindication to ALL standard treatment options for the requested indication? (Provide supporting documentation)

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

8. Is the requested treatment dose appropriate? (Provide supporting documentation)

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

9. Is the treatment being prescribed by or in consultation with an appropriate specialist?

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

Note:

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

References:

1. Protopic (tacrolimus ointment) [Prescribing Information]. Northbrook, IL: Astellas Pharma Tech Co., LTD. November 2018.
2. Protopic. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed March 5, 2019.
3. Protopic. Lexicomp Online, Pediatric and Neonatal Lexi-Drugs Online, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2013. Available at: http://online.lexi.com/lco/action/home. Accessed March 5, 2019.
4. Oregon Health Plan. Prioritized List of Health Services. January 1, 2022. Available at: https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx. Accessed August 4, 2022.
5. Goldstein MD, Goldstein MD, MPH. General principles of dermatologic therapy and topical corticosteroid use. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com. Accessed March 5, 2019.

Last Reviewed: 4/2/19, 3/11/20, 11/10/21, 9/14/22, 7/12/23, 1/10/24
Effective Date: 5/1/19, 1/1/20, 8/15/23, 2/15/24

OHSU Health Services

Tavneos® (avacopan)
Prior Authorization Guidelines

Affected Medication(s)

- Tavneos oral capsule

FDA Approved Indication(s)

- Adjunctive treatment of severe active antineutrophil cytoplasmic autoantibody-associated vasculitis (granulomatosis with polyangiitis and microscopic polyangiitis) in combination with standard therapy, including glucocorticoids, in adults

Dosing

- 30 mg orally twice daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request a renewal of a previously approved Tavneos (avacopan) prior authorization and provided indication is the same as previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a diagnosis of granulomatosis with polyangiitis or microscopic polyangiitis? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the member 18 years of age or older?
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have a positive test for anti-PR3 or anti-MPO? (Provide supporting documentation)

Last Reviewed: 1/12/22, 1/11/23, 1/10/24
Effective Date: 3/1/22, 2/15/24

OHSUHealth Services

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

7. Does the member have at least 1 major item, or 3 non-major items, or the 2 renal items of proteinuria and hematuria on Birmingham Vasculitis Activity Score (BVAS)? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Does the member have a recent documented 3-month trial or longer with inadequate response to a maximally indicated dose of systemic steroids? (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, continue to #10
9. Is use of systemic steroids contraindicated or has the member had clinically significant adverse effects from a systemic steroid trial? (Provide supporting documentation)
    a. If yes, continue to #10
    b. If no, clinical review required
10. Is Tavneos prescribed in combination with either cyclophosphamide or rituximab?
    a. If yes, continue to #11
    b. If no, clinical review required
11. Is the medication prescribed by, or in consultation with, a rheumatologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within 1 year) demonstrating at least a 50% reduction in BVAS from baseline or remission? (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 reauthorization
    b. If no, clinical review required

Note:

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

References:

1. TAVNEOS (avacopan) capsules, [package insert]. Cincinnati, OH: ChemoCentyx, Inc; 2021.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 23 Nov. 2021].
3. UpToDate [internet database]. Hudson, OH: Wolters Kluwer. Updated periodically. Accessed December 31,2021.
4. Lexi-Drugs [internet database]. Hudson, OH: Lexicomp, Inc. Wolter Kluwer. Updated periodically. Accessed December 31,2021.
5. Yates, Max, et al. "EULAR/ERA-EDTA recommendations for the management of ANCA-associated vasculitis." Annals of the rheumatic diseases 75.9 (2016): 1583-1594.

Last Reviewed: 1/12/22, 1/11/23, 1/10/24
Effective Date: 3/1/22, 2/15/24

OHSU Health Services

Tegsedi® (inotersen sodium) | Wainua™ (eplontersen)
Prior Authorization Guidelines

Affected Medication(s)

- Tegsedi (inotersen) subcutaneous solution
- Wainua (eplontersen) subcutaneous solution

FDA Approved Indication(s)

- Treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults

Dosing

- Tegsedi: 284 mg subcutaneously once weekly
- Wainua: 45 mg subcutaneously once monthly

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    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. Does the member have documentation confirming the presence of a transthyretin (TTR) mutation? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have documentation of a biopsy that was found to be positive for amyloid deposits? (Provide documentation of biopsy)

Last Reviewed: 5/8/24
Effective Date: 6/15/24

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

7. Has the member had an orthotopic liver transplant?

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

8. Does the member meet the diagnosis and clinical requirements for at least one of the following below? (Provide supporting documentation)

    - Subjective patient symptoms are suggestive of neuropathy
    - Abnormal nerve conduction studies are consistent with polyneuropathy
    - Abnormal neurological examination is suggestive of neuropathy

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

9. Is the member's peripheral neuropathy attributed to hereditary transthyretin-mediated amyloidosis and have other causes of neuropathy been excluded? (Provided supporting documentation)

    a. If yes, continue to #10
    b. If no, clinical review required

10. Is the treatment being prescribed by, or in consultation with, a neurologist, geneticist, or provider who specializes in the management of amyloidosis?

    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 or major compendia supported? (Provide supporting documentation)

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

2. Were updated chart notes (within past year) provided with documentation of significant clinical response to therapy received? (ex. improvement in neuropathy 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 neurologist, geneticist, or provider who specializes in the management of amyloidosis?

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

Note:

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

References:

1. Tegsedi (inotersen sodium) subcutaneous injection [package insert]. Boston, MA: Akcea Therpeutics, Inc; June 2022.
2. WAINUA™ (eplontersen) subcutaneous injection [package insert]. Wilmington, DE: AstraZeneca; December 2023.
3. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 8 Jan, 2019].
4. Ando Y, Coelho T, Berk JL, Cruz MW, Ericzon BG, Ikeda SI, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet Journal of Rare Diseases. 2013;8(1):1-18.
5. Hawkins PN, Ando Y, Dispenzeri A, Gonzalez-Duarte A, Adams D, Suhr OB. Evolving landscape in the management of transthyretin amyloidosis. Annals of Medicine. 2015;47(8):625-38.
6. Ando Y, Adams D, Benson MD, et al. Guidelines and new directions in the therapy and monitoring of ATTRv amyloidosis. Amyloid. 2022;29(3):143-155.

OHSU Health Services

Therapeutic Immunomodulators
Prior Authorization Guidelines

Affected Medication(s)

- Actemra (tocilizumab) subcutaneous solution
- Adalimumab-fkjp subcutaneous solution
- Cimzia (certolizumab) subcutaneous solution
- Cosentyx (secukinumab) subcutaneous solution
- Enbrel (etanercept) subcutaneous solution
- Hadlima (adalimumab) subcutaneous solution
- Otezla (apremilast) oral tablet
- Stelara (ustekinumab) subcutaneous solution
- Rinvoq (upadacitinib) oral tablet

FDA Approved Indication(s)

	RA	JIA	PsA	Non-radiographic axial spondyloarthritis (nr-axSpA)	AS	Crohn's Disease	UC	Ps	HS	Uveitis	Other
Hadlima	X	X	X		X	X	X	X	X	X	
Adalimumab-fkjp	X	X	X		X	X	X	X	X	X	
Enbrel	X	X	X		X			X			
Cimzia	X		X	X	X	X		X			
Stelara			X			X	X	X			
Cosentyx			X	X	X			X	X		X
Otezla			X					X			X
Actemra	X	X									X
Rinvoq	X		X	X	X	X	X				X

Dosing

- Refer to corresponding package insert for information

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)

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

Last Reviewed: 11/26/19, 11/10/21, 3/9/22, 9/14/22, 11/8/23, 3/13/24, 5/8/24
Effective Date: 1/1/20, 1/1/22, 5/1/22, 1/1/24, 6/15/24

2. Is the request for renewal of therapeutic immunomodulatory therapy prior authorization previously approved for the same indication?

    a. If yes, continue to Reauthorization
    b. If no, continue to #3

3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

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

4. Will the requested medication be used concurrently with other biologic therapy? (Examples: Enbrel, Actemra, Cimzia, Humira, Otelza, Cosentyx, etc.)

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

5. What is the diagnosis that the medication is being requested for?

    a. Rheumatoid arthritis (RA), continue to corresponding criteria
    b. Juvenile idiopathic arthritis (JIA), continue to corresponding criteria
    c. Ankylosing spondylitis (AS)/Non-radiographic axial spondyloarthritis (nr-axSpA), continue to corresponding criteria
    d. Psoriatic arthritis (PsA), continue to corresponding criteria
    e. Crohn's disease, continue to corresponding criteria
    f. Ulcerative colitis, continue to corresponding criteria
    g. Plaque psoriasis (Ps), continue to corresponding criteria
    h. Hidradenitis suppurativa, continue to corresponding criteria
    i. Uveitis, continue to corresponding criteria
    j. Atopic dermatitis, continue to corresponding criteria
    k. Other indication, continue to corresponding criteria

Rheumatoid Arthritis

1. Does the member have moderate to severe active rheumatoid arthritis (RA) confirmed by one of the tests below despite the current RA management regimen? (Provide supporting documentation)

    - Patient Activity Scale (PAS) or PASII of 3.7 or higher
    - Routine Assessment of Patient Index Data 3 (RAPID3) of 2.3 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 #2
b. If no, clinical review required

2. Did the member have an inadequate response to a 12-week trial of methotrexate? (Provide supporting documentation)

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

3. Does the member have a contraindication or history of intolerance to methotrexate? (Note: Alcohol consumption is not considered a contraindication and nausea to oral formulation is not considered an intolerance) (Provide supporting documentation)

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

4. Did the member have an inadequate response to a 12-week trial with one of the following disease-modifying antirheumatic drugs: leflunomide, sulfasalazine, or hydroxychloroquine? (Provide supporting documentation)

    a. If yes, continue to #6
    b. If no, continue to #5

5. Does the member have a contraindication or history of intolerance to ALL of the following: leflunomide, sulfasalazine, and hydroxychloroquine? (Provide supporting documentation)

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

6. Is the request for Hadlima, adalimumab-fkjp, or Enbrel (etanercept)?

    a. If yes, continue to #10
    b. If no, continue to #7

7. Does the member have documentation of an inadequate response, intolerance, or contraindication to Hadlima, adalimumab-fkjp, or Enbrel (etanercept)?? (Provide supporting documentation)

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

8. Is the request for Cimzia?

    a. If yes, continue to #10
    b. If no, continue to #9

9. Does the member have documentation of an inadequate response, intolerance, or contraindication to Cimzia? (Provide supporting documentation)

    a. If yes, continue to #10
    b. If no, clinical review required

10. Is the requested treatment dose appropriate?

    a. If yes, continue to #11
    b. If no, clinical review required

11. Is the medication being prescribed by or in consultation with a rheumatologist?

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

Juvenile Idiopathic Arthritis (JIA/pJIA)

1. Does the member have moderate to severe active polyarticular JIA defined as greater or equal to 5 swollen joints and at least 3 joins with limitation in motion? (Provide documentation of affected joints and current and prior treatment regimen)

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

2. Did the member have an inadequate response to a 12-week trial of methotrexate? (Provide supporting documentation)

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

3. Does the member have a contraindication or history of intolerance to methotrexate? (Note: 1. Alcohol consumption is not considered a contraindication 2. Nausea to oral formulation is not considered an intolerance) (Provide supporting documentation)

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

4. Did the member have an inadequate response or documented intolerance to a 12-week trial of leflunomide or sulfasalazine? (Provide supporting documentation)

    a. If yes, continue to #6
    b. If no, continue to #5

5. Does the member have a contraindication or history of intolerance to leflunomide or sulfasalazine? (Provide supporting documentation)

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

6. Is the request for Hadlima, adalimumab-fkjp, or Enbrel (etanercept)?

    a. If yes, continue to #8
    b. If no, continue to #7

7. Does the member have documentation of an inadequate response, intolerance, or contraindication to Hadlima, adalimumab-fkjp, or Enbrel (etanercept)? (Provide supporting documentation)

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

8. Is the requested treatment dose appropriate?

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

9. Is the medication being prescribed by or in consultation with a rheumatologist?

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

<u>Ankylosing Spondylitis (AS), Non-radiographic axial spondyloarthritis (nr-axSpA)</u>

1. Does the member currently have active ankylosing spondylosis despite current treatment regimen? (Defined as: 1. Bath ankylosing spondylitis disease activity index (BASDAI) greater or equal to 4 OR Ankylosing Spondylitis Disease Activity Score (ASDAS) greater or equal to 2.1 AND 2. Elevated CRP or positive MRI or Radiographic sacroiliitis) (Provide supporting documentation)

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

2. Did the member have an inadequate response or intolerance to TWO separate 4 week trials of prescription strength oral nonsteroidal anti-inflammatory drugs (NSAIDs)? (Provide supporting documentation)

    a. If yes, continue to #4
    b. If no, continue to #3

3. Does the member have a contraindication to oral NSAIDs? (Provide supporting documentation)

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

4. Does the member have isolated sacroiliitis or enthesitis disease? (Provide supporting documentation)

    a. If yes, continue to #5
    b. If no, continue to #7

5. Did the member have an inadequate response to a locally administered parenteral glucocorticoid injection? (Provide supporting documentation)

    a. If yes, continue to #7
    b. If no, continue to #6

6. Does the member have a contraindication to a locally administered parenteral glucocorticoid injection? (Provide supporting documentation)

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

7. Does the member have predominantly active axial or peripheral disease? (Provide supporting documentation)

    a. If axial disease, continue to #10
    b. If peripheral disease, continue to #8

8. Did the member have an inadequate response to a 12-week trial with sulfasalazine (Azulfidine)? (Provide supporting documentation)

    a. If yes, continue to #10
    b. If no, continue to #9

9. Does the member have a contraindication or history of intolerance to sulfasalazine (Azulfidine)? (Provide supporting documentation)

a. If yes, continue to #10
b. If no, clinical review required

10. Is the request for Hadlima, adalimumab-fkjp, or Enbrel (etanercept)?

    a. If yes, continue to #14
    b. If no, continue to #11

11. Does the member have documentation of an inadequate response, intolerance, or contraindication to Hadlima, adalimumab-fkjp, or Enbrel (etanercept)? (Provide supporting documentation)

    a. If yes, continue to #12
    b. If no clinical review required

12. Is the request for Cimzia?

    a. If yes, continue to #14
    b. If no, continue to #13

13. Does the member have documentation of an inadequate response, intolerance, or contraindication to Cimzia? (Provide supporting documentation)

    a. If yes, continue to #14
    b. If no, clinical review required

14. Is the requested treatment dose appropriate?

    a. If yes, continue to #15
    b. If no, clinical review required

15. Is the medication being prescribed by, or in consultation with, a rheumatologist?

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

<u>Psoriatic Arthritis (PsA)</u>

1. Does the member currently have active psoriatic arthritis (PsA) defined as greater or equal to 3 points on the CASPAR scale below? (Provide supporting documentation)

    i. Skin psoriasis present (2 points)
    ii. Skin psoriasis previously present (1 point)
    iii. Family history of psoriasis (1 point)
    iv. Nail lesions (1 point)
    v. Past or present dactylitis (1 point)

vi. Negative rheumatoid factor (1 point)
vii. Juxtaarticular bone formation on radiographs (1 point)

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

2. Does the member have predominantly axial disease or severe enthesitis? (Provide supporting documentation)

a. If yes, continue to #3
b. If no, continue to #5

3. Did the member have an inadequate response or intolerance to TWO separate 4 week trials of oral prescription strength nonsteroidal anti-inflammatory drugs (NSAIDs) OR a prescription strength oral NSAID and parenteral glucocorticoid injection? (Provide supporting documentation)

a. If yes, continue to #9
b. If no, continue to #4

4. Does the member have a contraindication to oral NSAIDs? (Provide supporting documentation)

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

5. Did the member have an inadequate response to a 12-week trial of methotrexate? (Provide supporting documentation)

a. If yes, continue to #9
b. If no, continue to #6

6. Does the member have a contraindication or history of intolerance to methotrexate? (Note: Alcohol consumption is not considered a contraindication and nausea to oral formulation is not considered an intolerance) (Provide supporting documentation)

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

7. Did the member have an inadequate response to a 12-week trial with one of the following: leflunomide or sulfasalazine? (Provide supporting documentation)

a. If yes, continue to #9
b. If no, continue to #8

OHSUHealth Services

8. Does the member have a contraindication or history of intolerance to BOTH of the following: leflunomide and sulfasalazine? (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, clinical review required
9. Is the request for Hadlima, adalimumab-fkjp, or Enbrel (etanercept)?
    a. If yes, continue to #15
    b. If no, continue to #10
10. Does the member have documentation of an inadequate response, intolerance, or contraindication to Hadlima, adalimumab-fkjp, or Enbrel (etanercept)? (Provide supporting documentation)
    a. If yes, continue to #11
    b. If no, clinical review required
11. Is the request for Cimzia?
    a. If yes, continue to #15
    b. If no, continue to #12
12. Does the member have documentation of an inadequate response, intolerance, or contraindication to Cimzia? (Provide supporting documentation)
    a. If yes, continue to #13
    b. If no, clinical review required
13. Is the request for Stelara (ustekinumab)?
    a. If yes, continue to #15
    b. If no, continue to #14
14. Did the member have an inadequate response, intolerance, or contraindication to Stelara (ustekinumab)? (Provide supporting documentation)
    a. If yes, continue to #15
    b. If no, clinical review required
15. Is the requested treatment dose appropriate?
    a. If yes, continue to #16
    b. If no, clinical review required
16. Is the medication being prescribed by, or in consultation with, a rheumatologist or dermatologist?

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

Crohn's Disease (CD)

1. Does the member currently have active Crohn's Disease despite the current treatment regimen? (Defined as Crohn's Disease Activity Index (CDAI) greater than 220, record CDAI) (Provide supporting documentation)

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

2. Did the member have an inadequate response to TWO separate 12 week trials with TWO of the following oral agents: 6-mercaptopurine, azathioprine, corticosteroid, methotrexate, mesalamine? (Provide supporting documentation)

    a. If yes, continue to #4
    b. If no, continue to #3

3. Does the member have a contraindication or history of intolerance to ALL of the following oral agents: 6-mercaptopurine, azathioprine, corticosteroids, methotrexate, mesalamine, sulfasalazine? (Provide supporting documentation)

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

4. Is the request for Hadlima or adalimumab-fkjp?

    a. If yes, continue to #10
    b. If no, continue to #5

5. Does the member have documentation of an inadequate response, intolerance, or contraindication to Hadlima or adalimumab-fkjp? (Provide supporting documentation)

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

6. Is the request for Cimzia?

    a. If yes, continue to #10
    b. If no, continue to #7

7. Does the member have documentation of an inadequate response, intolerance, or contraindication to Cimzia? (Provide supporting documentation)

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

8. Is the request for Stelara?

    a. If yes, continue to #10
    b. If no, continue to #9

9. Does the member have documentation of an inadequate response, intolerance, or contraindication to Stelara? (Provide supporting documentation)

    a. If yes, continue to #10
    b. If no, clinical review required

10. Is the requested treatment dose appropriate?

    a. If yes, continue to #11
    b. If no, clinical review required

11. Is the medication being prescribed by, or in consultation with, a gastroenterologist?

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

<u>Ulcerative Colitis (UC)</u>

1. Does the member currently have active Ulcerative Colitis despite the current treatment regimen? (Diagnosis confirmed by endoscopy, colonoscopy, or sigmoidoscopy with Mayo score of greater than 6) (Provide supporting documentation)

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

2. Did the member have an inadequate response to TWO separate 12 week trials with TWO of the following oral agents: aminosalicylates (sulfasalazine, mesalamine, balsalazide), corticosteroids, azathioprine, 6-mercaptopurine? (Provide supporting documentation)

    a. If yes, continue to #4
    b. If no, continue to #3

3. Does the member have a contraindication or history of intolerance to ALL of the following oral agents: 6-mercaptopurine, azathioprine, corticosteroids, methotrexate, mesalamine, sulfasalazine? (Provide supporting documentation)

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

4. Is the request for Hadlima or adalimumab-fkjp?

    a. If yes, continue to #8
    b. If no, continue to #5

5. Does the member have documentation of an inadequate response, intolerance, or contraindication to Hadlima or adalimumab-fkjp? (Provide supporting documentation)

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

6. Is the request for Stelara?

    a. If yes, continue to #8
    b. If no, continue to #7

7. Does the member have documentation of an inadequate response, intolerance, or contraindication to Stelara? (Provide supporting documentation)

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

8. Is the requested treatment dose appropriate?

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

9. Is the medication being prescribed by, or in consultation with, a gastroenterologist?

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

<u>Plaque Psoriasis (Ps)</u>

1. Does the member currently have moderate to severe chronic plaque psoriasis defined as having functional impairment (e.g. inability to use hands or feet or activities of daily living, or significant facial involvement preventing normal social interaction) AND one or more of the following: 1. At least 10% body

surface area involvement AND/OR 2. Hand, foot, face or mucous membrane involvement? (Provide supporting documentation)

   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 with **TWO** of the following systemic therapies: methotrexate, cyclosporine, acitretin, or phototherapy? (Provide supporting documentation)

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

3. Is the request for Hadlima, adalimumab-fkjp, or Enbrel (etanercept)?

   a. If yes, continue to #9
   b. If no, continue to #4

4. Does the member have documentation of an inadequate response, intolerance, or contraindication to Hadlima, adalimumab-fkjp, or Enbrel (etanercept)? (Provide supporting documentation)

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

5. Is the request for Cimzia?

   a. If yes, continue to #9
   b. If no, continue to #6

6. Does the member have documentation of an inadequate response, intolerance, or contraindication to Cimzia? (Provide supporting documentation)

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

7. Is the request for Stelara (ustekinumab)?

   a. If yes, continue to #9
   b. If no, continue to #8

8. Did the member have an inadequate response, intolerance, or contraindication to Stelara (ustekinumab)? (Provide supporting documentation)

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

OHSUHealth Services

9. Is the requested treatment dose appropriate?
    a. If yes, continue to #10
    b. If no, clinical review required
10. Is the treatment being prescribed by or in consultation with a dermatologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Hidradenitis Suppurativa

1. Does the member have Hurley stage II or 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 an inadequate response to a 90-day trial of oral antibiotics? (Provide documentation of oral antibiotic regimen trialed and inadequate response)
    a. If yes, continue to #4
    b. If no, continue to #3
3. Does the member have a contraindication or history of intolerance to oral antibiotics? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the request for Hadlima or adalimumab-fkjp?
    a. If yes, continue to #6
    b. If no, continue to #5
5. Does the member have documentation of an inadequate response, intolerance, or contraindication to Hadlima or adalimumab-fkjp? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no clinical review required
6. Is the requested treatment dose appropriate?
    a. If yes, continue to #5
    b. If no, clinical review required
7. Is the treatment being prescribed by, or in consultation with, a dermatologist?

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

Uveitis

1. Does the member currently have non-infectious intermediate uveitis, posterior uveitis, or panuveitis? (Provide supporting documentation)

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

2. Did the member have an inadequate response to TWO separate 12 week trials with two of the following oral agents: cyclosporine, tacrolimus, azathioprine, methotrexate, mycophenolate? (Provide supporting documentation)

    a. If yes, continue to #4
    b. If no, continue to #3

3. Does the member have a contraindication or history of intolerance to ALL of the following oral agents: cyclosporine, tacrolimus, azathioprine, methotrexate, mycophenolate? (Provide supporting documentation)

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

4. Is the requested treatment dose appropriate?

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

5. Is the medication being prescribed by or in consultation with an ophthalmologist or rheumatologist?

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

Atopic Dermatitis

1. Is the requested drug Rinvoq?

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

2. Does the member currently have severe inflammatory skin disease defined as having functional impairment (e.g. inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction)? (Provide supporting documentation)

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

3. Does the member have one or more of the following: A) At least 10% body surface area involved AND/OR B) Hand, face, foot or mucous membrane involvement? (Provide supporting documentation)

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

4. Does the member have a documented trial with an insufficient response, intolerance or contraindication to a minimum 4-week trial with at least one of the following? (Provide supporting documentation)

    - Moderate to high potency topical steroids AND a topical non-steroidal agent (i.e. tacrolimus)
    - An oral immunomodulator (i.e. cyclosporine, methotrexate, or oral corticosteroids)

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

5. Does the member have a previous trial with inadequate response, intolerance, or contraindication to Dupixent? (Provide supporting documentation)

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

6. Is the requested treatment dose appropriate?

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

7. Is the requested drug being prescribed by, or in consultation with, a dermatologist, allergist, or immunologist?

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

Other Indications

1. Is the requested use supported by major compendia? (Examples: Micromedex, Clinical Pharmacology, etc.) (Provide supporting documentation)

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

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

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

3. Is the requested treatment dose appropriate?

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

4. Will the requested medication be used with other biologic therapy? (Examples: Enbrel, Actemra, Cimzia, Simponi, Orencia, Taltz, Cosentyx, Otezla, etc.)

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

5. Is the treatment being prescribed by or in consultation with an appropriate specialist?

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

Reauthorization Criteria

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

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

2. Were updated chart notes (dated within 1 year) provided with documentation of significant clinical response to therapy? (Provide supporting documentation)

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

3. Is the requested treatment dose appropriate?

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

4. Will the requested medication be used with other biologic therapy? (Examples: Enbrel, Actemra, Cimzia, Simponi, Orencia, Taltz, Cosentyx, Otezla, etc.)
    a. If yes, clinical review required
    b. If no, continue to #5
5. Is the treatment being prescribed by or in consultation with an appropriate specialist?
    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

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

References:

1. Actemra (tocilizumab) [Prescribing Information]. South San Francisco, CA: Genentech, Inc. June 2019.
2. Cimzia (certolizumab pegol) [Prescribing Information]. Smyrna, GA: UCB, Inc. September 2019.
3. Cosentyx (secukinumab) [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. October 2023.
4. Enbrel (etanercept) [Prescribing Information]. Thousand Oaks, CA: Immunex Corporation. June 2019.
5. Hadlima (adalimumab) [Prescribing Information]. Jersey City, NJ: Organon LLC. July 2023.
6. Hulio (adalimumab-fkjp) [Prescribing Information]. Basking Ridge, NJ: Mylan Specialty L.P. August 2023.
7. Otezla (apremilast) [Prescribing Information]. Summit, NJ: Celgene. July 2019.
8. Soriatane (acitretin capsule) [Prescribing Information]. Austria: Stiefel Laboratories, Inc. October 2018.
9. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; March 2024.
10. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; November 2023.
11. Mease PJ, Goffe BS, Metz J, et al. Etanercept in the treatment of Psoriatic Arthritis and Psoriasis: a Randomised Trial. The Lancet. 2000;356:9277:385-390. Available at: https://www.sciencedirect.com/science/article/pii/S0140673600025307?via%3Dihub. Accessed March 23, 2018.

Last Reviewed: 11/26/19, 11/10/21, 3/9/22, 9/14/22, 11/8/23, 3/13/24, 5/8/24
Effective Date: 1/1/20, 1/1/22, 5/1/22, 11/15/22, 1/1/24, 6/15/24

12. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) Recommendations for the Management of Psoriatic arthritis with Pharmacological Therapies: 2015 update. Annals of the Rheumatic Diseases. 2016;75:499-510. Available at: http://ard.bmj.com/content/75/3/499. Accessed March 23, 2018.
13. Gossec L, Baraliakos X, Kerschbaumer A, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. Annals of the Rheumatic Diseases 2020;79:700-712. Available at: https://ard.bmj.com/content/79/6/700.1 . Accessed October 24, 2023.
14. Oregon Health Plan. Prioritized List of Health Services. January 1, 2022 (Revised). Available at: http://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Prioritized-List.aspx. Accessed August 30, 2022.
15. Smith CH, Jabbar-Lopez, Yiu ZZ, et al. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017. Br J Dermatol. 2017;177(3):628-636. Available at: https://www.ncbi.nlm.nih.gov/pubmed/28513835. Accessed March 23, 2018.
16. Otezla. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed March 23, 2018.
17. Rau R. Adalimumab (a fully human anti-tumour necrosis factor α monoclonal antibody) in the treatment of active rheumatoid arthritis: the initial results of five trials. Annals of the Rheumatic Diseases 2002;61:ii70-ii73. Available at: http://ard.bmj.com/content/61/suppl_2/ii70. Accessed March 7, 2018.
18. Aletaha D, Neogi T, Silman AJ, et al. 2010 Rheumatoid Arthritis Classification Criteria. Arthritis & Rheumatism. 2010;62(9):2569-2581. Available at: https://www.rheumatology.org/Portals/0/Files/2010_revised_criteria_classification_ra.pdf. Accessed March 7, 2018
19. Singh JA, Saag KG, Bridges L Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2016;68(1):1-26. Available at: https://www.rheumatology.org/Portals/0/Files/ACR%202015%20RA%20Guideline.pdf. Accessed March 7, 2018.
20. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. Available at: https://assets.contentstack.io/v3/assets/bltee37abb6b278ab2c/blt9e44ccb701e1918c/63360f6775c0be225b8d943a/ra-guideline-2021.pdf. Accessed October 23, 2023.

21. Lovell DJ, Ruperto N, Goodman S, et al. Adalimumab with or without Methotrexate in Juvenile Rheumatoid Arthritis. N Engl J Med. 2008;359:810-820. Available at: http://www.nejm.org/doi/full/10.1056/NEJMoa0706290. Accessed March 7, 2018.

22. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children with Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. Arthritis & Rheumatism. 2013;65(10):2499-2512. Available at: https://www.rheumatology.org/Portals/0/Files/2013%20Update%20of%20the%202011%20ACR%20Recommendations%20for%20the%20Treatment%20of%20Juvenile%20Idiopathic%20Arthritis.pdf. Accessed March 9, 2018.

23. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Care Res (Hoboken). 2019;71(6):717-734. Available at: https://assets.contentstack.io/v3/assets/bltee37abb6b278ab2c/bltea21f1baaea35cf3/63321ee13df1404a8501fc67/jia-guideline-2019.pdf. Accessed October 23, 2023.

24. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) Recommendations for the Management of Psoriatic arthritis with Pharmacological Therapies: 2015 update. Annals of the Rheumatic Diseases. 2016;75:499-510. Available at: http://ard.bmj.com/content/75/3/499. Accessed March 12, 2018.

25. Smolen JS, Landewe R, Bijlsma J, et al. EULAR Recommendations for the Management of Rheumatoid Arthritis with Synthetic and Biological Disease-Modifying Antirheumatic Drugs: 2016 update. Ann Rheum Dis. 2017;0:1-18. Available at: https://ard.bmj.com/content/annrheumdis/early/2017/03/17/annrheumdis-2016-210715.full.pdf. Accessed March 19, 2019.

26. Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Care Research (Hoboken). 2016;68(2):151-66. Available at: http://onlinelibrary.wiley.com/doi/10.1002/acr.22708/full. Accessed March 13, 2018.

27. van der Heijde D, Ramiro S, Landewé R, et al. 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. Annals of the Rheumatic Diseases 2017;76:978-991. Available at: http://ard.bmj.com/content/76/6/978. Accessed March 13, 2018.

28. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613. Available at: https://assets.contentstack.io/v3/assets/bltee37abb6b278ab2c/blt74558fbe6f37b611/6328a49019c64564c313f918/axial-spa-guideline-2019.pdf . Accessed October 23, 2023.

29. Terdiman JP, Gruss CB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute Guideline on the Use of Thiopurines, Methotrexate, and Anti-TNF-alpha Biologic Drugs for the Induction and Maintenance of Remission in Inflammatory Crohn's Disease. Gastroenterology. 2013;145:1459-63. Available at: http://www.gastrojournal.org/article/S0016-5085(13)01521-7/pdf. Accessed March 27, 2018.

30. Nguyen GC. Loftus EV Jr, Hirano I, et al. American Gastroenterological Association Institute Guideline on the Management of Crohn's Disease After Surgical Resection. Gastroenterology. 2017;152:271-5. Available at: http://www.gastrojournal.org/article/S0016-5085(16)35285-4/pdf. Accessed March 28, 2018.

31. Kornbluth A, Sachar DB, The Practice Parameters Committee of the American College of Gastroenterology. Erratum: Ulcerative Colitis Practice Guidelines in Adults: American College of Gastroenterology, Practice Parameters Committee. The American Journal of Gastroenterology. 2010;105:501-23. Available at: http://s3.gi.org/physicians/guidelines/UlcerativeColitis.pdf. Accessed March 28, 2018.

32. Harbord M, Eliakim R, Bettenworth D, et al. Third European Evidence-based Consensus on Diagnosis and Management of Ulcerative Colitis. Part 2: Current Management. Journal of Crohn's and Colitis. 2017;11(7):769-84. Available at: https://academic.oup.com/ecco-jcc/article/11/7/769/2962457. Accessed March 28, 2018.

33. Smith CH, Jabbar-Lopez, Yiu ZZ, et al. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017. Br J Dermatol. 2017;177(3):628-636. Available at: https://www.ncbi.nlm.nih.gov/pubmed/28513835. Accessed March 16, 2018.

34. Barry RJ, Nguyen QD, Lee RW, et al. Pharmacotherapy for Uveitis: Current Management and Emerging Therapy. Clinical Ophthalmology. 2014;8:1891-911. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4181632/. Accessed March 29, 2018.

35. Plaque Psoriasis – Drug Therapy Guideline. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed March 19, 2019.

36. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations:

Part I: Diagnosis, evaluation, and the use of complementary and procedural management. J Am Acad Dermatol. 2019;81(1):76-90.
37. Weston MD, Howe MD. Treatment of atopic dermatitis (eczema). Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed April 25, 2024.
38. Chu, Derek K., et al. "Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE–and Institute of Medicine–based recommendations." Annals of Allergy, Asthma & Immunology 132.3 (2024): 274-312.

Tobramycin
Prior Authorization Guidelines

Affected Medication(s)

- Tobramycin 300mg/5mL ampule

FDA Approved Indication(s)

- For the management of cystic fibrosis in adult and pediatric patients 6 years of age and older with *P. aeruginosa*. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV1 <25% or >75% predicted, or patients colonized with *Burkholderia cepcia*

Dosing

- 300 mg by oral inhalation twice a day in alternating periods of 28 days on and 28 days off

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request a renewal of a previously approved tobramycin prior authorization and provided indication is for the same as previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, clinical review required
4. 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 #5
    b. If no, clinical review required
5. Does the member have baseline FEV1 less than 25% or greater than 75% predicated? (Provide baseline FEV1 for review)
    a. If yes, clinical review required

Last Reviewed: 11/26/19, 7/14/21, 9/8/21, 9/14/22, 9/13/23
Effective Date: 2/1/20

b. If no, continue to #6

6. Does the member have *Burkholderia cepcia* colonization? (Provide supporting culture result)
    a. If yes, clinical review required
    b. If no, continue to #7
7. Is the treatment being initiated by a specialist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
    a. If yes, continue to #2
    b. If no, 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
    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. Tobi (tobramycin) solution [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals. October 2018.

Last Reviewed: 11/26/19, 7/14/21, 9/8/21, 9/14/22, 9/13/23
Effective Date: 2/1/20

OHSU Health Services

Topical Acne Agents
Prior Authorization Guidelines

Affected Medication(s)

- Tretinoin 0.025% cream
- Adapalene 0.1% gel
- Clindamycin 1% solution
- Benzoyl Peroxide 5% gel/cleanser
- Benzoyl Peroxide 10% gel/cleanser

FDA Approved Indication(s)

- Refer to specific product package insert

Dosing

- Refer to specific product package insert

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
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 clindamycin 1% solution or benzoyl peroxide gel/cleanser being requested?
    a. If yes, approve for 12 months
    b. If no, continue to #4
4. Does the member have a previous trial with inadequate response, intolerance, or contraindication to benzoyl peroxide and clindamycin solution? (Provide supporting documentation)
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and

Last Reviewed: 7/14/21, 11/9/22, 1/11/23, 1/10/24
Effective Date: 9/1/21, 1/1/23, 3/15/23, 2/15/24

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. Retin-A (tretinoin) [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC. September 2019.
2. Clindamycin. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed June 14, 2021.
3. Differin (adapalene) [Prescribing Information]. Fort Worth, TX: Galderma Laboratories, L.P. February 2018.
4. Benzoyl peroxide. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed November 30, 2022.

Last Reviewed: 7/14/21, 11/9/22, 1/11/23, 1/10/24
Effective Date: 9/1/21, 1/1/23, 3/15/23, 2/15/24

Topical Moisturizers
Prior Authorization Guidelines

Affected Medication(s)

- Formulary topical emollients, protectants, and moisturizers

FDA Approved Indication(s)

- Refer to corresponding package insert or major compendia

Dosing

- Refer to corresponding package insert

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member currently have severe skin disease defined as having functional impairment (e.g. inability to use hands or feet or actives of daily living, or significant facial involvement preventing normal social interaction) AND one or more of the following? (Provide supporting documentation)
    - At least 10% of body surface area involved
    - Hand, foot, face, or mucous membrane involvement

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

Note:

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

References:

1. Oregon Health Plan. Prioritized List of Health Services. January 1, 2024. Available at: https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx. Accessed February, 7 2024.

Last Reviewed: 3/13/24
Effective Date: 5/1/24

OHSU Health Services

Trikafta (elexacaftor/tezacaftor/ivacaftor)
Prior Authorization Guidelines

Affected Medication(s)

- Trikafta oral tablet
- Trikafta oral granules

FDA Approved Indication(s)

- Treatment of patients with cystic fibrosis (CF) ages 2 years and older who have at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene

Dosing

- Refer to package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Trikafta (elexacaftor/tezacaftor/ivacaftor) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is Trikafta (elexacaftor/tezacaftor/ivacaftor) being requested for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the patient have a documentation of at least one *F508del* mutation in the CFTR gene confirmed by a FDA-cleared CF mutation test? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the patient at least 2 years of age?
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 3/11/20, 5/12/21, 7/14/21, 7/13/22, 7/12/23
Effective Date: 5/1/20, 9/1/21, 8/15/23

OHSUHealth Services

6. Does the patient have documentation of baseline FEV1, ALT, AST, and bilirubin? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is Trikafta (elexacaftor/tezacaftor/ivacaftor) being prescribed by, or in consult with, a pulmonologist or a specialist experienced in treating cystic fibrosis patient?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

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

Note:

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

Last Reviewed: 3/11/20, 5/12/21, 7/14/21, 7/13/22, 7/12/23
Effective Date: 5/1/20, 9/1/21, 8/15/23

References:

1. Trikafta™ (elexacaftor/tezacaftor, and ivacaftor) [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc. April 2023.
2. Trikafta™. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com.
3. Simon, MD. Cystic fibrosis: Overview of the treatment of lung disease. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com.

Last Reviewed: 3/11/20, 5/12/21, 7/14/21, 7/13/22, 7/12/23
Effective Date: 5/1/20, 9/1/21, 8/15/23

OHSUHealth Services

Truqap (capivasertib)
Prior Authorization Guidelines

Affected Medication(s)

- Truqap oral tablet

FDA Approved Indication(s)

- Treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy

Dosing

- 400 mg orally twice daily, with or without food, for 4 days followed by 3 days off until disease progression or unacceptable toxicity

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of therapy with same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the medication being requested for an FDA approved indication or supported by NCCN recommendation with an evidence level of 2A or higher? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, continue to #4
4. Is the medication being requested for an indication supported by the National Comprehensive Cancer Network (NCCN) recommendation with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
    a. If yes, continue to #5
    b. If no, clinical review required

Last Reviewed: 1/10/24
Effective Date: 2/15/24

OHSUHealth Services

5. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have an identified alteration in PIK3CA only? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, continue to #8
7. Does the member have a previous trial with inadequate response, intolerance or contraindication to Piqray (alpelisib)? (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, an oncologist?
    a. If yes, approve for 4 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by NCCN recommendation with an evidence level of 2A or higher? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Example include reduction in tumor size, objective response, delay in progression, partial response, etc.) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with an oncologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and

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

References:

1. Truqap (capivasertib) tablets, [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2023.
2. Drugs@FDA: FDA Approved Drug Products. 2023. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 11 Dec. 2023].
3. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Breast Cancer. Version 5.2023 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed December 12, 2023.
4. Turner NC, Oliveira M, Howell SJ, et al. Capivasertib in Hormone Receptor-Positive Advanced Breast Cancer. N Engl J Med. 2023;388(22):2058-2070.

OHSU Health Services

Vigabatrin
Prior Authorization Guidelines

Affected Medication(s)

- Vigabatrin oral packet
- Vigabatrin oral tablet

FDA Approved Indication(s)

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

Dosing

Refractory Complex Partial Seizures:

- Pediatric (≥2 years of age to adolescents ≤16 years):
  - 10 to 15kg: 175mg twice daily initially, maintenance dose 525mg twice daily
  - >15 to 20kg: 225mg twice daily initially, maintenance dose 650mg twice daily
  - >20 to 25kg: 250mg twice daily initially, maintenance dose 750mg twice daily
  - >25kg to 60kg: 250mg twice daily initially, maintenance dose 1000mg twice daily
- Adolescents ≤16 years and weighing >60 kg or Adolescents ≥17 years:
  - 500 mg twice daily initially, maintenance 1,500 mg twice daily

Infantile Spasms: maximum daily dose of 150 mg/kg

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the request for renewal of a previously approved vigabatrin prior authorization with the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3
3. What is the diagnosis that vigabatrin is being requested for?
   a. Refractory complex partial seizures, continue to corresponding criteria

Last Reviewed: 7/17/18, 1/22/19, 3/11/20, 5/12/21, 7/13/22, 7/12/23
Effective Date: 8/15/18, 3/1/19, 1/1/20, 7/1/21

b. Infantile spasm, continue to corresponding criteria
c. Other indication, clinical review required

Refractory Complex Partial Seizures

1. Did the member have inadequate seizure control with at least TWO of the following anticonvulsants in the past: felbamate, lamotrigine, levetiracetam, oxcarbazepine, gabapentin, topiramate, tiagabine, zonisamide, lacosamide? (Provide supporting documentation)

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

2. Does documentation indicate potential benefits from treatment outweigh the risk of vision loss provided?

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

3. Is documentation of a baseline vision assessment provided?

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

4. Is the medication being prescribed by or in consultation with a neurologist who is certified with the Vigabatrin REMS program?

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

Infantile Spasm

1. Does the documentation indicate potential benefits from treatment outweigh the risk of vision loss provided? (Provide supporting documentation)

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

2. Is the medication being prescribed by or in consultation with a neurologist who is certified with the SHARE program?

    a. If yes, approve for 2 months
    b. If no, clinical review required

OHSU Health Services

Reauthorization Criteria

1. Is Vigabatrin being prescribed for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within 1 year) with documentation of routine vision assessment and significant clinical response to prior therapy received? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with a neurologist who is certified with the Vigabatrin REMS program?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. Sabril (vigabatrin) [Prescribing Information]. Deerfield, IL: Lundbeck. October 2021.
2. Sabril. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed June 25, 2018.
3. Glaze, MD. Management and prognosis of infantile spasms. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed June 25, 2018.
4. National Institute for Health and Care Excellence (NICE): Epilepsies: diagnosis and management. National Institute for Health and Care Excellence (NICE). London, United Kingdom. Available at: https://www.nice.org.uk/guidance/cg137/resources/epilepsies-diagnosis-and-management-35109515407813. Accessed June 27, 2018.

Last Reviewed: 7/17/18, 1/22/19, 3/11/20, 5/12/21, 7/13/22, 7/12/23
Effective Date: 8/15/18, 3/1/19, 1/1/20, 7/1/21, 9/1/22

OHSU Health Services

Vijoice® (alpelisib)
Prior Authorization Guidelines

Affected Medication(s)

- Vijoice (alpelisib) oral tablet

FDA Approved Indication(s)

- Treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS)

Dosing

- Adult: 250mg once daily until disease progression or unacceptable toxicity
- Pediatric: Initial dose of 50mg once daily, with a potential to increase to 125mg once daily after 24 weeks in patients 6-17 years old

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Vijoice (alpelisib) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is Vijoice (alpelisib) being requested for an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member at least 2 years of age or older? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have documentation of PIK3CA-Related Overgrowth Spectrum (PROS) with confirmed PIK3CA gene mutation? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 7/13/22, 7/12/23
Effective Date: 9/15/22

6. Does the member have severe clinical manifestations resulting from a lesion associated with PROS and is the lesion both inoperable and causing functional impairment? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Has the member previously trialed sirolimus for at least 6 months with inadequate response or does the member have a documented intolerance or contraindication to sirolimus? (Note: inadequate response defined as continuing to have severe clinical manifestations resulting from the lesion with the lesion being inoperable and causing functional impairment despite current treatment)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Is Vijoice (alpelisib) being prescribed by, or in consult with, a specialist with experience in the treatment of PROS?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of significant clinical response to therapy defined by the following? (Provide supporting documentation)
        - ≥20 % reduction from baseline in the sum of measurable target lesion volume confirmed by imaging
        - Absence of a ≥20% increase from baseline in any target lesion, progression of non-target lesions, or appearance of new lesion
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is Vijoice (alpelisib) being prescribed by, or in consult with, a specialist with experience in the treatment of PROS?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. VIJOICE® (alpelisib) tablets, [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; 2022.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 26 May. 2022].
3. Canaud, G., et al. "LBA23 EPIK-P1: Retrospective chart review study of patients (pts) with PIK3CA-related Overgrowth Spectrum (PROS) who have received alpelisib (ALP) as part of a compassionate use programme." Annals of Oncology 32 (2021): S1297.
4. Douzou S, Rawson M, Faivre L, et al. A standard of care for individuals with PIK3CA related disorders: an international expert consensus statement. Clinical Genetics. 2022; 101:32-47.
5. Canuad G, Hammill AM, Adams D, Vikkula M, and Keppler-Noreuil KM. A review of mechanisms of disease across PIK3CA-related disorders with vascular manifestations. Orphanet J Rare Dis. 2021;16:306.
6. Parker, Victoria ER, et al. "Safety and efficacy of low-dose sirolimus in the PIK3CA-related overgrowth spectrum." Genetics in Medicine 21.5 (2019): 1189-1198.

Last Reviewed: 7/13/22, 7/12/23
Effective Date: 9/15/22

OHSU Health Services

Voriconazole
Prior Authorization Guidelines

Affected Medication(s)

- Voriconazole oral tablet
- Voriconazole oral suspension

FDA Approved Indication(s)

- For the treatment of the following fungal infections:
  - Invasive aspergillosis in patients 2 years of age and older
  - Candidemia in nonneutropenic patients and the following *candida* infections: disseminated infections in skin and infections in abdomen, kidney, bladder wall, and wounds in patients 2 years of age and older
  - Esophageal candidiasis in patients 2 years of age and older
  - Serious fungal infections caused by *Scedosporium apiospermum* and *Fusarium spp.* in patients intolerant of, or refractory to, other therapy in patients 2 years of age and older

Dosing

- Refer to package insert for indication specific treatment dose and treatment duration

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)

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

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

   a. If yes, continue to #4
   b. If no, continue to #3

3. Is the request for use to treat a major compendium supported indication? (Provide documentation of diagnosis)

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

4. Is the request for the treatment of esophageal candidiasis?

   a. If yes, continue to #5
   b. If no, continue to #7

Last Reviewed: 11/26/19, 7/14/21, 9/14/22, 9/13/23
Effective Date: 1/15/20

OHSUHealth Services

5. Does the member have inadequate response to fluconazole therapy?
    a. If yes, continue to #7
    b. If no, continue to #6
6. Does the member have a contraindication to fluconazole therapy?
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the treatment being initiated by an infectious disease specialist?
    a. If yes, approve for compendia supported treatment duration up to 6 months
    b. If no, clinical review required

Note:

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

References:

1. Vfend [Prescribing Information]. New York, NY: Roerig, Division of Pfizer Inc. March 2022.
2. Vfend. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed November 25, 2019.
3. Patterson TF, Thompson GR, Denning DW, et al. Practice guidelines for the diagnosis and management of aspergillosis: 2016 update by the Infectious Diseases Society of America. Clin Infect Dis. 2016;63(4):e1-e60.
4. Pappas PG, Kauffman CA, Andes DR, et al. Clinical practice guidelines for the management of candidiasis: 2016 update by the Infectious Diseases Society of America. Clin Infect Dis. 2016;62(4):e1-50.

Last Reviewed: 11/26/19, 7/14/21, 9/14/22, 9/13/23
Effective Date: 1/15/20

OHSU Health Services

Vowst® (fecal microbiota spores, live-brpk)
Prior Authorization Guidelines

Affected Medication(s)

- Vowst (fecal microbiota spores, live-brpk) oral capsules

FDA Approved Indication(s)

- To prevent the recurrence of Clostridiodides difficile infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI (rCDI)

Dosing

- 4 capsules orally once daily for 3 consecutive days

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is Vowst (fecal microbiota spores, live-brpk) being requested for an FDA approved indication? (Provide supporting documentation)
    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. Has the member had a previous treatment course of Vowst for recurrent CDI?
    a. If yes, clinical review required
    b. If no, continue to #5
5. Has the member had 3 or more episodes of CDI within the past 12 months that were treated with oral vancomycin and/or Dificid (fidaxomicin)? (CDI defined as diarrhea for 2+ days and a confirmatory C. difficile toxin assay) (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 7/12/23
Effective Date: 8/15/23

OHSUHealth Services

6. Does the member have a contraindication, intolerance, or trial with ineffective response to Rebyota (fecal microbiota spores, rectal suspension) and Zinplava (bezlotoxumab)? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Will the member have completed antibiotic treatment for recurrent CDI within 2 to 4 days prior to starting Vowst with resolution of active CDI? (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 gastroenterologist or infectious disease specialist?
    a. If yes, approve for 7 days
    b. If no, clinical review required

Note:

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

References:

1. VOWST (fecal microbiota spores, live-brpk) capsules, [package insert]. Cambridge, MA: Seres Therapeutics, Inc; 2023
2. Drugs@FDA: FDA Approved Drug Products. 2023. https://www.fda.gov/vaccines-blood-biologics/vowst [online] Available at: https://www.fda.gov/vaccines-blood-biologics/vowst [Accessed 14 Jun. 2023].
3. Kelly CR, Fischer M, Allegretti JR, et al. ACG Clinical Guidelines: Prevention, Diagnosis, and Treatment of Clostridioides difficile Infections [published correction appears in Am J Gastroenterol. 2022 Feb 1;117(2):358]. Am J Gastroenterol. 2021;116(6):1124-1147.
4. McDonald LC, Gerding DN, Johnson S, et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis. 2018;66(7):e1-e48.
5. Johnson S, Lavergne V, Skinner AM, et al. Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of Clostridioides difficile Infection in Adults. Clin Infect Dis. 2021;73(5):e1029-e1044.

Last Reviewed: 7/12/23
Effective Date: 8/15/23

OHSUHealth Services

Voxzogo (vosoritide)
Prior Authorization Guidelines

Affected Medication(s)

- Voxzogo (vosoritide subcutaneous solution)

FDA Approved Indication(s)

- To increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses

Dosing

- Refer to package insert for weight based dosing

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the medication being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member age 5 to 17 years old?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a diagnosis of achondroplasia confirmed by molecular testing of FGFR3 gene? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the member's baseline height and growth velocity provided and is the member's growth velocity at least 1.5cm/yr? (Provide supporting documentation)

Last Reviewed: 3/9/22, 5/10/23, 5/8/24
Effective Date: 5/1/22, 6/15/24

OHSUHealth Services

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

7. Is there documentation of open epiphyses? (Provide supporting documentation)

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

8. Has the member previously had or planning to have limb lengthening surgery? (Provide supporting documentation)

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

9. Is the medication being prescribed by, or in consultation with, a pediatric endocrinologist, orthopedist, or other prescriber specialized in the treatment of achondroplasia?

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

Reauthorization Criteria

1. Is Voxzogo (vosoritide) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)

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

2. Is there documentation of continued open epiphyses? (Provide supporting documentation)

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

3. Has there been an increase in growth velocity compared to baseline and does the member's growth velocity remain greater than 1.5cm/yr? (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 pediatric endocrinologist, orthopedist, or other prescriber specialized in the treatment of achondroplasia?

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

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and

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

References:

1. VOXZOGO (vosoritide) for injection, [package insert]. Novato, CA: BioMarin Pharmaceutical, Inc; 2021.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 09 Dec. 2021].
3. Pauli, Richard M. "Achondroplasia: a comprehensive clinical review." Orphanet Journal of Rare Diseases 14.1 (2019): 1-49.
4. Ornitz, David M., and Laurence Legeai-Mallet. "Achondroplasia: Development, pathogenesis, and therapy." Developmental dynamics 246.4 (2017): 291-309.

Last Reviewed: 3/9/22, 5/10/23, 5/8/24
Effective Date: 5/1/22, 6/14/24

OHSU Health Services

Vyndamax (tafamidis), Vyndaqel (tafamidis)
Prior Authorization Guidelines

Affected Medication(s)

- Vyndaqel: 80mg (four 20-mg capsules) orally
- Vyndamax: 61mg (one capsule) orally

FDA Approved Indication(s)

- Treatment of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization

Dosing

- Vyndaqel: 80mg (four 20-mg capsules) orally one time daily
- Vyndamax: 61mg (one capsule) orally one time daily
- Vyndamax and Vyndaqel are not substitutable on a per mg basis

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request a renewal of a previously approved Vyndamax or Vyndaqel prior authorization for the same indication as the previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member 18 years of age or older?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have documentation confirming the presence of a transthyretin (TTR) mutation or TTR precursor protein? (Provide supporting documentation)
    a. If yes, continue to #6

Last Reviewed: 11/26/19, 7/14/21, 7/13/22, 7/12/23
Effective Date: 1/1/20, 9/1/21

b. If no, clinical review required

6. Does the member have documentation of a biopsy that was found to be positive for amyloid deposits? (Provide documentation of biopsy)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Does the member have cardiomyopathy caused by transthyretin-mediated amyloidosis? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Does the member have NYHA Class III or IV heart failure?
    a. If yes, clinical review required
    b. If no, continue to #9
9. Has the member had a liver transplant?
    a. If yes, clinical review required
    b. If no, continue to #10
10. Is the requested medication being prescribed by, or in consultation with, a cardiologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia? (Provide 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 or stabilization in cardiomyopathy symptoms? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the requested medication being prescribed by, or in consultation with, a cardiologist?
    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. VYNDAQEL (tafamidis meglumine) and VYNDAMAX (tafamidis) oral capsules [package insert]. New York, NY: Pfizer Labs; 2019.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 30 July. 2019].
3. DailyMed - VYNDAQEL (tafamidis meglumine) and VYNDAMAX (tafamidis) oral capsules capsule. 2019. U.S. National Library of Medicine. National Institutes of Health. [online]
4. Maurer MS, Schwartz JH, Gundapaneni B, Elliott PM, Merlini G, Waddington-Cruz M, Kristen AV, Grogan M, Witteles R, Damy T, Drachman BM, Shah SJ, Hanna M, Judge DP, Barsdorf AI, Huber P, Patterson TA, Riley S, Schumacher J, Stewart M, Sultan MB, Rapezzi C; ATTR-ACT Study Investigators. Tafamidis Treatment for Patients with Transthyretin Amyloid Cardiomyopathy. N Engl J Med. 2018 Sep 13; 379(11):1007-1016. doi: 10.1056/NEJMoa1805689. Epub 2018 Aug 27.
5. Ando, Yukio, et al. "Guideline of transthyretin-related hereditary amyloidosis for clinicians." Orphanet journal of rare diseases 8.1 (2013): 1-18.

Last Reviewed: 11/26/19, 7/14/21, 7/13/22, 7/12/23
Effective Date: 1/1/20, 9/1/21

OHSUHealth Services

Wake Promoting Agents
Prior Authorization Guidelines

Affected Medication(s)

- Xyrem oral solution
- Sodium oxybate oral solution
- Xywav oral solution
- Lumryz ER oral suspension

FDA Approved Indication(s)

- Excessive somnolence: Narcolepsy
- Cataplexy in narcolepsy
- Treatment of idiopathic hypersomnia in adults – Xywav only

Dosing

- Refer to package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of sodium oxybate (Xyrem), Lumryz, or Xywav therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member 7 years of age or older?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the treatment prescribed by or in consultation with a sleep specialist (e.g. neurology, pulmonology)?
    a. If yes, continue to #6

Last Reviewed: 1/13/21, 9/8/21, 9/14/22, 5/10/23, 7/12/23
Effective Date: 3/1/21, 11/1/21, 6/15/23, 8/15/23

b. If no, clinical review required

6. Has this member's diagnosis been confirmed by overnight polysomnogram? Note: narcolepsy may be confirmed by low levels of orexin or hypocretin within cerebrospinal fluid (<110pg/mL or less than one third of the normative value of the lab)

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

7. What is the predominant symptom causing this request?

    a. Excessive somnolence, continue to #8
    b. Cataplexy, continue to #10
    c. Other, clinical review required

8. Has this member had a documented trial and failure, intolerance, or contraindication to at least one medication in each of the following groups? (Note: Requests for idiopathic hypersomnia do not require trial of solriamfetol)

    - Group 1: Modafinil or Armodafinil
    - Group 2: Stimulants (e.g. Methylphenidate, dextroamphetamine/amphetamine, etc.)
    - Group 3: Solriamfetol (Sunosi)

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

9. Have all other causes of excessive daytime sleepiness been ruled out or treated (e.g. obstructive sleep apnea, restless leg syndrome, periodic limb movements, substance abuse, etc)?

    a. If yes, continue to #11
    b. If no, clinical review required

10. Has this member had a documented trial and failure, intolerance, or contraindication to the use of a SSRI or SNRI (e.g. fluoxetine or venlafaxine)?

    a. If yes, continue to #11
    b. If no, clinical review required

11. Is the requested medication sodium oxybate?

    a. If yes, approve for 3 months
    b. If no, continue to #12

OHSUHealth Services

12. Has this member had a documented trial and failure, intolerance, or contraindication to sodium oxybate OR is the requested drug being used for management of idiopathic hypersomnia? (Provide supporting documentation)

    a. If yes, continue to #13
    b. If no, clinical review required

13. Does this patient have a clinically significant comorbidity requiring a low dietary sodium intake (e.g. congestive heart failure, uncontrolled hypertension)?

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

Reauthorization Criteria

1. Were updated chart notes provided with documentation of significant clinical response to therapy (e.g. reduction in cataplexy events or reduction in Epworth Sleepiness Scale [ESS])?

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

Note:

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

References:

1. Morgenthaler TI, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. Sleep. 2007;30(12): 1705-1711.
2. Billiard M, Bassetti C, Dauvilliers Y, et al. EFNS guidelines on management of narcolepsy. Eur J Neurol. 2006;13(10):1035-1048.
3. Barateau L, Lopez R, Dauvilliers Y. Treatment options for narcolepsy. CNS Drugs. 2016;30:369-379.
4. Barateau L, Dauvilliers Y. Recent advances in treatment for narcolepsy. Ther Adv Neurol Disord. 2019;12:1-12.
5. Thorpy M, Bogan R. Update on the pharmacologic management of narcolepsy: mechanisms of action and clinical implications. Sleep Medicine. 2020;68:97-109.

Last Reviewed: 1/13/21, 9/8/21, 9/14/22, 5/10/23, 7/12/23
Effective Date: 3/1/21, 11/1/21, 6/15/23, 8/15/23

6. Bogan RK, Thorpy MJ, Dauvilliers Y, et al. Efficacy and safety of calcium, magnesium, potassium and sodium oxybates (lower-sodium oxybate [LXB]; JZP-258) in a placebo-controlled, double-blind, randomized withdrawal study in adults with narcolepsu with cataplexy. SleepJ. 2020:1-13.
7. Xyrem (sodium oxybate) [Prescribing Information]. Palo Alto, CA. Jazz Pharmaceuticals, Inc. October 2022.
8. Xywav (calcium, magnesium, potassium and sodium oxybate) [Prescribing Information]. Palo Alto, CA. Jazz Pharmaceuticals Inc. March 2022.
9. Lumryz (sodium oxybate) [Prescribing Information]. Chesterfield, MO. Avadel Pharmaceuticals, LLC. May 2023.

OHSUHealth Services

Wakix® (pitolisant)
Prior Authorization Guidelines

Affected Medication(s)

- Wakix 4.45 mg and 17.8 mg oral tablets

FDA Approved Indication(s)

- Excessive somnolence: Narcolepsy
- Cataplexy in narcolepsy

Dosing

- 8.9 mg – 35.6 mg once daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of Wakix (pitolisant) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    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 the treatment prescribed by or in consultation with a sleep specialist (e.g. neurology, pulmonology)?
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 1/13/21, 1/12/22, 1/11/23, 1/10/24
Effective Date: 3/1/21, 2/15/24

OHSUHealth Services

6. Has this member's diagnosis been confirmed by overnight polysomnogram? Note: narcolepsy may be confirmed by low levels of orexin or hypocretin within cerebrospinal fluid (<110 pg/mL or less than one third of the normative value of the lab)

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

7. What is the predominant symptom causing this request?

    a. Excessive somnolence, continue to question #8
    b. Cataplexy, continue to question #10
    c. Other, clinical review required

8. Has this member had a documented trial and failure, intolerance or contraindication to at least one medication in each of the following groups?

    - Group 1: modafinil or armodafinil
    - Group 2: Stimulants (e.g. methylphenidate, dextroamphetamine/amphetamine, etc.)
    - Group 3: Sunosi (solriamfetol)

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

9. Have all other causes of excessive daytime sleepiness been ruled out or treated (e.g. obstructive sleep apnea, restless leg syndrome, periodic limb movements, substance abuse, etc).

    a. If yes, continue to #11
    b. If no, clinical review required

10. Has this member had a documented trial and failure, intolerance or contraindication to the use of a SSRI or SNRI (e.g. fluoxetine or venlafaxine)?

    a. If yes, continue to #11
    b. If no, clinical review required

11. Has this member had a documented trial and failure, intolerance, or contraindication to sodium oxybate? (Provide supporting documentation)

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

Reauthorization Criteria

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

Last Reviewed: 1/13/21, 1/12/22, 1/11/23, 1/10/24
Effective Date: 3/1/21, 2/15/24

OHSUHealth Services

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

2. Were updated chart notes provided with documentation of significant clinical response to therapy (e.g. reduction in cataplexy events or reduction in Epworth Sleepiness Scale [ESS])?

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

Note:

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

References:

1. Morgenthaler TI, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. Sleep. 2007;30(12): 1705-1711.
2. Billiard M, Bassetti C, Dauvilliers Y, et al. EFNS guidelines on management of narcolepsy. Eur J Neurol. 2006;13(10):1035-1048.
3. Barateau L, Lopez R, Dauvilliers Y. Treatment options for narcolepsy. CNS Drugs. 2016;30:369-379.
4. Barateau L, Dauvilliers Y. Recent advances in treatment for narcolepsy. Ther Adv Neurol Disord. 2019;12:1-12.
5. Thorpy M, Bogan R. Update on the pharmacologic management of narcolepsy: mechanisms of action and clinical implications. Sleep Medicine. 2020;68:97-109.
6. Dauvilliers Y, Bassetti C, Lammars GJ, et al. Pitolisant versus placebo or modafinil in patients with narcolepsy: a double-blind, randomised trial. Lancet Neurol. 2013; 12:1068-1075.
7. Dauvilliers Y, Arnulf I, Szakacs Z, et al. Long-term use of pitolisant to treat patients with narcolepsy: Harmony III study. SleepJ. 2019; 42(11):1-11.
8. Szakacs A, Dauvilliers Y, Mikhaylov V, et al. Safety and efficacy of pitolisant on cataplexy in patients with narcolepsy: a randomised, double-blind, placebo-controlled trial. Lancet Neurol. 2017;16:200-207.
9. Wakix (pitolisant) [Prescribing Information]. Plymouth Meeting, PA. Harmony Biosciences, LLC. Oct 2020.
10. Maski, Kiran, et al. "Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline." Journal of Clinical Sleep Medicine 17.9 (2021): 1881-1893.

Last Reviewed: 1/13/21, 1/12/22, 1/11/23, 1/10/24
Effective Date: 3/1/21, 2/15/24

OHSUHealth Services

Xcopri (cenobamate)
Prior Authorization Guidelines

Affected Medication(s)

- Xcopri oral tablet

FDA Approved Indication(s)

  - patients 4 years of age and older.
- Treatment of partial-onset seizures in adult patients

Dosing

- Initial dosage is 12.5mg one time daily, titrated to the recommended maintenance dosage of 200mg one time daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Xcopri (cenobamate) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Has the member had a trial of at least TWO of the following anticonvulsants but continued to have inadequate seizure control: felbamate, lamotrigine, levetiracetam, oxcarbazepine, gabapentin, topiramate, tiagabine, or zonisamide? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required

Last Reviewed: 7/17/18, 3/11/20, 1/13/21, 5/12/21, 11/10/21, 5/11/22, 5/10/23, 1/10/24
Effective Date: 8/15/18, 1/1/20, 3/1/21, 7/1/21, 1/1/22, 6/15/23, 2/15/24

OHSUHealth Services

5. Does the member have a previous trial with inadequate response, intolerance or contraindication to lacosamide?
    a. If yes, continue to #6
    b. If no, clinical review required

6. Is the treatment being 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 Xcopri being prescribed for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within 1 year) with documentation of significant clinical response to prior therapy received? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by or in consultation with a neurologist?
    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

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

References:

1. National Institute for Health and Care Excellence (NICE): Epilepsies: diagnosis and management. National Institute for Health and Care Excellence (NICE). London, United Kingdom. Available at: https://www.nice.org.uk/guidance/cg137/resources/epilepsies-diagnosis-and-management-35109515407813. Accessed June 27, 2018.

Last Reviewed: 7/17/18, 3/11/20, 1/13/21, 5/12/21, 11/10/21, 5/11/22, 2/17/23, 5/10/23, 1/10/24
Effective Date: 8/15/18, 1/1/20, 3/1/21, 7/1/21, 1/1/22, 7/1/22, 6/15/23, 2/15/24

2. XCOPRI® (cenobamate tablets) oral tablet, [package insert]. Paramus, NJ: SK Life Science, Inc.; 2022.
3. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 30 Nov. 2020].
4. Kanner, Andres M., et al. "Practice guideline update summary: efficacy and tolerability of the new antiepileptic drugs I: treatment of new-onset epilepsy." Epilepsy currents 18.4 (2018): 260-268.
5. Nunes, Vanessa Delgado, et al. "Diagnosis and management of the epilepsies in adults and children: summary of updated NICE guidance." Bmj 344 (2012): e281.
6. Chung, Steve S., et al. "Randomized phase 2 study of adjunctive cenobamate in patients with uncontrolled focal seizures." Neurology 94.22 (2020): e2311-e2322.
7. Krauss, Gregory L., et al. "Safety and efficacy of adjunctive cenobamate (YKP3089) in patients with uncontrolled focal seizures: a multicentre, double-blind, randomised, placebo-controlled, dose-response trial." The Lancet Neurology 19.1 (2020): 38-48.

Last Reviewed: 7/17/18, 3/11/20, 1/13/21, 5/12/21, 11/10/21, 5/11/22, 2/17/23, 5/10/23, 1/10/24
Effective Date: 8/15/18, 1/1/20, 3/1/21, 7/1/21, 1/1/22, 7/1/22, 6/15/23, 2/15/24

OHSU Health Services

Xifaxan (rifaximin)
Prior Authorization Guidelines

Affected Medication(s)

- Xifaxan oral tablet

FDA Approved Indication(s)

- Traveler's Diarrhea (TD): Treatment of traveler's diarrhea caused by noninvasive strains of Escherichia coli in adults and pediatric patients 12 years of age and older
- Hepatic Encephalopathy (HE): For reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults
- Irritable Bowel Syndrome with diarrhea (IBS-D): Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults

Dosing

- TD: 200 mg three times daily for 3 days
- HE: 400mg three times daily or 550 mg twice daily
- IBS-D: 550 mg by mouth three times daily for 14 days

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Xifaxan (rifaximin) prior authorization for treatment of hepatic encephalopathy (HE)?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. What is the diagnosis that Xifaxan (rifaximin) is being requested for?
    a. Traveler's Diarrhea, clinical review required
    b. Hepatic Encephalopathy, continue to corresponding criteria
    c. Irritable Bowel Syndrome with Diarrhea, clinical review required
    d. Other indication, continue to corresponding criteria

Hepatic Encephalopathy

1. Is the member 18 years of age or older?

Last Reviewed: 11/27/18, 11/26/18, 3/11/20, 5/12/21, 7/13/22, 7/12/23
Effective Date: 1/15/19, 1/1/20, 7/1/21

OHSUHealth Services

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

2. Does the member have a trial with insufficient response to lactulose in the past 30 days up to the maximum indicated dose? (Insufficient response defined as continued altered mental status) (Provide supporting documentation)

    a. If yes, continue to #3
    b. If no, continue to #4

3. Will the member continue to take lactulose concurrently with Xifaxan (rifaximin)? (Provide supporting documentation)

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

4. Does the member have an intolerance or contraindication to lactulose? (Note: Dose dependent GI discomfort and/or diarrhea is not considered as intolerance) (Provide supporting documentation)

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

5. Does the member have altered mental status? (Provide supporting documentation)

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

Other Indications

1. Is the requested use supported by major compendia? (Examples: Micromedex, Clinical Pharmacology, etc.) (Provide supporting documentation)

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

2. Has the member tried and had an inadequate response OR does the member have a contraindication to ALL standard treatment options of the required indication? (Provide supporting documentation)

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

3. Is the requested treatment dose and treatment duration appropriate? (Provide supporting documentation)

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

4. Is the treatment being prescribed or in consultation with an appropriate specialist?

    a. If yes, approve up to 6 months (based on appropriate treatment duration)
    b. If no, clinical review required

Reauthorization Criteria

1. Is Xifaxan (rifaximin) being used concurrently with lactulose unless a contraindication or intolerance is present? (Note: Dose dependent GI discomfort and/or diarrhea is not considered as intolerance) (Provide supporting documentation)

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

2. Is the member responding positively to therapy as defined by a decrease in symptoms? (Provide supporting documentation)

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

Note:

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

References:

1. Xifaxan Prescribing Information. Bridgewater, NJ: Salix Pharmaceuticals; January 2018. Available at https://www.xifaxan.com/.
2. Vilstrup H, Amodio P, Bajaj J, et al. Hepatic encephalopathy in chronic liver disease: 2014 practice guideline by AASLD-EASL. Hepatology. 2014; 60 (2): 715-735.
3. Xifaxan. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed October 11, 2018.

Last Reviewed: 11/27/18, 11/26/18, 3/11/20, 5/12/21, 7/13/22, 7/12/23
Effective Date: 1/15/19, 1/1/20, 7/1/21

OHSU Health Services

Zilbrysq® (zilucoplan)
Prior Authorization Guidelines

Affected Medication(s)

- Zilbrysq (zilucoplan) subcutaneous injection

FDA Approved Indication(s)

- Treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive

Dosing

- Subcutaneous daily dose:
  - Less than 56 kg: 16.6 mg
  - 56 to 77 kg: 23 mg
  - 77 kg or greater: 32.4 mg

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the request for continuation of therapy with the same medication for the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Is the member 18 years of age or older? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required
5. Does the member have Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required

Last Reviewed: 5/8/24
Effective Date: 6/15/24

6. Does the member have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Has the member had a thymectomy? (Note: Applicable only to patients with thymomas OR non-thymomatous patients who are 50 years of age or younger)
    a. If yes or N/A, continue to #8
    b. If no, clinical review required
8. Does the member have MG-Activities of Daily Living (MG-ADL) total score of ≥6? (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, clinical review required
9. Will the member avoid or use with medications known to worsen or exacerbate symptoms of MG (e.g., certain antibiotics, beta-blockers, botulinum toxins, hydroxychloroquine, etc.)? (Provide supporting documentation)
    a. If yes, continue to #10
    b. If no, clinical review required
10. Has the member had an inadequate response after a minimum one-year trial with two (2) or more immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.) or did the member require chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy? (Provide supporting documentation)
    a. If yes, continue to #11
    b. If no, clinical review required
11. Is Zilbrysq (zilucoplan) being prescribed by, or in consult with, a specialist?
    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 or major compendia supported? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required

2. Has the member developed a severe bone marrow failure syndrome, experienced spontaneous disease remission, or received a curative allogeneic stem cell transplant?
    a. If yes, clinical review required
    b. If no, continue to #3
3. Were updated chart notes (within past year) provided with documentation of significant clinical response to therapy received? (Ex. improvement from baseline in Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score or Quantitative Myasthenia Gravis (QMG) total score) (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is Zilbrysq (zilucoplan) being prescribed by, or in consult with, a specialist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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

References:

1. ZILBRYSQ (zilucoplan) subcutaneous injection, [package insert]. Smyrna, GA.: UCB, Inc; 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2022. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 17 Jan. 2024].
3. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. Neurology. 2016;87(4):419-425.
4. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. Neurology. 2021;96(3):114-122.
5. Howard JF Jr, Bresch S, Genge A, et al. Safety and efficacy of zilucoplan in patients with generalised myasthenia gravis (RAISE): a randomised, double-blind, placebo-controlled, phase 3 study. Lancet Neurol. 2023;22(5):395-406.

Zokinvy (lonafarnib)
Prior Authorization Guidelines

Affected Medication(s)

- Zokinvy (lonafarnib oral capsule)

FDA Approved Indication(s)

- Patients 12 months of age and older with a body surface area of 0.39m^2 and above:
  - To reduce risk of mortality in Hutchinson-Gilford progeria syndrome
  - For treatment of processing-deficient progeroid laminopathies with either:
    - Heterozygous LMNA mutation with progerin-like protein accumulation
    - Homozygous or compound heterozygous ZMPSTE24 mutations

Dosing

- Start at 115 mg/m2 twice daily with morning and evening meals. After 4 months, increase to 150 mg/m2 twice daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)

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

2. Is the request for renewal of a previously approved Zokinvy (lonafarnib) prior authorization with the same indication?

   a. If yes, continue to Reauthorization
   b. If no, continue to #3

3. Is this being requested for an FDA or major compendia supported indication?

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

4. Does the member have a confirmed diagnosis of one of the following? (Provide supporting documentation)

   - HGPS confirmed by G608G mutation in the lamin A gene
   - Processing-deficient progeroid laminopathy with either:
     - Heterozygous LMNA mutation with progerin-like protein accumulation
     - Homozygous or compound heterozygous ZMPSTE24 mutations

Last Reviewed: 7/14/21, 1/11/23, 1/10/24
Effective Date: 9/1/21

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

5. Is the member 12 months of age or older with a BSA of ≥0.39m^2?

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

6. Is the members BSA (or height and weight) provided and is dosing consistent with FDA approved dosing? (Provide BSA for review)

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

7. Is there documentation of baseline monitoring and planned ongoing monitoring of all of the following? (Provide baseline labs and monitoring plan for review)
    - Comprehensive metabolic panel
    - CBC
    - Ophthalmological evaluation
    - Blood pressure

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

8. Does the patient's baseline monitoring meet all of the following? (Provide baseline labs for review)
    - APC >1,000/ml
    - Platelets >75,000/ml (transfusion independent)
    - Hemoglobin >9g/dl
    - Creatinine ≤ 1.5 ULN for age or GFR >70ml/min/1.73m^2
    - Bilirubin ≤ 1.5 ULN for age
    - ALT and AST <5 x normal range for age

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

9. Is there documentation of avoidance of strong CYP3A inhibitors/inducers, midazolam, lovastatin, simvastatin, or atorvastatin? (Provide supporting documentation)

    a. If yes, continue to #10
    b. If no, clinical review required

10. Is the member a female of reproductive potential?

    a. If yes, continue to #11
    b. If no, continue to #12

11. Does the member have documentation of a negative pregnancy test and documentation of contraceptive use throughout planned treatment?

    a. If yes, continue to #12
    b. If no, clinical review required

12. Is the requested medication being prescribed by, or in consultation with, a specialist with experience in treating progeria and/or progeroid laminopathies?

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

Reauthorization Criteria

1. Is Zokinvy (lonafarnib) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)

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

2. Is there documentation of disease stabilization compared to natural disease progression? (Provide supporting documentation)

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

3. Is the requested medication being prescribed by, or in consultation with, a specialist with experience in treating progeria and/or progeroid laminopathies?

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

Note:

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

References:

1. ZOKINVY (lonafarnib) capsules, [package insert]. Palo Alto, CA: Eiger Biopharmaceuticals, Inc.; 2021.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 5 FEB. 2021].

Last Reviewed: 7/14/21, 1/11/23, 1/10/24
Effective Date: 9/1/21

3. Gordon, Leslie B., et al. "Impact of farnesylation inhibitors on survival in Hutchinson-Gilford progeria syndrome." Circulation 130.1 (2014): 27-34.
4. Gordon, Leslie B., et al. "Association of lonafarnib treatment vs no treatment with mortality rate in patients with Hutchinson-Gilford progeria syndrome." Jama 319.16 (2018): 1687-1695.
5. Gordon, Leslie B., et al. "Clinical trial of the protein farnesylation inhibitors lonafarnib, pravastatin, and zoledronic acid in children with Hutchinson-Gilford progeria syndrome." Circulation 134.2 (2016): 114-125.
6. Gordon, Leslie B., et al. "Clinical trial of a farnesyltransferase inhibitor in children with Hutchinson–Gilford progeria syndrome." Proceedings of the National Academy of Sciences 109.41 (2012): 16666-16671.

OHSU Health Services

Ztalmy® (ganaxolone)
Prior Authorization Guidelines

Affected Medication(s)

- Ztalmy oral suspension

FDA Approved Indication(s)

- Treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older.

Dosing

- 28kg or less: 6mg/kg orally three times daily through day 7; then 11 mg/kg three times daily through day 14; then 16 mg/kg three times daily through day 21; and 21 mg/kg three times daily thereafter
- Greater than 28kg: 150 mg/3 mL orally 3 times daily through day 7; then 300 mg/6 mL three times daily through day 14; then 450 mg/9 mL three times daily through day 21; and 600 mg/12 mL three times daily thereafter

Initial Authorization Criteria

1. Is the diagnosis provided and covered by the Oregon Health Plan (OHP) or is the member covered under the EPSDT program? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for renewal of a previously approved Ztalmy (ganaxolone) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member currently 2 years of age or older?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member currently have confirmed diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder confirmed by genetic testing? (Provide supporting documentation)

Last Reviewed: 9/14/22, 9/13/23
Effective Date: 11/15/22

OHSU Health Services

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

6. Has the member previously trialed at least 2 regimens containing two or more of the following used in combination? (Provide supporting documentation)

    i. Clobazam, valproate, topiramate, levetiracetam, vigabatrin

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

7. Does the member continue to have uncontrolled seizures despite previous therapy? (Provide supporting documentation)

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

8. 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 documented indication Food and Drug Administration (FDA) approved or supported by major compendia?

    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 therapy received? (Significant clinical response is defined by a decrease in seizure frequency compared to pre-treatment baseline) (Provide supporting documentation)

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

3. Is the treatment being prescribed by, or in consultation with, a neurologist?

    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

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

Last Reviewed: 9/14/22, 9/13/23
Effective Date: 11/15/22

References:

1. ZTALMY® (ganaxolone) oral suspension, [package insert]. Radnor, PA: Marinus Pharmaceuticals, Inc.; 2022.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 3 Aug. 2022].
3. Knight, Elia M. Pestana, et al. "Safety and efficacy of ganaxolone in patients with CDKL5 deficiency disorder: results from the double-blind phase of a randomised, placebo-controlled, phase 3 trial." The Lancet Neurology 21.5 (2022): 417-427.
4. Leonard, Helen, et al. "CDKL5 deficiency disorder: clinical features, diagnosis, and management." The Lancet Neurology (2022).
5. Olson, Heather E., et al. "Current neurologic treatment and emerging therapies in CDKL5 deficiency disorder." Journal of neurodevelopmental disorders 13.1 (2021): 1-11.

Last Reviewed: 9/14/22, 9/13/23
Effective Date: 11/15/22