# Oregon Medicaid Pharmaceutical Services Prior Authorization Criteria

Oregon Health Authority

HEALTH SYSTEMS DIVISION

Prior authorization (PA) criteria for fee-for-service prescriptions for Oregon Health Plan clients

**October 1, 2025**

Oregon HEALTH PLAN

# Contents

# Introduction

## About this guide

The *Oregon Medicaid Pharmaceutical Services PA Criteria* is designed to assist the following providers:

- Prescribing providers seeking approval of fee-for-service (FFS, or "open card") prescriptions for Oregon Health Plan (OHP) clients
- Pharmacies filling FFS prescriptions for OHP clients

## How to use this guide

The table of contents is not interactive. When viewing this guide electronically, do the following to quickly access PA criteria:

- Click the **Bookmarks** button in your PDF viewer to view the bookmarks in this guide.
- Click on the bookmark you wish to view to go to that page.
- A plus sign next to the bookmark name means there are additional items within that bookmark. Click the plus sign to see the additional bookmarks.
- To turn pages within the PDF, use the arrow buttons (normally located at the top or bottom of your PDF viewer).

## Administrative rules and supplemental information

Use this guide with the Pharmaceutical Services provider guidelines (administrative rules and supplemental information), which contain information on policy and covered services specific to your provider type.

You can find these guidelines at
www.oregon.gov/OHA/HSD/OHP/Pages/Policy-Pharmacy.aspx

# Update information

## Effective October 1, 2025

The Health Systems Division made substantive changes to listed criteria, deleted criteria, and made minor, non-substantive formatting updates to the entire guide.

### Substantive updates and new criteria

- Diazoxide choline
- Hepatitis B antivirals
- Sickle Cell Gene Therapy
- Sleep Wake Medications
- Exagamglogene autotemcel – RETIRED; replaced with Sickle Cell Gene Therapy
- Lovotibeglogene autotemcel – RETIRED; replaced with Sickle Cell Gene Therapy

### Clerical changes

- Antipsychotics in children
- Buprenorphine and buprenorphine/naloxone
- New Drug Policy
- Oncology Agents
- Orphan Drugs
- Pimavanserin
- Quetiapine, low-dose
- Risperdal Consta
- Xanomeline-trospium

For questions, contact the Division's Pharmacy Program at:
dmap.rxquestions@odhsoha.oregon.gov

# General PA information

## Overview

For drugs that require PA on Point of Sale (POS) claims:

- A new evaluation feature of the Oregon Medicaid POS system, DUR Plus, reviews incoming POS claims and issues PA when the drug meets appropriate clinical criteria.
- For drugs that do not pass DUR Plus review, pharmacies must contact the prescribing provider, who then requests PA from the Oregon Pharmacy Call Center.

## Drugs requiring PA - See OAR 410-121-0040 for more information

The Division may require PA for individual drugs and categories of drugs to ensure that the drugs prescribed are indicated for conditions funded by OHP and consistent with the Prioritized List of Health Services and its corresponding treatment guidelines (see OAR 410-141-0480 and 410-141-0520).

## DUR Plus review

The Oregon Medicaid POS system initially evaluates incoming pharmacy claims for basic edits and audits. If the drug on the claim requires PA and requires DUR Plus evaluation, the claim passes through a series of clinical criteria rules to determine whether DUR Plus can issue PA and allow dispensing the drug to the client.

DUR Plus checks the current drug claim as well as the client's medical and claims history for the appropriate criteria.

- If suitable criteria are found, a prior authorization will be systematically created, applied to the claim, and the claim will be paid. This interactive process occurs with no processing delays and no administrative work for the pharmacy or prescribing provider.
- If all criteria are not met, the claim will be denied, and PA will be required. The prescriber will be responsible for requesting PA, using procedures outlined in OAR 410-121-0060.

## Early and Periodic Screening Diagnostic and Treatment (EPSDT) Review

The EPSDT benefit includes comprehensive preventative health care services for Medicaid members until they turn age 21 and for members with qualifying special health care needs as they turn 21.

People eligible for EPSDT review include:

- People <21 years of age OR

- Youth with special healthcare needs (YSHCN) who are turning 21 in 2025 (birthdays between 1/1/2004 and 12/31/2004). Members eligible for YSCHN can be identified based on client case descriptors YS1 or YS2.

For more information about EPSDT benefits, providers may refer to https://www.oregon.gov/oha/hsd/ohp/pages/epsdt.aspx

## How to request PA

For prescriptions covered by the client's coordinated care organization (CCO), contact the CCO for their PA procedures.

For prescriptions covered by OHA on a fee-for-service ("open card") basis, use the following contact information:

### For prescriptions and oral nutritional supplements

The Oregon Pharmacy Call Center is available 24 hours per day, seven days a week, 365 days a year and processes PA requests within 24 hours. When calling in a PA request, have the diagnosis code ready.

Phone: 888-202-2126
Fax: 888-346-0178

Refer to PA procedures outlined in OAR 410-121-0060.

### For emergent or urgent prescriptions that require PA

The Oregon Pharmacy Call Center may authorize up to a 96-hour emergency supply for drugs that require PA, but have no PA on file. Refer to 410-121-0060(4) Emergency Need.

The Pharmacist may request an emergent or urgent dispensing from the Pharmacy Call Center when the client is eligible for covered fee-for-service drug prescriptions.

a) Clients who do not have a PA pending may receive an emergency dispensing for a 96-hour supply.
b) Clients who do have a PA pending may receive an emergency dispensing for up to a seven-day supply.

### For diabetic supplies (lancets, test strips, syringe and glucose monitor supplies)

Diabetic supplies in excess of OHA's utilization guidelines require PA from the Division:

**Health Systems Division – Provider Clinical Support Unit**
500 Summer St NE, E44
Salem, OR 97301-1078
503-945-6821 (direct)
800-642-8635 (in-state only)

Use the MSC 3971 form to submit PA requests. Fax the completed form using an EDMS Coversheet (MSC 3970) to one the following fax numbers:

- Routine requests: 503-378-5814
- Immediate/urgent requests: 503-378-3435

## Client hearings and exception requests

For any PA requests that are denied due to OHA criteria not being met, the right of a client to request a contested case hearing is otherwise provided by statute or rule, including OAR 410-141-0264(10).

- This rule describes when a client may request a state hearing. Clients may request a hearing based upon information included in the PA denial notice.
- Information on how to file an appeal is attached to all PA notices to clients and providers from the Oregon Pharmacy Call Center.

Providers may contact Provider Services at 800-336-6016 to file an exception request on a PA denial. For information regarding OAR 410-120-1860, refer to the Division's General Rules at www.oregon.gov/OHA/HSD/OHP/Pages/Policy-General-Rules.aspx

## DMAP 3978 - Pharmacy Prior Authorization Request

This form is the paper option for submitting pharmacy PA requests. Prescribers should submit their PA requests for fee-for-service prescriptions and oral nutritional supplements with required documentation to the Oregon Pharmacy Call Center at 888-346-0178.

This form **does not** require an EDMS Coversheet. This form is also available on the DHS/OHA website at https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/he3978.pdf

### Information needed to request PA

Complete the form as follows. The Oregon Pharmacy Call Center may ask for some or all of the following information, depending upon the class of the drug requested:

| DMAP 3978 section | Information needed |
|---|---|
| Section I: | Requesting provider name and National Provider Identifier<br>• FQHC/RHC and AI/AN providers - Also enter the pharmacy or clinic NPI for your facility |
| Section II | Type of PA Request: Mark "Pharmacy"<br>• FQHC/RHC and AI/AN providers -Mark "Other," followed by provider type (FQHC, RHC, IHS or Tribal 638) |
| Section III: | Client name and recipient ID number |
| Section IV: | Diagnosis code |
| Section V: | Drug name, strength, size and quantity of medication<br>• Participating pharmacy: Include the dispensing pharmacy's name and phone number (if available) |
| Section VI: | Date of PA Request Begin and End Dates of Service |
| Section VII: | Complete for EPIV and oral nutritional supplements only |

| DMAP 3978 section | Information needed |
|---|---|
| Section VIII: | Complete for oral nutritional supplements only |

HEALTH SYSTEMS DIVISION
Medicaid Programs

Print | Clear Form

Oregon Health Authority

# Prior Authorization Request for Medications and Oral Nutritional Supplements

Fax to: Oregon Pharmacy Call Center
888-346-0178 (fax); 888-202-2126 (phone)

**Confidentiality Notice:** The information contained in this request is confidential and legally privileged. It is intended only for use of the recipient(s) named. If you are not the intended recipient, you are hereby notified that the disclosure, copying, distribution, or taking of any action in regard to the contents of this fax document - except its direct delivery to the intended recipient - is strictly prohibited. If you received this request in error, please notify the sender immediately and destroy all copies of this request along with its contents and delete from your system, if applicable.

**Instructions:** Complete all fields marked with an asterisk (*), if applicable.

## I – Request information

Requesting provider's name* _____ NPI* _____

Contact name _____ Contact phone

Contact fax

Type of PA request* *(assignment code - check appropriate box):*

☐ Pharmacy ☐ Oral nutritional supplements ☐ Physician-administered drug

☐ Other *(please specify):* _____

Client ID* _____ Client name *(Last, First MI)*: _____

Date of request _____ Client date of birth*

Processing timeframe *(select one):* ☐ Routine ☐ Urgent *(72 hours)* ☐ Immediate *(24 hours)*

Supporting justification for urgent/immediate processing:

_____

## II – Service information

Estimated length of treatment*: If neither box is checked, OHA will approve the maximum allowed.

☐ Maximum allowed by criteria

☐ Limited duration (please specify end date below)

Start date* _____ End date _____

Primary diagnosis _____ Primary diagnosis code* _____

Frequency _____

Other pertinent diagnosis *(for prescriptions and oral nutritional supplements, list all applicable diagnosis codes or contributing factors causing or exacerbating a funded condition, including any relevant comorbid conditions or impacts on growth, learning or development)*:

_____

## III – Drug/product Information

Name _____ *Strength _____ Quantity _____

*NDC _____

**Participating pharmacy:**

Name _____ Phone number _____ Date _____

## IV – Line item information – *Required for oral nutritional supplements*

| Line Item | Procedure Code | Modifier | Description | Units | From | To | Total Dollars |
|---|---|---|---|---|---|---|---|
| 1 | | | | | | | |
| 2 | | | | | | | |
| 3 | | | | | | | |
| 4 | | | | | | | |
| 5 | | | | | | | |
| | | | Total Units | 0 | | Total Dollars | 0 |

## V – Patient questionnaire – *Complete for oral nutritional supplements only*

Is the patient fed via G-tube? ☐ Yes ☐ No

Is the patient currently on oral nutritional supplements? ☐ Yes ☐ No
- If Yes, date product started: _____
- How is it supplied *(e.g., self-pay, friends/family supply)*?

Does the patient have failure to thrive (FTT)? ☐ Yes ☐ No

Does the patient have a long history *(more than one year)* of malnutrition and cachexia? ☐ Yes ☐ No

Does the patient reside in a long-term care facility or chronic home care facility? ☐ Yes ☐ No
- If Yes, list name of residence:

Does the patient have:
- Increased metabolic need from severe trauma *(e.g., severe burn, major fracture)*? ☐ Yes ☐ No
- Malabsorption difficulties *(e.g., Crohn's disease, cystic fibrosis, short gut syndrome, bowel resection/removal, gastric bypass, renal dialysis, dysphagia, achalasia)*? ☐ Yes ☐ No
- A diagnosis that requires additional calories and/or protein intake *(e.g., cancer, AIDS, pulmonary insufficiency, MS, ALS, Parkinson's, cerebral palsy, Alzheimer's)*? ☐ Yes ☐ No
- If Yes, list the diagnosis code(s):

Date of last MD assessment for continued use of supplements:

Date of Registered Dietician visit indicating inadequate intake with regular, liquefied or pureed foods:

Serum protein level: _____ Date taken: _____

Albumin level: _____ Date taken: _____

Current weight: _____ Normal weight: _____

## Section VI – *Complete for Citizenship Waived Medical (CWM) prescriptions only*

Is the drug prescribed in conjunction with a behavioral health crisis visit (e.g., CPT codes 90839 & 90840)? If Yes, visit date: ☐ Yes ☐ No

Is the drug needed to help the patient tolerate or complete cancer therapy? ☐ Yes ☐ No

Is the drug an immunosuppressant for a kidney transplant? ☐ Yes ☐ No

## Written justification and attachments:

## Requesting physician's signature:

Signature _____ Date _____

# PA criteria for fee-for-service prescriptions

## About the PA criteria

The following pages include specific drugs, goals or directives in usage, length of authorization, covered alternatives, approval criteria and more.

The Division's prior authorization policy is reviewed by the Oregon Pharmacy and Therapeutic Committee (P&T Committee) and is subject to the Oregon Administrative Rule writing process.

- To learn more about the P&T Committee, please visit the web page at https://www.oregon.gov/oha/HPA/DSI-Pharmacy/Pages/Pharmacy-Therapeutics-Committee.aspx
- For summaries of P&T Committee recommendations approved by OHA for policy implementation, view the OHA Recommendations posted at https://www.oregon.gov/oha/HPA/DSI-Pharmacy/Pages/PT-Recordings.aspx

## Contact for questions about PA policy

For general questions about the Division's prior authorization policy for fee-for-service prescriptions, please contact:

**Roger A. Citron, RPh**
OSU College of Pharmacy
Drug Use Research & Management at
OHA Health Systems Division
500 Summer Street NE, E-35
Salem, OR 97301-1079

Roger.A.CITRON@odhsoha.oregon.gov

Voicemail: 503-947-5220
Fax: 503-947-2596

# Acne Medications

**Goal(s):**
- Ensure that medications for acne are used appropriately for OHP-funded conditions for adults.
- Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- All drugs in the Acne medications class

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for an FDA-approved indication? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the diagnosis funded by OHP?<br><br>HERC guideline notes 65 and 132 describe funding status based on disease severity: https://www.oregon.gov/oha/HPA/DSI-HERC/SearchablePLdocuments//Prioritized-List-GN-132.docx https://www.oregon.gov/oha/HPA/DSI-HERC/SearchablePLdocuments//Prioritized-List-GN-065.docx | **Yes:** Approve for 12 months. | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #4. |
| 4. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical necessity. |
| 5. Is the request for a preferred product OR has the patient failed to have benefit with, or have contraindications or intolerance to, at least 2 preferred products?<br><br>Message: Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Approve for 12 months. | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Inform prescriber of covered alternatives in class and process appropriate PA. |

*P&T/DUR Review: 12/22; 02/21 (SF); 06/20; 11/18*
*Implementation: 1/1/23; 7/1/20; 1/1/1*

# Topical Therapies for Actinic Keratosis

**Goal(s):**

- To ensure appropriate drug use and restrict to indications supported by medical literature. Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**

- Up to 3 months

**Requires PA:**

- Non-preferred agents for pharmacy claims
- Aminolevulinic ointment for provider administered claims

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1**. Topical Medications FDA-Approved in Actinic Keratosis and Other Indications

| Generic Drug Name (BRAND NAME) | Strength/ Formulation | FDA-Approved Indications in Adults | Patient or Health Care Provider Administered | Dosing Guidance |
|---|---|---|---|---|
| 5-fluorouracil (TOLAK, EFUDEX) | 0.5% cream<br>4% cream<br>5% cream<br>2% solution<br>5% solution | • Actinic Keratosis<br>• Basal Cell Carcinoma (5% cream or solution) | Patient | Maximum duration of therapy: 2 months<br>Actinic Keratosis:<br>• Fluorouracil 0.5% and 4% cream: Apply once daily up to 4 weeks.<br>• Fluorouracil 1% cream: Apply twice daily for an average of 2-6 weeks.<br>• Fluorouracil 5% cream: Apply twice daily for an average of 2-4 weeks.<br>• Fluorouracil 2% and 5% solution: Apply twice daily for an average of 2-4 weeks.<br>Basal Cell Carcinoma:<br>• Fluorouracil 5% cream or solution: Apply twice daily for an average of 2-4 weeks. |
| Imiquimod (ALDARA, ZYCLARA)[1] | 2.5% cream<br>3.75% cream<br>5% cream | • Actinic Keratosis in adults (2.5%, 3.75%, and 5% cream)<br>• Basal Cell Carcinoma in adults (5% cream only)<br>• Genital and Perianal Warts (3.75% | Patient | Actinic Keratosis:<br>• Imiquimod 2.5% and 3.75% cream: Apply at bedtime (remove in 8 hours) x 2 weeks, off for 2 weeks then repeat x 2 weeks. Apply up to 0.5 grams per application.<br>• Imiquimod 5% cream: Apply once daily before bedtime 2 times per week for 16 weeks. Apply no more than 1 packet per application.<br>Basal Cell Carcinoma:<br>• Imiquimod 5% cream: Apply once daily before bedtime 5 times per week for 6 weeks. Amount of cream used is based on target tumor diameter. |

| | | | | |
|---|---|---|---|---|
| | | cream & 5% cream) approved in children and adolescents ≥ 12 years) | | Genital Warts:<br>• Imiquimod 3.75% cream: Apply once daily (remove in 8 hours) up to 8 weeks. Apply up to 0.25 grams per application.<br>• Imiquimod 5% cream: Apply once daily before bedtime 3 times per week until total clearance or for a maximum of 16 weeks. |
| Diclofenac Sodium (SOLARAZE) | 3% gel | • Actinic Keratosis | Patient | • Apply twice daily for 60 to 90 days. |
| Tirbanibulin (KLISYRI) | 1% ointment | • Actinic Keratosis | Patient | • Apply once daily (max one single dose packet) x 5 consecutive days. |
| Aminolevulinic acid (AMELUZ, LEVULAN) | 10% gel (red or blue light)<br>20% solution (red light) | • Actinic Keratosis prior to photodynamic therapy | Health Care Provider | • 10% gel: Apply a maximum of 6 grams (3 tubes) at one time. Retreat lesions that have not completely resolved 3 months after the initial treatment.<br>• 20% gel: Apply one treatment and may repeat after 8 weeks. |

| **Approval Criteria** | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this an FDA approved indication (see **Table 1**)? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Has the patient tried a preferred agent and do they have a contraindication, intolerance, or failure with this therapy? | **Yes**: Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 4. Is the diagnosis funded by OHP? | **Yes:** Go to #5 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP.<br><br>If eligible for EPSDT review: Go to #5. |
| 5. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.) | **Yes:** Approve for up to 4 months based on dosing parameters in Table 1. | **No:** Pass to RPh. Deny; medical necessity. |

*P&T/DUR Review: 6/25 (DM)*
*Implementation: 8/1/25*

# Alzheimer's Disease (Monoclonal Antibodies)

**Goal(s):**

- To support medically appropriate and safe use of Alzheimer Dementia drugs (as designated by the FDA)
- To limit off-label use of Alzheimer's Dementia drugs

**Length of Authorization:**

- Up to 6 months

**Requires PA:**

- Pharmacy point-of-sale and provider-administered claims

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at http://www.orpdl.org/drugs/

Table 1. Dosing and ARIA Monitoring

| Drug | MRI Timing for ARIA Monitoring | Dosing | Frequency of Administration |
|---|---|---|---|
| Donanemab | Prior to Infusion 2 (no longer than 1 year) | See Prescribing Information for dosing recommendations and for interruptions in therapy due to ARIA. | Every 4 Weeks |
| | Prior to Infusion 3 | | |
| | Prior to Infusion 4 | | |
| | Prior to Infusion 7 | | |
| | Annually | | |
| Lecanemab | Prior to infusion 1 (no longer than 1 year) | | Every 2 Weeks |
| | Prior to Infusion 5 | | |
| | Prior to Infusion 7 | | |
| | Prior to infusion 14 | | |
| | Annually | | |

ARIA = amyloid related imaging abnormalities; IV = intravenous; MRI = magnetic resonance imaging

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the drug to be used for treatment of a patient diagnosed with Alzheimer's Dementia **AND** has the prescriber ruled out other types of dementia (e.g., vascular dementia, Lewy body, and frontotemporal)? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the request for continuation of therapy in a patient previously approved by FFS? | **Yes:** Go to Renewal Criteria | **No:** Go to #4 |

| Approval Criteria | | |
|---|---|---|
| 4. Is the therapy prescribed by or in consultation with a neurologist? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the patient between 50 and 90 years of age? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is there documented evidence that the patient has **mild** cognitive impairment due to Alzheimer's disease or **mild** Alzheimer's dementia as evidenced by the following assessments performed within the last 6 months:<br>• Clinical Dementia Rating-Global Score (CDR-GS) of 0.5 or 1.0 **AND**<br>• Mini-Mental Status Exam (MMSE) score between 22 and 30 (inclusive) **AND**<br>• Positron Emission Tomography (PET) scan positive for elevated amyloid beta plaque or presence of elevated amyloid and/or elevated phosphorylated tau confirmed in cerebrospinal fluid (CSF)? | **Yes:** Go to #7<br><br>Document test results and dates.<br><br>_____ | **No:** Pass to RPh. Deny; medical appropriateness<br><br>There is insufficient evidence for use of this agent in treating moderate or severe AD |
| 7. Has the prescriber assessed and documented baseline disease severity within the last 6 months utilizing an objective measure/tool (e.g. Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating-Sum of Boxes [CDR-SB], MMSE, or other validated AD monitoring tool)? | **Yes:** Record baseline measurement.<br><br>_____<br><br>Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Has the patient received a baseline brain magnetic resonance imaging (MRI) within 1 year prior to initiating treatment with no evidence of pre-treatment localized superficial siderosis or brain hemorrhage? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 9. Has the prescriber scheduled additional brain MRIs to be obtained as outlined in Table 1 to evaluate for the presence of asymptomatic amyloid related imaging abnormalities<br>[**ARIA-E**]-edema (brain swelling)<br>and/or<br>[**ARIA-H**]-hemorrhage (brain bleeding or protein deposits on brain/spinal cord)? | **Yes:** Record scheduled appointment dates:<br><br>_____<br><br>Go to #10 | **No:** Pass to RPh. Deny; medical appropriateness |
| 10. Is the patient currently receiving anticoagulant or antiplatelet therapy (excluding aspirin 81 mg)? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #11. |
| 11. Is there documentation based on medical records that the prescriber has tested the patient for the presence of apolipoprotein E4 (ApoE4) and, if a carrier, has discussed benefits and risks associated with therapy?<br><br>Note: Patients who are ApoE4 homozygotes have a higher risk of ARIA, including symptomatic, serious, and severe radiographic ARIA compared to heterozygotes and non-carriers. | **Yes:** Approve for up to 6 months | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is there documented evidence that the patient has mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia as evidenced by the following assessments performed within the last 30 days:<br><br>• Clinical Dementia Rating-Global Score (CDR-GS) of 0.5 or 1.0; **AND**<br>• Objective evidence of cognitive impairment at screening; **AND**<br>• Mini-Mental Status Exam (MMSE) score between 22 and 30 (inclusive) | **Yes:** Go to #2<br><br>Document test results and dates:<br><br>_____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 2. Is there documented evidence of follow-up MRIs performed and/or scheduled as recommended in Table 1 for therapy safety surveillance? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 3. Was there a serious adverse event (symptomatic moderate to severe ARIA-H or ARIA-E [brain microhemorrhage, superficial siderosis, or edema]) observed or reported with therapy? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #4 |
| 4. Has the patient received at least 6 months of uninterrupted therapy? | **Yes:** Go to #5 | **No:** Approve remaining duration of the 6-month titration period |
| 5. Is the request for donanemab? | **Yes:** Go to #6 | **No:** Go to #8 |
| 6. Has PET imaging been performed within the last 6 months to confirm the presence of amyloid plaques? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Does the patient have amyloid plaque levels at <11 centiloids on a single PET scan or 11 to <25 on consecutive months | **Yes:** Pass to RPh. Deny; medical Appropriateness<br><br>In clinical studies, dosing was stopped based on a reduction of amyloid levels below predefined thresholds on PET imaging. | **No:** Go to #8 |
| 8. Is there documentation that, compared to baseline assessment, therapy has resulted in:<br>• cognitive or functional improvement **OR**<br>• disease stabilization **OR**<br>• a reduction in rate of clinical decline compared to the natural disease progression?<br><br>The same clinical measure used to assess AD (e.g., CDR-GS, MMSE, ADAS-Cog, ADCS-ADL-MCI, etc) is recommended to document clinical benefit. | **Yes:** Approve for up to 6 months<br><br>Document benefit:<br><br>_____ | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 12/24 (DE);10/23;10/21*
*Implementation: 1/1/25; 11/1/23; 1/1/22*

# Amifampridine

**Goal(s):**
- Promote safe and effective use of amifampridine in the treatment of LEMS symptoms

**Length of Authorization:**
- Initial: 14 days
- Renewal: 1 to 3 months

**Requires PA:**
- Amifampridine

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1: Maximum Recommended Dose**

| Formulation | Minimum age (years) | Weight (kg) | Single Dose Maximum | Cumulative Daily Maximum |
|---|---|---|---|---|
| Ruzurgi® | ≥ 6 | < 45 | 15 mg | 50 mg |
| | | ≥ 45 | 30 mg | 100 mg |
| Firdapse® | ≥ 6 | < 45 | 15 mg | 50 mg |
| | | ≥ 45 | 20 mg | 100 mg |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for continuation of therapy previously approved by the FFS program? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Is the diagnosis for Lambert-Eaton Myasthenic Syndrome (LEMS)? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the request for a non-preferred product and will the prescriber consider a change to a preferred product?<br><br>Message:<br><br>• Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics Committee. | **Yes:** Inform prescriber of preferred alternatives. | **No:** Go to #5 |
| 5. Is the medication being prescribed by or in consultation with a neurologist? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 6. Is there evidence based on chart notes or claims that the patient has a seizure disorder diagnosis or history of seizures? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #7 |
| 7. Is there evidence based on chart notes or claims that the patient has active brain metastases? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #8 |
| 8. Does the patient have a documented baseline ECG in the past 12 months demonstrating a QT interval < 450 milliseconds? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Is the amifampridine dose within the appropriate limits? (See **Table 1** in criteria) | **Yes:** Go to #10 | **No:** Pass to RPh. Deny; medical appropriateness |
| 10. Has the patient been assessed with a baseline quantitative myasthenia gravis (QMG) exam (score>5), 3TUG walking test, or other validated measure of LEMS patient physical functioning? | **Yes:** Go to #11<br><br>Document baseline results. | **No:** Pass to RPh. Deny; medical appropriateness |
| 11. Does the patient have follow-up appointments scheduled during weeks 1 and 2 after the proposed therapy initiation date? | **Yes:** Go to #12<br><br>Document appointment dates. | **No:** Pass to RPh. Deny; medical appropriateness |
| 12. Will the patient and provider comply with all case management interventions and adherence monitoring requirements required by the Oregon Health Authority? | **Yes:** Approve for 2 weeks | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Has the patient been taking amifampridine for ≥1 week AND has there been documented improvement from baseline in ambulation or physical functioning as assessed via the 3TUG, QMG score, or other validated LEMS assessment scale? | **Yes:** Document follow-up assessment scores<br><br>Go to #2 | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 2. Is the amifampridine dose within appropriate limits?<br><br>(See **Table 1** in criteria) | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Has the patient experienced any new adverse effects since starting amifampridine therapy (e.g. seizures, arrhythmias)? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #4 |
| 4. Does the patient have documented evidence of >90% adherence to amifampridine for the previous approval period? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Has the patient been on >30 days of continuous amifampridine therapy? | **Yes:** Approve for 3 months | **No:** Approve for 30 days; Renewal consideration will require documentation of tolerance, clinical benefit, and adherence. |

*P&T/DUR Review: 11/19 (DE)*
*Implementation: 1/1/2019*

# Amikacin Liposome Inhalation Suspension

**Goal(s):**
- Limit the use of amikacin liposome inhalation suspension to adult patients with 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.

**Length of Authorization:**
- 6-month initial approval; Up to 12 months renewal

**Requires PA:**
- Amikacin Liposome Inhalation Suspension (ALIS)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. Is this a request for continuation of therapy previously approved by the FFS program? | **Yes**: Go to **Renewal Criteria** | **No**: Go to #2 |
| 2. Is this request for treatment of an adult ≥18 years of age with Mycobacterium avium complex (MAC) lung disease verified through sputum culture? | **Yes:** Record ICD10 code. Go to #3. | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is this agent being prescribed by or in consultation with an infectious disease specialist, pulmonologist, or a specialist in the treatment of MAC lung infections? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 4. Has the patient been adherent for the past 6-months to a course of a guideline-based 3-drug antibacterial treatment regimen including a macrolide, a rifamycin, and ethambutol? | **Yes:** List the antibiotic regimen.<br>Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>6-month trial of guideline-based, 3-drug antibacterial regimen is required before starting amikacin liposome inhalation suspension. |

| Approval Criteria | | |
|---|---|---|
| 5. Will the patient be using amikacin liposome inhalation suspension as add on therapy to a guideline-based, 3-drug antibacterial MAC treatment regimen as described in question #4? | **Yes:** Approve for 6 months.<br><br>Dose not to exceed 1 vial per day (590 mg/8.4 ml vial).<br><br>Renewal consideration will require documentation of monthly MAC sputum cultures and regimen adherence. | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Concurrent guideline-based, 3-drug antibacterial MAC regimen is required per product labeling. |

| Renewal Criteria | | |
|---|---|---|
| 1. Has the patient experienced evidence of respiratory adverse effects since treatment initiation such as hypersensitivity pneumonitis, hemoptysis, bronchospasm, or exacerbation of underlying pulmonary disease? | **Yes**: Pass to RPh. Deny; medical appropriateness. | **No**: Go to #2 |
| 2. Has the patient been adherent to both amikacin LIS and guideline-based background MAC antibiotic regimen? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is there documentation of at least 3 consecutive negative monthly sputum cultures in the first 6 months of amikacin LIS therapy or a minimum of 2 consecutive negative monthly sputum cultures in the last 2 months of amikacin LIS therapy? | **Yes**: Document results of sputum culture.<br><br>Approve for additional 3 months.<br><br>Therapy not to exceed 12 months after converting to negative sputum status (≥3 consecutive negative MAC cultures). | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T/DUR Review: 11/19 (DE)*
*Implementation: 1/1/2020*

# Analgesics, Non-Steroidal Anti-Inflammatory Drugs

**Goal(s):**
- To ensure that non-preferred oral and nasal spray NSAIDs are used for conditions funded by the OHP and support individual review for the EPSDT program.
- Restrict ketorolac to short-term use (5-day supply every 60 days) per the FDA black boxed warning.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Non-preferred oral and nasal spray NSAIDs.
- Ketorolac: Maximum of one claim per 60 days, with a maximum 20 tablets/5-day supply or 126 mg/day for nasal spray (maximum 5-day combined duration of treatment every 60 days).

**Preferred Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the diagnosis funded by the Oregon Health Plan? | **Yes:** Go to #4 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #3. |
| 3. Is there documentation of medical appropriateness and medical necessity?<br><br>Definitions for medical appropriateness include use for an FDA indication AND use, contraindication, or intolerance to preferred agents in the class.<br>Medical necessity includes documentation that the diagnosis impacts the patient's health. | **Yes:** Go to #4 | **No:** Pass to RPh; deny medical appropriateness or medical necessity |
| 4. Is this a request for ketorolac, new or continuation of current therapy (i.e. filled prescription within prior 90 days)? Verify via pharmacy claims. | **Yes:** Document prior therapy in PA record. Go to #5. | **No:** Go to #6 |

| Approval Criteria | | |
|---|---|---|
| 5. Is request for more than a 5-day supply of ketorolac within 60 days (200 mg total over 5 days for tablets, 630 mg total over 5 days for the nasal spray)? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #6 |
| 6. Will the prescriber consider switching to a preferred product?<br><br>Message:<br>• Preferred products do not require PA.<br>• Preferred products are evidence-based and reviewed for comparative effectiveness & safety by the Pharmacy and Therapeutics (P&T) Committee. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Approve for up to 12 months. |

*P&T Review:* *12/22; 2/21 (KS), 3/16 (MH); 11/14; 9/13; 2/12; 9/09; 2/06*
*Implementation:* *1/1/23; 1/1/15, 1/1/14, 5/14/12, 1/1/10*

# Anifrolumab-fnia

**Goal(s):**
- Promote use that is consistent with medical evidence.

**Length of Authorization:**
- Up to 6 months

**Requires PA:**
- Anifrolumab-fnia provider administered and pharmacy claims

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD-10 code. | |
| 2. Is this an FDA approved indication? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Does the patient have severe active central nervous system lupus or severe, active lupus nephritis? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #4 |
| 4. Is this a request for continuation of therapy previously approved by fee-for-service (FFS)? | **Yes**: Go to **Renewal Criteria** | **No:** Go to #5 |
| 5. Is the patient currently on other biologic therapy? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #6 |
| 6. Is the drug being prescribed by or in consultation with a rheumatologist, nephrologist, or a provider with experience treating SLE? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 7. Does the patient have a baseline assessment of SLE disease activity available using one of the following functional assessment tools:<br>• SLE Index Score (SIS)<br>• British Isles Lupus Assessment Group (BILAG)<br>• Systemic Lupus Activity Measure (SLAM)<br>• Systemic Lupus Erythematosus Disease Activity Score (SLEDAI or modified versions, e.g. SLEDAI-2K, SELENA-SLEDAI)<br>• Physicians Global Assessment (PGA)<br>• Systemic Lupus International Collaborating Clinic (SLICC) Damage Index | **Yes:** Go to #8<br>Document baseline assessment _____. | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Is the patient currently taking ALL of the following or have a documented contraindication:<br>• Hydroxychloroquine<br>• Glucocorticoids (e.g. prednisone)<br>• Methotrexate OR Azathioprine OR Mycophenolate | **Yes:** Approve for 6 months. | **No:** Pass to RPh. Deny; medical appropriateness. |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the patient currently on other biologic therapy? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #2 |

| Renewal Criteria | | |
|---|---|---|
| 2. Has the patient's SLE disease activity improved or stabilized as assessed by one of the following functional assessment tools:<br>• SLE Index Score (SIS)<br>• British Isles Lupus Assessment Group (BILAG)<br>• Systemic Lupus Activity Measure (SLAM)<br>• Systemic Lupus Erythematous Disease Activity Score (SLEDAI or modified versions, e.g. SLEDAI-2K, SELENA-SLEDAI)<br>• Physicians Global Assessment (PGA)<br>• Systemic Lupus International Collaborating Clinic (SLICC) Damage Index | **Yes:** Approve for 6 months. | **No:** Pass to RPh; Deny; medical appropriateness. |

*P&T/DUR Review: 2/22 (SF)*
*Implementation: 4/1/22*

# Anticholinergics, Topical

**Goal(s):**
- Promote coverage in evidence-supported conditions and in people with severe symptoms that interfere with daily activities.
- Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Topical anticholinergics (e.g., sofpironium, glycopyrronium)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1.** Topical anticholinergics approved by the FDA

| Drug | Age | Indication |
|---|---|---|
| Glycopyrronium | ≥ 9 years | Primary axillary hyperhidrosis |
| Sofpironium | ≥ 9 years | Primary axillary hyperhidrosis |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for renewal of a product previously approved by FFS? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Is the diagnosis funded by OHP? | **Yes:** Go to #5 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #4. |
| 4. Is there documentation that the diagnosis detrimentally impacts at least one of the following?<br>a. disability or health impairment (e.g., complications, comorbidities, etc)<br>b. age-appropriate growth or development<br>c. independence in self-care or activities of daily living<br>d. ability to live and work in the setting of the patient's choice | **Yes:** Go to #5 | **No:** Pass to RPh; Deny; medical necessity |

| Approval Criteria | | |
|---|---|---|
| 5. Is there documentation of severe symptoms which interfere with daily activities more than once per week as indicated by one of the following:<br>• Hyperhidrosis Disease Severity Scale (HDSS) ≥ 3<br>• Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax) ≥ 3<br>• Axillary Sweating Daily Diary – item 2 (sweating severity) ≥ 4 on a 0-10 point scale<br><br>Note: these same assessments should be evaluated for continuation of treatment. | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical necessity |
| 6. Is this an FDA approved age and indication (**Table 1**)?<br><br>Note: secondary axillary hyperhidrosis related to comorbid conditions and non-axillary hyperhidrosis are not FDA-approved. | **Yes**: Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is the requested product prescribed by, or in consultation with, a dermatologist? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Is there documentation indicating lack of adequate response with non-pharmacologic lifestyle management (e.g., trigger identification and avoidance, clothing modification, use of topical antiperspirants)? | **Yes**: Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Has the patient had lack of benefit, inadequate response, intolerance or contraindication to preferred therapy options for hyperhidrosis (e.g., botulinum toxins)? | **Yes**: Approve for 3 months | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is there documentation of symptom improvement from baseline as assessed by the prescribing provider?<br><br>Note: the following are described as clinically relevant responses to therapy:<br>• Total score ≤ 2 on the Hyperhidrosis Disease Severity Scale (HDSS) or Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax)<br>• ≥ 4 point improvement on the Axillary Sweating Daily Diary – item 2 (a 10 point scale assessing sweating severity) | **Yes**: Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 4/25 (SS)*
*Implementation: 5/12/25*

# Antiemetics

**Goal(s):**
- Promote use of preferred antiemetics.
- Restrict use of costly antiemetic agents for appropriate indications.

**Length of Authorization:**
- Up to 6 months

**Requires PA:**
- Non-preferred drugs (oral and topical) will be subject to PA criteria.

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What is the diagnosis being treated? | Record ICD10 Code. | |
| 2. Will the prescriber consider a change to the preferred product?<br>Message:<br>• Preferred products do not require a PA.<br>• Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&T) Committee. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Go to #3 |
| 3. Is the request for doxylamine/pyridoxine (Diclegis® or Bonjesta) for pregnancy-related nausea or vomiting? | **Yes:** Go to #4 | **No:** Go to #5 |
| 4. Has the patient failed a trial of pyridoxine?<br>Message:<br>• Preferred vitamin B products do not require a PA.<br>• Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&T) Committee. | **Yes:** Approve for up to 3 months | **No:** Pass to RPh; deny and recommend a trial of pyridoxine. |
| 5. Is the request for dronabinol (Marinol®)? | **Yes:** Go to #6 | **No:** Go to #7 |
| 6. Does the patient have anorexia associated with HIV/AIDS? | **Yes:** Approve for up to 6 months.* | **No:** Go to #7 |

| | | |
|---|---|---|
| 7. Does the patient have a cancer diagnosis AND receiving chemotherapy or radiation? | **Yes:** Approve for up to 6 months. | **No:** Go to #8 |
| 8. Does patient have refractory nausea/vomiting that has resulted in hospitalizations or ED visits? | **Yes:** Approve for up to 6 months.* | **No:** Go to #9 |
| 9. Has the patient tried and failed, or have contraindications, to at least 2 preferred antiemetics? | **Yes:** Approve for up to 6 months.* | **No:** Pass to RPh. Deny; medical appropriateness. Must trial at least 2 preferred antiemetics |
| * If the request is for dronabinol (Marinol®) do not exceed 3 doses/day for 2.5 mg and 5 mg strengths and 2 doses/day for the 10 mg strength. | | |

*P&T/DUR Review:* *2/21 (KS); 9/17; 1/17; 1/16; 11/14; 9/09; 2/06; 2/04; 11/03; 9/03; 5/03; 2/03*
*Implementation:* *1/1/18; 4/1/17; 2/12/16; 1/1/15; 1/1/14; 1/1/10; 7/1/06; 3/20/06; 6/30/04; 3/1/04; 6/19/03; 4/1/03*

# Antifungals

**Goal(s):**

- Approve use of antifungals only for OHP-funded diagnoses. Minor fungal infections of skin, such as dermatophytosis and candidiasis are only funded when complicated by an immunocompromised host.
- Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**

- See criteria

**Requires PA:**

- Non-preferred drugs

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1: Examples of FUNDED indications (10/19/23)**

| ICD-10 | Description |
|---|---|
| B37.3 | Candidiasis of vulva and vagina (vaginitis and cervicitis) |
| B37.1 | Candidiasis of the lung |
| B37.7 | Disseminated Candidiasis |
| B37.5-37.6, B37.81-37.84, B37.89-37.90 | Candidiasis of other specified sites |
| B38.0-B38.4, B38.7, B38.9 | Coccidiomycosis various sites |
| B39.0-39.5, B39.9, G02, I32, I39, J17 | Histoplasmosis, subacute meningitis, acute bacterial meningitis |
| B40.9,B41.0, B41.9, B48.0 | Blastomycosis |
| B42.0-42.9,, B43.9, B44.9-45.0, B45.7, B45.9, B46.9, B48.1-48.2, B49 | Rhinosporidiosis, Sporotrichosis, Chromoblastomycosis, Aspergillosis, Mycosis Mycetomas, Cryptococcosis, Allescheriosis, Zygomycosis, Dematiacious Fungal Infection, Mycoses Nec and Nos |
| B48.8 | Mycosis, Opportunistic |
| B44.81 | Bronchopulmonary Aspergillus, Allergic |
| N73.9-75.1, N76.0-N77.1 | Acute inflammatory pelvic disease |
| L03.019,L03.029, L03.039, L03.049 | Cellulitis and abscess of finger and toe |
| P37.5 | Neonatal Candida infection |
| B37.42,B37.49 | Candidiasis of other urogenital sites |
| L30.4 | Severe intertrigo (see HERC guideline note 21 for definition of severe inflammatory skin disease) |

**Table 2: Examples of NON-FUNDED indications (12/16/21)**

| ICD-10 | Description |
|---|---|
| L2.083, L2.10-2.11, L21.8-21.9, | Erythematosquamous dermatosis |
| L22 | Diaper or napkin rash |
| L20.0-20.84, L20.89-20.9 | Other atopic dermatitis and related conditions |
| L24.0-24.2, L25.1-25.5, L57.8, L57.9, | Contact dermatitis and other eczema |

| | |
|---|---|
| L23.0, L23.81, L24.81, L25.0, L25.2, L25.8-25.9, L55.1-55.2 , L56.8, L58.9 | |
| L53.0-53.2, L51.0, L51.8-51.9, L52, L71.0-71.1, L71.8, L93.0, L93.2, L49.0-L49.9, L26, L30.4, L53.8, L92.0, L95.1, L98.2, L53.9 | Erythematous conditions |
| L43.8,L44.1-44.3, L44.9,L66.1 | Lichen Planus |
| L70.0-70.2, L70.8 | Rosacea or acne |
| B36.0 | Pityriasis versicolor |
| B36.2 | Tinea blanca |
| B36.3 | Black piedra |
| B36.8, B36.9 | Mycoses, superficial |
| B37.2 | Cutaneous candidiasis |
| B37.9 | Candidiasis, unspecified |
| R21 | Rash and other nonspecific skin eruption |

**Table 3: Criteria driven diagnoses (1/1/24)**

| ICD-10 | Description |
|---|---|
| B35.0 | Dermatophytosis of scalp and beard (tinea capitis/ tinea barbae) |
| B35.1 | Tinea unguium (onychomycosis) |
| B35.2 | Dermatophytosis of hand (tinea manuum) |
| B35.6 | Dermatophytosis of groin and perianal area (tinea cruris) |
| B353 | Dermatophytosis of foot (tinea pedis) |
| B35.5 | Dermatophytosis of body (tinea corporis / tinea imbricate) |
| B35.8 | Deep seated dermatophytosis |
| B35.8-B35.9 | Dermatophytosis of other specified sites - unspecified site |
| B36.1 | Tinea nigra |
| B37.83 | Candidiasis of mouth |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is the diagnosis funded by OHP? (See examples in Table 1). | **Yes:** Go to #3 | **No:** Go to #8 |
| 3. Is the request for oteseconazole? | **Yes:** Go to #4 | **No:** Go to #7 |
| 4. Does the patient have a diagnosis of recurrent vulvovaginal candidiasis (RVVC) defined as a history of 3 or more episodes of acute vulvovaginal candidiasis (VVC) in the previous 12 months? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 5. Has the patient failed to have benefit with, or have contraindications or intolerance to, a course of oral fluconazole for recurrent vulvovaginal candidiasis? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 6. Is the patient of reproductive potential? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Approve up to 18 capsules for 12 months |
| 7. Will the prescriber consider a change to a preferred product?<br>Message:<br>• Preferred products do not require PA.<br>• Preferred products are evidence-based reviewed for comparative effectiveness and safety. | **Yes:** Inform prescriber of preferred alternatives. | **No:** Approve for 3 months or course of treatment. |
| 8. Is the prescriber a hematology, oncology or infectious disease specialty prescriber requesting voriconazole or posaconazole? | **Yes:** Approve for 3 months or course of treatment. | **No:** Go to #9 |
| 9. Is the diagnosis not funded by OHP? (see examples in Table 2). | **Yes:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #10 | **No:** Go to #10 |
| 10. Is the diagnosis funded by OHP if criteria are met? (see examples in Table 3). | **Yes:** Go to #11 | **No:** Go to #16 |
| 11. Is the patient immunocompromised (examples below)?<br>• Does the patient have a current (not history of) diagnosis of cancer **AND** is currently undergoing Chemotherapy or Radiation? Document therapy and length of treatment. **OR**<br>• Does the patient have a diagnosis of HIV/AIDS? **OR**<br>• Does the patient have sickle cell anemia?<br>• Poor nutrition, elderly or chronically ill?<br>• Other conditions as determined and documented by a RPh. | **Yes:** Record ICD-10 code. Approve as follows: (immunocompromised patient)<br><br>ORAL & TOPICAL<br>• Course of treatment.<br>• If length of therapy is unknown, approve for 3 months. | **No:** Go to #12 |

<table>
<tr><th colspan="3">Approval Criteria</th></tr>
<tr>
<td>12. Is the patient currently taking an immunosuppressive drug? Document drug.<br><br>Pass to RPh for evaluation if drug not in list.<br><br>Immunosuppressive drugs include but are not limited to:
<table>
<tr><td>azathioprine</td><td>leflunomide</td></tr>
<tr><td>basiliximab</td><td>mercaptopurine</td></tr>
<tr><td>cyclophosphamide</td><td>methotrexate</td></tr>
<tr><td>cyclosporine</td><td>mycophenolate</td></tr>
<tr><td>etanercept</td><td>rituximab</td></tr>
<tr><td>everolimus</td><td>sirolimus</td></tr>
<tr><td>hydroxychloroquine</td><td>tacrolimus</td></tr>
<tr><td>infliximab</td><td></td></tr>
</table>
</td>
<td>Yes: Approve as follows: (immunocompromised patient)<br><br>ORAL & TOPICAL<br>• Course of treatment.<br>• If length of therapy is unknown, approve for 3 months.</td>
<td>No: Go to #13</td>
</tr>
<tr>
<td>13. Is the request for treatment of a foot condition and does the member meet criteria for high-risk foot care?<br><br>Antifungals are funded when all of the following criteria are met:<br>1) The patient is at high risk for nail/foot complications due to severe circulatory insufficiency and/or areas of desensitization OR resides in an institutional setting (e.g., skilled nursing/rehabilitation facility, group home, etc)<br>AND<br>2) There is clinical evidence of mycosis of the toenail;<br>AND<br>3) The patient has documented marked limitation of ambulation, pain, and/or secondary bacterial infection resulting from the thickening and dystrophy of the infected toenail plate.</td>
<td>Yes: Approve as follows:<br>ORAL & TOPICAL<br>• Course of treatment.<br>• If length of therapy is unknown, approve for 3 months.</td>
<td>No: If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #14</td>
</tr>
<tr>
<td>14. Is there documentation that the condition is of sufficient severity that it impacts the patient’s health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)?</td>
<td>Yes: Go to #15</td>
<td>No: Pass to RPh. Deny; medical necessity.</td>
</tr>
</table>

| Approval Criteria | | |
|---|---|---|
| 15. Is the request for a preferred product OR has the patient failed to have benefit with, or have contraindications or intolerance to, at least 2 preferred products?<br><br>Message:<br>Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Approve for 12 months. | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Inform prescriber of covered alternatives in class and process appropriate PA. |

16. RPh only: All other indications need to be evaluated to see if it is an OHP-funded diagnosis:

- If funded: may approve for treatment course with PRN renewals. If length of therapy is unknown, approve for 3-month intervals only.
- If not funded:
    - If the member is eligible for EPSDT review, is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)?
        - Is yes, may approve for treatment course with PRN renewals. If length of therapy is unknown, approve for 3-month intervals only.
        - If No, Deny (medical appropriateness)
    - If the member is not eligible for EPSDT, Deny; not funded by the OHP.
        - Deny non-fungal diagnosis (medical appropriateness)
        - Deny fungal ICD-10 codes that do not appear on the OHP list pending a more specific diagnosis code (not funded by the OHP).
        - Forward any fungal ICD-10 codes not found in the Tables 1, 2, or 3 to the Lead Pharmacist. These codes will be forwarded to DMAP to be added to the Tables for future requests.

*P&T Review:* *12/23 (KS);12/22; 2/22; 11/19; 7/15; 09/10; 2/06; 11/05; 9/05; 5/05*
*Implemented:* *1/1/24; 1/1/23; 4/1/22; 5/1/16; 8/15; 1/1/11; 7/1/06; 11/1/0; 9/1/0*

# Antihistamines

**Goals:**

- Approve antihistamines only for conditions funded by the OHP in adults. Allow case-by-case review for members covered under the EPSDT program.
- Allergic rhinitis treatment is covered by the OHP only when complicated by other diagnoses (e.g. asthma, sleep apnea).
- Promote use that is consistent with Oregon Asthma Guidelines and medical evidence. http://public.health.oregon.gov/DiseasesConditions/ChronicDisease/Asthma/Pages/index.aspx

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Non-preferred oral antihistamines and combinations

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Will the prescriber consider a change to a preferred product?<br>Message:<br>• Preferred products do not require a PA.<br>• Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Go to #3 |
| 3. Does patient have a diagnosis of allergic rhinitis, allergic conjunctivitis, or chronic rhinitis/pharyngitis/nasopharyngitis? | **Yes:** Go to #4 | **No:** Go to #8 |
| 4. Does the patient have asthma or reactive airway disease exacerbated by chronic/allergic rhinitis or allergies? | **Yes:** Go to #5 | **No:** Go to #6 |

| Approval Criteria | | |
|---|---|---|
| 5. Does the drug profile show an asthma controller medication (e.g. ORAL corticosteroid, etc.) and/or inhaled rescue beta-agonist (e.g. albuterol, ICS/formoterol) within the last 6 months?<br><br>*Keep in mind: albuterol may not need to be used as often if asthma is controlled on other medications.* | **Yes:** Approve for 6 months | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>*Oregon Asthma guidelines recommend all asthma clients have access to rescue inhalers and those with persistent disease should use anti-inflammatory medicines daily (preferably orally inhaled corticosteroids).* |
| 6. Does patient have other co-morbid conditions or complications that are funded?<br>• Acute or chronic inflammation of the orbit<br>• Chronic Sinusitis<br>• Acute Sinusitis<br>• Sleep apnea<br>• Wegener's Granulomatosis | **Yes:** Document ICD-10 codes. Go to #7 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #10 |
| 7. Does patient have contraindications (e.g. pregnancy), or had insufficient response to available treatment alternatives for the funded condition? Document. | **Yes:** Approve for up to 6 months | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Is the diagnosis COPD or Obstructive Chronic Bronchitis? | **Yes:** Pass to RPh. Deny; medical appropriateness. Antihistamine not indicated. | **No:** Go to #9 |
| 9. Is the diagnosis funded?<br>Note: Chronic Bronchitis, acute upper respiratory infections, and urticarial are not funded by the OHP | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #10 |

| Approval Criteria | | |
|---|---|---|
| 10. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #11 | **No:** Pass to RPh. Deny; medical necessity. |
| 11. Is the request for a preferred product OR has the patient failed to have benefit with, or have contraindications or intolerance to, at least 2 preferred products?<br><br>Message:<br>Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Approve for 12 months. | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Inform prescriber of covered alternatives in class. |

*P&T Review:* *12/22; 5/15 (AG); 9/10; 9/08; 2/06; 9/04; 5/04; 2/02*
*Implementation:* *1/1/23; 5/1/16; 7/15, 1/11, 7/09, 7/06, 3/06, 10/04, 8/02, 9/06*

# Antimigraine – Serotonin Agonists

**Goal(s):**
- Decrease potential for medication overuse headache through quantity limits and therapeutic duplication denials.
- Promote PDL options.

**Length of Authorization:**
- Up to 6 months

**Requires PA:**
- Non-preferred drugs

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Check the Reason for PA:**
- Non-Preferred drugs will deny on initiation
- Preferred drugs will deny only when maximum dose exceeded
- Both will deny for concurrent therapy (concurrent triptans by different routes is allowed)

**Quantity Limits per Labeling.**

| Generic | Brand | Max Daily Dose | Dosage Form | Quantity Limit Per 30 days |
|---|---|---|---|---|
| Almotriptan | Axert | 25 mg | 6.25 mg tab<br>12.5 mg tab | 12 tabs |
| Eletriptan | Relpax | 80 mg | 20 mg tab<br>40 mg tab<br>(blister pack 6, 12) | 6 tabs |
| Frovatriptan | Frova | 7.5 mg | 2.5 mg tab<br>(blister pack 9) | 9 tabs |
| Lasmiditan | Reyvow | 200 mg | 50 mg tab<br>100 mg tab | 8 tabs |
| Naratriptan | Amerge | 5 mg | 1 mg tab<br>2.5 mg tab (blister pack 9) | 9 tabs |
| Rizatriptan | Maxalt<br>Maxalt MLT<br>Rizafilm | 30 mg | 5 mg tab<br>10 mg tab (blister pack 6, 12)<br>10 mg film | 12 tabs |
| Rizatriptan/ meloxicam | Symbravo | 10 mg/ 20 mg | 10 mg/ 20 mg tab | 9 tabs |
| Sumatriptan tablets | Imitrex & generics | 200 mg | 25 mg tab, 50 mg tab,<br>100 mg tab (blister pack 9) | 9 tablets |
| Sumatriptan nasal spray | Imitrex & generics | 40 mg | 5 mg, 10 mg (box of 6) | 18 spray units |
| Sumatriptan nasal powder | Onzetra Xsail | 44 mg | 22 mg (11 mg in each nostril) | 6 nosepieces |
| Sumatriptan injectable | Imitrex & generics | 12 mg | 6 mg/0.5 mL | 6 vials |

| Generic | Brand | Max Daily Dose | Dosage Form | Quantity Limit Per 30 days |
|---|---|---|---|---|
| Sumatriptan injectable | Sumavel | 12 mg | 6 mg/0.5 mL units (package of 6) | 6 jet injectors |
| Sumatriptan injectable | Zembrace Symtouch | 12 mg | 3 mg/0.5 mL (package of 4) | 12 auto-injectors |
| Sumatriptan /naproxen | Treximet | 170/1000 mg (2 tablets) | 85/500 mg tab (box of 9) | 9 tablets |
| Zolmitriptan | Zomig,Zomig ZMT & generics | 10 mg | 2.5 mg tab and ODT<br>5 mg tab and ODT<br>(blister pack, 3, 6) | 6 tabs |
| Zolmitriptan nasal spray | Zomig NS | 10 mg | 5 mg (box of 6) | 3 packages (18 spray units) |

Abbreviations: d = days; MR = may repeat; NS = nasal spray; PO = orally

## Approval Criteria

| | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Does the patient have a diagnosis of migraine headaches? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is requested drug a preferred product? | **Yes:** Go to #5 | **No:** Go to #4 |
| 4. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products do not require PA within recommended dose limits.<br>• Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Inform prescriber of covered alternatives in class and dose limits. | **No:** Go to #5 |

| Approval Criteria | | |
|---|---|---|
| 5. Is request for a higher dose than listed in quantity limit chart? | **Yes:** Pass to RPh. Deny; medical appropriateness.<br><br>• May recommend use of migraine prophylactic therapy and reinforce that doses above those recommended by the manufacturer increase the incidence of medication overuse headache.<br>• One lifetime 90-day taper may be approved at pharmacist's discretion.<br>• Document. | **No:** Trouble-shoot claim payment (e.g., days' supply?).<br><br>Go to #6. |
| 6. Is the request for lasmiditan? | **Yes:** Go to #9 | **No:** Go to #7 |
| 7. Is the request for two different oral triptans concurrently? | **Yes:** Go to #8 | **No:** Approve for 6 months |
| 8. Is this a switch in triptan therapy due to intolerance, allergy or ineffectiveness? | **Yes:** Document reason for switch and override for concurrent use for 30 days. | **No:** Pass to RPh. Deny; medical appropriateness. |
| 9. Has the patient tried two triptan products or have a contraindication to triptans? | **Yes:** Approve for 6 months | **No:** Pass to RPh. Deny; medical appropriateness. Recommend triptan trial. |

*P&T Review:* *8/20 (KS), 5/19; 3/16; 3/10; 9/09; 11/03; 5/03*
*Implementation:* *9/1/20; 5/1/16, 3/23/10; 1/1/10; 7/1/06; 5/31/05; 6/30/04*

# Antipsychotics in Children

**Goal(s):**
- Ensure safe and appropriate use of antipsychotics in children
- Discourage off-label use not supported by compendia

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Antipsychotic use beyond 60 days in children 3-6 years of age
- All antipsychotic use in children 2 years of age or younger
- For quetiapine requests in children ≥7 years of age, see criteria for Low Dose Quetiapine

Note: olanzapine can be automatically approved in patients with a recent cancer diagnosis

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. FDA-Approved Indications and Ages for Oral Second-generation Antipsychotics in Children**

| FDA-Approved Indications and Ages | | | | |
|---|---|---|---|---|
| **Drug** | **Schizophrenia** | **Bipolar I disorder** | **Major depressive disorder (adjunct)** | **Other** |
| aripiprazole | ≥13 yrs | ≥10 yrs | ≥18 yrs | Irritability associated with Autistic Disorder ≥6 yrs<br>Tourette's Disorder ≥6 yrs |
| asenapine maleate | ≥18 yrs | ≥10 yrs | | |
| brexpiprazole | ≥13 yrs | | | |
| lurasidone HCl | ≥13 yrs | ≥10 yrs | | |
| olanzapine | ≥13 yrs | ≥13 yrs | ≥18 yrs | |
| paliperidone | ≥12 yrs | | | Schizoaffective disorder ≥18 yrs |
| quetiapine fumarate | ≥13 yrs | ≥10 yrs | | Bipolar depression ≥18 yrs |
| risperidone | ≥13 yrs | ≥10 yrs | | Irritability associated with Autistic Disorder ≥5 yrs |

| **Approval Criteria** | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for use of olanzapine as an antiemetic associated with cancer or chemotherapy? | **Yes:** Approve for 12 months | **No:** Go to #3 |
| 3. Has the patient been screened for diabetes (blood glucose or A1C) within the last 12 months? | **Yes:** Go to #5 | **No:** Go to #4 |

| Approval Criteria | | |
|---|---|---|
| 4. Is there documented clinical rationale for lack of metabolic monitoring (e.g. combative behaviors requiring sedation) OR documentation of patient weight before and after initiation of treatment?<br><br>Note: Caregivers failing to take patients to the laboratory is not a clinical rationale for lack of monitoring. | **Yes:** Document rationale. Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Annual metabolic screening or consistent evaluation for rapid weight gain is required for chronic use of antipsychotics. Refer denied requests to the OHA for follow-up. |
| 5. Is the patient engaged in, been referred for, or have documented inability to access evidence based first-line non-pharmacological therapy (e.g., applied behavior analysis therapy for autism, parent behavioral therapy, or parent child interaction therapy)? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Refer denied requests to the OHA for follow-up. |
| 6. Is the drug prescribed by or in consultation with a child psychiatrist or developmental pediatrician? | **Yes:** Approve for up to 12 months or length of therapy, whichever is less | **No:** Go to #7 |

| Approval Criteria | | |
|---|---|---|
| 7. Is there detailed documentation regarding risk/benefit assessment and the decision to prescribe antipsychotic therapy?<br><br>A thorough assessment should include ALL the following:<br>a. Multidisciplinary review including a mental health specialist<br>b. Mental health assessment including documentation of diagnoses, symptoms, and disease severity<br>c. Discussion and consideration of first-line non-pharmacological therapies<br>d. Assessment of antipsychotic risks and monitoring strategies<br>e. Specific therapeutic goals of antipsychotic therapy, and for ongoing therapy, discussion of progress toward or achievement of therapeutic goals (or reasons for lack of progress and remediation strategies)<br>f. Anticipated duration of therapy<br>g. Detailed follow-up plan | **Yes:** Approve for up to 12 months or length of therapy, whichever is less | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Refer denied requests to the OHA for follow-up. |

*P&T/DUR Review: 8/25; 2/24 (SS); 6/21*
*Implementation: 4/1/24; 10/1/22*

# Antivirals for Herpes Simplex Virus

**Goal(s):**
- Cover oral and/or topical antivirals only for funded diagnoses. HSV infections are funded only when complicated by an immunocompromised host.
- Support individual review under the EPSDT benefit.

**Length of Authorization:**
- Up to 12 months (criteria specific)

**Requires PA:**
- Non-preferred drugs

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products do not require a PA.<br>• Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Go to #3 |
| 3. Is the diagnosis uncomplicated herpes simplex virus infection? | **Yes:** Go to #4 | **No:** Go to #6 |
| 4. Pass to RPh: Is the patient immunocompromised (document ICD10 code)? Examples:<br>• Diagnosis of cancer AND currently undergoing chemotherapy or radiation. Document therapy and length of treatment.<br>• Solid organ transplant<br>• HIV/AIDS | **Yes:** Approve for up to 12 months | **No:** Go to #5 |

| Approval Criteria | | |
|---|---|---|
| 5. Is the patient currently taking an immunosuppressive drug?<br><br>Document name of drug. If is drug not in the list below, pass to RPh for evaluation. Immunosuppressive drugs include, but are not limited to:<br><br>**Immunosuppressants**<br>Abatacept<br>Adalimumab<br>Anakinra<br>Apremilast<br>Azathioprine<br>Basiliximab<br>Certolizumab pegol<br>Cyclosporine<br>Etanercept<br>Golimumab<br>Hydroxychloroquine<br>Infliximab<br>Leflunomide<br>Methotrexate<br>Natalizumab<br>Rituximab<br>Secukinumab<br>Sirolimus<br>Tacrolimus<br>Tocilizumab<br>Tofacitinib<br>Ustekinumab<br>Vedolizumab | **Yes:** Approve for up to 90 days | **No:** Pass to RPh. Go to #6. |
| 6. RPh only: All other indications need to be evaluated as to whether they are an OHP-funded condition.<br><br>Note: Viral ICD-10 codes that do not appear on the OHP funding list pending a more specific diagnosis code should be treated as not funded by the OHP. | If funded and clinic provides supporting literature, approve for length of therapy or 3 months whichever is less.<br><br>Note: deny non-viral diagnoses (medical appropriateness) | Non-funded and not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #7. |
| 7. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** If clinic provides supporting literature, approve for length of therapy or 3 months whichever is less.<br><br>Note: deny non-viral diagnoses (medical appropriateness) | **No:** Pass to RPh. Deny; medical necessity. |

*P&T Review:* *9/19 (KS), 7/16 (KS); 1/14; 1/12; 9/10 (KS)*
*Implementation:* *8/16; 1/1/11*

# Antivirals - Influenza

**Goal:**

- Restrict use of extended prophylactic influenza antiviral therapy to high-risk populations recognized by the Centers for Disease Control and Prevention (CDC) and Infectious Diseases Society of America (IDSA).

**Length of Authorization:**

- Up to 30 days

**Requires PA:**

- Non-preferred drugs
- Oseltamivir therapy for greater than 7 days

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the antiviral agent to be used to treat a current influenza infection? | **Yes:** Go to #3 | **No:** Go to #4 |
| 3. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products do not require PA<br>• Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Inform prescriber of covered alternatives in class and approve for length of therapy or 5 days, whichever is less. | **No:** Approve based on standard FDA or compendia-supported dosing for influenza treatment.<br><br>Note: baloxavir and peramivir are FDA approved as a single dose for treatment of influenza. |
| 4. Is the antiviral prescribed oseltamivir, zanamivir, or baloxavir? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 5. Is the request for post-exposure chemoprophylaxis AND does the patient have any of the following CDC[1] and IDSA[2] criteria that may place them at increased risk for complications?<br>• Persons at high risk of influenza complications during the first 2 weeks following vaccination after exposure to an infectious person (6 weeks in children not previously vaccinated and require 2 doses of vaccine).<br>• Persons with severe immune deficiencies or others who might not respond to influenza vaccination, such as persons receiving immunosuppressive medications, after exposure to an infectious person.<br>• Persons at high risk for complications from influenza who cannot receive influenza vaccine after exposure to an infectious person.<br>• Residents of institutions, such as long-term care facilities, during influenza outbreaks in the institution.<br>• Pregnancy and individuals up to 2 weeks postpartum (including after pregnancy loss) who have been in close contact with someone suspected or confirmed of having influenza. | **Yes:** Approve for duration of prophylaxis or 30 days, whichever is less.<br><br>Current recommended duration of prophylaxis: 7 days (after last known exposure; minimum 2 weeks to control outbreaks in institutional settings and hospitals, and continue up to 1 week after last known exposure. | **No:** Go to #6 |

| Approval Criteria | | |
|---|---|---|
| 6. Is the request for pre-exposure prophylaxis with oseltamivir or zanamivir AND does the patient meet IDSA[2] criteria that would qualify for prophylaxis for duration of season?<br>a. Adults and children aged ≥3 months who are at very high risk of developing complications from influenza and for whom influenza vaccination is contraindicated, unavailable, or expected to have low effectiveness (eg, persons who are severely immunocompromised).<br>b. Adults and children aged ≥3 months who have the highest risk of influenza-associated complications, such as recipients of hematopoietic stem cell transplant in the first 6–12 months posttransplant and lung transplant recipients. | **Yes:** Approve for duration of prophylaxis or 9 months, whichever is less. | **No:** Pass to RPh. Deny; medical appropriateness. |

References:
1.Centers for Disease Control and Prevention. Influenza Antiviral Medications: Summary for Clinicians. Last reviewed Sept 9, 2022. https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm. Accessed October 11, 2022.
2. Uyeki TM, Bernstein HH, Bradley JS, et al. Clinical Practice Guidelines by the Infectious Diseases Society of America: 2018 Update on Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management of Seasonal Influenzaa. *Clin Infect Dis.* 2019;68(6):e1-e47.

*P&T/DUR Review:* *12/22 (SF); 1/19 (SS); 1/16; 1/12; 9/10*
*Implementation:* *1/1/23; 3/1/19; 4/1/18; 10/13/16; 2/12/16; 1/11*

# Aprocitentan (Tryvio)

**Goal(s):**
- To ensure medication use for FDA-approved indications supported by literature.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- aprocitentan

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is there a diagnosis of resistant hypertension?<br><br>NOTE: Resistant hypertension is defined as not achieving target blood pressure despite treatment with at least 3 antihypertensive medications from different classes for an adequate duration (~ 4 weeks) at maximally tolerated doses. | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the patient on concomitant therapy with at least three other antihypertensive agents at maximally tolerated doses, including the following:<br>a. Blocker of the renin-angiotensin system (angiotensin-converting enzyme [ACE] inhibitor or angiotensin II receptor locker [ARB])<br>b. Calcium channel blocker<br>c. Thiazide or thiazide-like diuretic | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 4. Does the patient meet ONE of the following:<br>a. Is currently taking a mineralocorticoid receptor antagonist (MRA) (e.g. spironolactone, eplerenone), with at least three other antihypertensive medications; OR<br>b. Has had an inadequate treatment response in blood pressure to an MRA; OR<br>c. Has an intolerance or contraindication to an MRA | **Yes:** Approve for 6 months | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 4/2025 (MH)*
*Implementation: 5/12/25*

# Attention Deficit Hyperactivity Disorder (ADHD) Safety Edit

**Goals:**

- Cover medications used for ADHD and narcolepsy if diagnosis is funded by the OHP, and medication use is consistent with best practices.
- Promote care by a psychiatrist for patients requiring therapy outside of best practices.
- Promote preferred drugs in class.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Non-preferred drugs on the enforceable preferred drug list.
- Regimens prescribed outside of standard doses and age range (Tables 1 and 2)
- Non-standard polypharmacy (Table 3)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. Age Range and Maximum Daily Doses for Drugs Approved for ADHD.**

| Drug | Brand Name (or generic equivalents) | Min Age | Max Age | Max Daily Dose |
|---|---|---|---|---|
| **STIMULANTS** | | | | |
| Amphetamine IR | Evekeo (tab) | 3 | NA | 40 mg |
| | Evekeo ODT (dist tab) | 3 | NA | 40 mg |
| Amphetamine ER | Adsensys ER (susp) and XR-ODT (tab) | 6 | 12 | 18.8 |
| | | 13 | NA | 12.5 mg |
| | Dyanavel XR (susp, tab) | 6 | NA | 20 mg |
| Dextroamphetamine IR | ProCentra (sol) | 3 | 16 | 40 mg |
| | Zenzedi (tab) | 3 | 16 | 40 mg |
| Dextroamphetamine ER | Dexedrine Spansule (cap) | 6 | 16 | 40 mg |
| | Xelstrym (transdermal patch) | 6 | NA | 18 mg/9 hour |
| Dextroamphetamine/ amphetamine salts IR | Adderall (tab) | 3 | NA | 40 mg |
| Dextroamphetamine/ amphetamine salts ER | Adderall XR (cap) | 6 | 12 | 30 mg |
| | | 13 | NA | 60 mg |
| | Mydayis (cap) | 13 | 17 | 25 mg |
| | | 18 | 55 | 50 mg |
| Dexmethylphenidate IR | Focalin (tab) | 6 | 17 | 20 mg |
| Dexmethylphenidate ER | Focalin XR (cap) | 6 | 17 | 30 mg |
| | | 18 | NA | 40 mg |
| Lisdexamfetamine | Vyvanse (cap; chew tab) | 6 | NA | 70 mg |
| Methamphetamine IR | Desoxyn (tab) | 6 | 17 | 25 mg |
| Methylphenidate IR | Methylin (sol) | 6 | NA | 60 mg |
| | Ritalin (tab) | 6 | NA | 60 mg |
| Methylphenidate ER | Adhansia XR (cap) | 6 | 17 | 85 mg |
| | | 18 | NA | 100 mg |
| | Aptensio XR (cap) | 6 | NA | 60 mg |
| | Concerta (tab) | 6 | 12 | 54 mg |
| | | 13 | 65 | 72 mg |
| | Cotempla XR-ODT (tab) | 6 | 17 | 51.8 mg |

| | | | | |
|---|---|---|---|---|
| | Daytrana (transdermal patch) | 6 | 17 | 30 mg/9 hour |
| | Jornay PM (cap) | 6 | NA | 100 mg |
| | Metadate CD (tab) | 6 | NA | 60 mg |
| | QuilliChew ER (chew tab) | 6 | NA | 60 mg |
| | Quillivant XR (susp) | 6 | NA | 60 mg |
| | Relexxi (tab) | 6 | 12 | 54 mg |
| | | 13 | 65 | 72 mg |
| | Ritalin LA (cap) | 6 | NA | 60 mg |
| Serdexmethylphenidate/ dexmethylphenidate | Azstarys (cap) | 6 | NA | 52.3 mg/10.4 mg |
| **NON-STIMULANTS** | | | | |
| Atomoxetine | Strattera (cap) | 6 | 17 | ≤70 kg: lesser of 1.4 mg/kg or 100 mg<br>>70 kg: 100 mg |
| | | 18 | NA | 100 mg |
| Clonidine ER | Kapvay (tab) | NA | NA | NA |
| | Onyda XR (susp) | 6 | NA | 0.4 mg |
| Guanfacine ER | Intuniv (tab) | NA | NA | NA |
| Viloxazine ER | Qelbree (cap) | 6 | 17 | 400 mg |
| | | 18 | NA | 600 mg |
| **Abbreviations:** cap = capsule; chew = chewable; dist = disintegrating; ER = extended-release formulation; IR = immediate-release formulation; NA = not applicable; sol = solution; susp = suspension; tab = tablet. | | | | |

**Table 2. Age Range and Maximum Daily Doses for Drugs Approved for Narcolepsy.**

| Drug | Brand Name (or generic equivalents) | Min Age | Max Age | Max Daily Dose |
|---|---|---|---|---|
| **STIMULANTS** | | | | |
| Amphetamine IR | Evekeo (tab) | 6 | 12 | 40 mg |
| | | 13 | NA | 60 mg |
| Dextroamphetamine IR | ProCentra (sol) | 3 | 17 | 40 mg |
| | | 18 | NA | 60 mg |
| | Zenzedi (tab) | 3 | 17 | 40 mg |
| | | 18 | NA | 60 mg |
| Dextroamphetamine ER | Dexedrine (cap) | 6 | 17 | 40 mg |
| | | 18 | NA | 60 mg |
| Dextroamphetamine/amphetamine salts IR | Adderall (tab) | 6 | 17 | 40 mg |
| | | 18 | NA | 60 mg |
| Methylphenidate IR | Methylin (sol) | 6 | NA | 60 mg |
| | Ritalin (tab) | 6 | NA | 60 mg |
| Methylphenidate ER | Ritalin LA (cap) | 6 | 12 | 60 mg |
| **Abbreviations:** cap = capsule; ER = extended-release formulation; IR = immediate-release formulation; NA = not applicable; sol = solution; tab = tablet. | | | | |

**Table 3. Standard Combination Therapy for ADHD**

| Age Group | Standard Combination Therapy |
|---|---|
| **Age <6 years** | **Combination therapy not recommended*** |
| **Age 6-17 years** | **1 Stimulant Formulation (ER or IR) + Guanfacine ER*<br>1 Stimulant Formulation (ER or IR) + Clonidine ER*** |
| **Age ≥18 years** | **Combination therapy not recommended**** |

Abbreviations: ER = extended-release; IR = immediate-release formulation.

* Recommended by the American Academy of Pediatrics. Wolraich ML, Hagan JF, Jr., Allan C, et al. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics. 2019;144(4).
**Identified by: Pharmacologic Treatments for Attention Deficit Hyperactivity Disorder: Drug Effectiveness Review Project, 2015.

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the drug being used to treat an OHP-funded condition? | **Yes:** Go to #3 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: go to #13. |
| 3. Is the requested for a preferred drug? | **Yes:** Go to #5 | **No:** Go to #4 |
| 4. Will the prescriber consider a change to a preferred agent?<br><br>Preferred drugs reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Inform prescriber of preferred alternatives | **No:** Go to #5 |
| 5. Is the request for an ADHD diagnosis? | **Yes:** Go to #6 | **No:** Go to #9 |
| 6. Are the patient's age and the prescribed dose within the limits defined in Table 1? | **Yes:** Go to #7 | **No:** Go to #11 |
| 7. Is the prescribed drug the only stimulant or non-stimulant filled in the last 30 days? | **Yes:** Approve for up to 12 months | **No:** Go to #8 |
| 8. Is the multi-drug regimen a standard combination therapy, as defined in Table 3? | **Yes:** Approve for up to 12 months | **No:** Go to #11 |
| 9. Is the request for a narcolepsy diagnosis? | **Yes:** Go to #10 | **No**: Pass to RPh. Deny; medical appropriateness. |
| 10. Are the patient's age and the prescribed dose within the limits defined in Table 2? | **Yes:** Approve for up to 12 months | **No:** Go to #11 |
| 11. Was the drug regimen developed by or in consultation with a relevant specialist (e.g., psychiatrist, developmental pediatrician, psychiatric nurse practitioner, sleep specialist, pulmonologist, or neurologist)? | **Yes:** Document name and contact information of consulting provider and approve for up to 12 months | **No:** Go to #12 |

| Approval Criteria | | |
|---|---|---|
| 12. Was the current drug regimen *initiated* at doses and ages recommended in Tables 1-3 and has the provider assessed ongoing need for treatment in the past year? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Ages or doses exceeding defined limits, or non-recommended multi-drug regimens, are only approved when prescribed by or in consultation with a mental health specialist. Specialist consultation is not required if patients age into a maximum age limit.<br><br>May approve continuation of existing therapy once up to 90 days to allow time to consult with a mental health specialist. |
| 13. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #14 | **No:** Pass to RPh. Deny; medical necessity. |
| 14. Is the request for an FDA-approved indication? | **Yes:** Go to #15 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 15. Is the request for a preferred product OR has the patient failed to have benefit with, or have contraindications or intolerance to, at least 2 preferred products?<br><br>Message: Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Approve for 12 months. | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Inform prescriber of covered alternatives in class and process appropriate PA. |

*P&T Review: 12/24 (DM); 6/24(SS); 10/22; 6/22; 8/20; 5/19; 9/18; 5/16; 3/16; 5/14; 9/09; 12/08; 2/06; 11/05; 9/05; 5/05; 2/01; 9/00; 5/00*
*Implementation: 7/1/24; 11/1/2018; 10/13/16; 7/1/16; 10/9/14; 1/1/15; 9/27/14; 1/1/10; 7/1/06; 2/23/06; 11/15/05*

# Becaplermin (Regranex®)

**Goal(s):**
- Restrict to indications supported by the medical literature.

**Length of Authorization:**
- Up to 6 months

**Requires PA:**
- Becaplermin topical gel (Regranex®)

**Covered Alternatives:**
- No preferred alternatives

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Does the patient have an ulcer(s) (ICD10 E0842; E0942; E1042; E1142; E1342; L97109; L97209; L97309; L97409; L97509; L97809; L98419; L98429; L98499)? | **Yes:** Go to #3. | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Does the patient have diabetes mellitus? | **Yes**: Approve ONLY 15 grams for 6-month supply. | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T/DUR Review:* *09/15 (AG)*
*Implementation:* *10/15*

# Belimumab (Benlysta®)

**Goal(s):**
- Promote use that is consistent with national clinical practice guidelines and medical evidence.

**Length of Authorization:**
- 6 months

**Requires PA:**
- Benlysta® (belimumab) pharmacy or provider administered claims.

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1: FDA approved ages

| Indication | Approved formulation | |
|---|---|---|
| | **Intravenous (IV) powder for solution** | **Subcutaneous (SC) Injection** |
| **Systemic Lupus Erythematosus (SLE)** | 5 years and older | 5 years and older |
| **Lupus Nephritis** | 5 years and older | 5 years and older |
| **IV** (usual adult dosage): **SLE or Lupus Nephritis:** 10 mg/kg IV infusion over 1 hour every 2 weeks for the first 3 doses, then every 4 weeks thereafter<br>**SC** (usual adult dosage): **SLE**: 200 mg SC once weekly<br>**Lupus Nephritis**:400 mg (two 200-mg injections) SC once weekly into abdomen or thigh for 4 doses, then 200 mg SC once weekly thereafter | | |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD-10 code. | |
| 2. Does the patient have severe active central nervous system lupus? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #3 |
| 3. Is this a request for continuation of therapy previously approved by fee-for-service (FFS)? | **Yes**: Go to **Renewal Criteria** | **No:** Go to #4 |
| 4. Is the patient diagnosed with lupus nephritis or systemic lupus erythematosus (SLE)? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 5. Is belimumab dosed appropriately and with an approved formulation for patient's age as outlined in Table 1? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is the patient currently on other targeted immune modulators? | **Yes:** Pass to RPh. Deny; medical appropriateness. Belimumab has not been studied in combination with other targeted immune modulators | **No:** Go to #7 |
| 7. Is the drug being prescribed by or in consultation with a rheumatologist, nephrologist, or a provider with experience treating SLE or lupus nephritis? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Does the patient have active autoantibody-positive SLE or lupus nephritis and is a baseline assessment of SLE disease activity available using one of the following functional assessment tools:<br>• SLE Index Score (SIS)<br>• British Isles Lupus Assessment Group (BILAG)<br>• Systemic Lupus Activity Measure (SLAM)<br>• Systemic Lupus Erythematosus Disease Activity Score (SLEDAI or modified versions, e.g. SLEDAI-2K, SELENA-SLEDAI)<br>• Physicians Global Assessment (PGA)<br>• Systemic Lupus International Collaborating Clinic (SLICC) Damage Index<br>• Urinary protein to creatinine ratio<br>• Most recent estimated Glomerular Filtration Rate (eGFR) | **Yes:** Go to #9<br>Document baseline assessment _____. | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Is the patient currently taking or have a contraindication to BOTH of the following:<br>• Hydroxychloroquine<br>• Glucocorticoids (e.g. prednisone) | **Yes:** Go to #10 | **No:** Pass to RPh. Deny; medical appropriateness. Belimumab has not been studied as monotherapy in patients with SLE. |

| Approval Criteria | | |
|---|---|---|
| 10. Does the patient have lupus nephritis AND a urine protein: creatinine ratio of >500 mg/g? | **Yes:** Go to #11 | **No:** Approve for 6 months |
| 11. Is the patient currently taking, or have a contraindication to, either an angiotensin-converting enzyme inhibitor (ACEI) OR an angiotensin II receptor blocker (ARB)? | **Yes:** Approve for 6 months | **No:** Pass to RPh. Deny; medical appropriateness. |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the patient currently on another therapeutic immune modulator?<br>Note: Belimumab has not been studied in combination with other therapeutic immune modulators. | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #2 |
| 2. Has the patient's SLE disease activity improved or stabilized as assessed by one of the following functional assessment tools:<br>• SLE Index Score (SIS)<br>• British Isles Lupus Assessment Group (BILAG)<br>• Systemic Lupus Activity Measure (SLAM)<br>• Systemic Lupus Erythematous Disease Activity Score (SLEDAI or modified versions, e.g. SLEDAI-2K, SELENA-SLEDAI)<br>• Physicians Global Assessment (PGA)<br>• Systemic Lupus International Collaborating Clinic (SLICC) Damage Index<br>• Urinary protein to creatinine ratio<br>• eGFR | **Yes:** Approve for 6 months. | **No:** Pass to RPh; Deny; medical appropriateness. |

*P&T/DUR Review:* *02/22 (SF); 8/21 (DM) 2/20, 5/18*
*Implementation:* *4/1/22; 3/1/2020; 7/1/18*

# Bempedoic Acid

**Goal(s):**
- Promote use of bempedoic acid that is consistent with medical evidence.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Bempedoic Acid (Nexletol™)
- Bempedoic acid and ezetimibe (Nexlizet™)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code; go to #2 | |
| 2. Does the patient have clinical atherosclerotic cardiovascular disease (ASCVD), defined as documented history of one or more ASCVD events (see below) **OR** a diagnosis of homozygous or heterozygous familial hypercholesterolemia (HeFH or HoFH) OR at high risk for CVD, including those with:<br>• Diabetes mellitus<br>OR<br>• 10-year ASCVD risk of 10% or greater?<br><br>Major ASCVD events<br>• Recent ACS (within past 12 months)<br>• History of MI (other than recent ACS from above)<br>• History of ischemic stroke<br>• Symptomatic peripheral artery disease<br>• Coronary artery disease | **Yes:** Go to #3 | **No:** Pass to RPh; deny for medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 3. Has the patient taken a daily high-intensity statin (see table below) for at least 3 months with a LDL-C still ≥ 70 mg/dl with ASCVD or ≥ 100 mg/dl with HeFH or HoFH or high-risk CVD?<br><br>Prescriber to submit chart documentation of:<br>1) Doses and dates initiated of statin<br>2) Baseline LDL-C (untreated)<br>3) Recent LDL-C | **Yes:** Confirm documentation; go to #5<br><br>1. Statin:<br>Dose:<br>Date Initiated:<br><br>Baseline LDL-C _____<br>Date:_____<br><br>Recent LDL-C _____<br>Date:_____ | **No:** Go to #4 |
| 4. Does the patient have a history of:<br>• rhabdomyolysis caused by a statin, OR<br>• a history of creatinine kinase (CK) levels >10-times upper limit of normal with muscle symptoms determined to be caused by a statin, OR<br>• statin intolerance, defined as one or more adverse effects associated with statin therapy that improves with dose reduction or discontinuation and a trial of at least 2 statin medications at the lowest approved daily dose?<br><br>Note: Prescriber must provide chart documentation of diagnosis or CK levels. A recent LDL-C level (within last 12 weeks) must also be submitted. | **Yes:** Confirm chart documentation of diagnosis or labs and go to #5<br><br>1. Statin #1:<br>Dose:<br>Date Initiated:<br><br>2. Statin #2<br>Dose:<br>Date Initiated:<br><br>Recent LDL-C _____<br>Date: _____ | **No:** Pass to RPh; deny for medical appropriateness |
| 5. Has the patient taken ezetimibe 10 mg daily for at least 3 months and still requires additional LDL-C lowering (LDL-C still ≥ 70 mg/dl with ASCVD or ≥ 100 mg/dl with HeFH or HoFH or high-risk CVD), **OR** have a contraindication to ezetimibe? | **Yes:** Go to #6 | **No:** Pass to RPH; deny for medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 6. Is the patient adherent with a high-intensity statin and/or ezetimibe? | **Yes:** Approve for up to 12 months<br><br>Note: pharmacy profile may be reviewed to verify >80% adherence (both lipid-lowering prescriptions refilled 5 months' supply in last 6 months) | **No:** Pass to RPh; deny for medical appropriateness |

**High- and Moderate-intensity Statins.**

| **High-intensity Statins** (≥50% LDL-C Reduction) | **Moderate-intensity Statins** (30 to <50% LDL-C Reduction) | |
|---|---|---|
| Atorvastatin 40-80 mg<br>Rosuvastatin 20-40 mg | Atorvastatin 10-20 mg<br>Fluvastatin 80 mg<br>Lovastatin 40-80 mg | Pitavastatin 1-4 mg<br>Pravastatin 40-80 mg<br>Simvastatin 20-40 mg<br>Rosuvastatin 5-10 mg |

*P&T / DUR Review:* *12/23 (MH), 08/20 (MH)*
*Implementation:* *1/1/24; 9/1/20*

# Benign Prostatic Hypertrophy (BPH) Medications

**Goal(s):**

- BPH with urinary obstruction is an OHP-funded treatment. BPH without obstruction is not a funded diagnosis.
- Restrict use for male pattern baldness and erectile dysfunction, which are not OHP-covered conditions.
- Allow case-by-case review for members covered under the EPSDT program for unfunded diagnoses.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Non-preferred drugs

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Will the prescriber consider switching to a preferred product?<br><br>Message:<br>• Preferred products do not require a PA.<br>• Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Go to #3 |
| 3. Is the request for an alpha-1 blocker? | **Yes:** Go to #4 | **No:** Go to #6 |
| 4. Does the patient have a diagnosis related to functional and mechanical disorders of the genitourinary system including bladder outlet obstruction? | **Yes:** Go to #5 | **No:** Go to #6 |
| 5. Has the patient tried and not tolerated or not obtained the desired treatment effect on a 2-month trial of a preferred alpha-1 blocker? | **Yes:** Approve an alpha-1 blocker for up to 12 months | **No:** Pass to RPh. Deny until patient has tried and failed a covered alternative |

| Approval Criteria | | |
|---|---|---|
| 6. Does the patient have a diagnosis of benign prostatic hyperplasia (BPH) or enlarged prostate with obstruction? | **Yes:** Approve for up to 12 months | **No:** Go to #7 |
| 7. Does the patient have a diagnosis of unspecified urinary obstruction or BPH without obstruction? | **Yes:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #8 "Not Funded" section. | **No:** Pass to RPh. Go to #8 |

8. RPh Only: All other conditions need to be evaluated to see if diagnosis is funded:

   **Funded:** covered diagnoses related to prostate may be approved for 1 year.
   **Not Funded:**
   - Unfunded diagnoses for patients with an EPSDT benefit should be reviewed for medical appropriateness/necessity under the EPSDT program
     - Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.)?
     - Is the request for a preferred product OR has the patient failed to have benefit with, or have contraindications or intolerance to, at least 2 preferred products?
     - If patient qualifies for EPSDT benefit and clinic provides supporting literature, approve for up to 12 months.
   - Unfunded diagnoses for people without an EPSDT benefit should be denied (not funded by the OHP).

   **Not Covered:** Cosmetic and uncovered diagnoses (e.g., hair growth, erectile dysfunction) should be denied (not covered by the OHP).
   - Alpha-1 blockers and 5-alpha reductase inhibitors may be used concurrently for BPH up to 1 year. Alpha-1 blockers may be discontinued once prostate is reduced to normal size.
   - If urine retention (obstructive), ask for more specific diagnosis.

*P&T Review:* *8/23 (KS); 7/16; 11/12; 9/10; 3/10; 5/08; 2/06*
*Implementation:* *9/1/23; 8/16, 2/21/13; 1/1/11; 4/20/10; 5/22/08; 7/1/06; 9/30/05*

# Benzodiazepines

**Goal(s):**

- Approve only for OHP-funded diagnoses.
- Prevent inappropriate long-term benzodiazepine use beyond 4 weeks for new starts (no history within the last 120 days).
- Approve long-term use only for indications supported by the medical literature.

**Length of Authorization:**

- 1 month to 12 months (criteria-specific)

**Requires PA:**

- All benzodiazepines used beyond 4 weeks. Short-term use does not require PA.

Note: Benzodiazepines indicated for seizure rescue (routes: rectal, nasal, buccal) are subject to the Non-preferred Drugs in PDL classes criteria

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Does the patient have a malignant neoplasm or other end-of-life diagnosis (ICD10 C00.xx-D49.xx or Z51.5)? | **Yes:** Approve for 12 months | **No:** Go to #3 |
| 3. Is the diagnosis an OHP-funded diagnosis? | **Yes:** Go to #4 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #5 |
| 4. Does the patient have a seizure disorder diagnosis or is the patient enrolled in a program for short-term outpatient management of alcohol withdrawal syndrome?<br><br>Note: benzodiazepines are not indicated for alcohol dependence. | **Yes:** Approve for 12 months for seizure disorder or up to 1 month for alcohol withdrawal | **No:** Go to #5 |

| Approval Criteria | | |
|---|---|---|
| 5. Is the prescriber enrolled in the Oregon Prescription Drug Monitoring Program (www.orpdmp.com) and has the prescriber evaluated the PDMP at least once in the past 3 months for this patient? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 6. Is the request for continuation of therapy previously approved by the FFS program? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #7 |
| 7. Is the request for treatment of post-traumatic stress disorder (PTSD)?<br><br>Note: Risks of benzodiazepine treatment outweigh benefits for patients with PTSD. Treatment with benzodiazepines is not recommended. | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #8 |
| 8. Is the request for treatment of anxiety or panic disorder? | **Yes:** Go to #9 | **No:** Go to #10 |
| 9. Is the medication prescribed by or in consultation with a prescribing mental health specialist OR does the patient have a documented trial and failure, contraindication, intolerance, or inability to access recommended first-line treatment options (first-line options include antidepressants AND psychotherapy [e.g. behavioral therapy, relaxation response training, mindfulness meditation training, eye movement desensitization and reprocessing])?<br><br>Note: An adequate trial to determine efficacy of an SSRI or SNRI is 4-6 weeks. | **Yes:** Go to #12<br><br>Document trial, contraindication, or intolerance to treatment options. | **No:** Pass to RPh; Deny; medical appropriateness.<br><br>Recommend adequate trial of first-line therapies.<br><br>If provider requests short-term approval with a plan to start additional therapy, approval may be granted for up to 3 months. Subsequent requests must document experience with first-line treatment options. |
| 10. Is the request for treatment of psychosis, schizophrenia or schizoaffective disorder? | **Yes:** Go to #11 | **No:** Go to #12 |

| Approval Criteria | | |
|---|---|---|
| 11. Is the medication prescribed by or in consultation with a prescribing mental health specialist OR does the patient have an adequate trial and failure, contraindication, intolerance, or inability to access recommended first-line treatment options (first-line options include second-generation antipsychotics AND psychotherapy [e.g. counseling, cognitive behavioral therapy, social skills training, or psychoeducation])?<br><br>Note: For continued symptoms, assess adherence and dose optimization. For patients on an adequate dose of antipsychotic, guidelines recommend trial of a second antipsychotic or augmentation with a mood stabilizer. | **Yes:** Go to #12<br><br>Document trial, contraindication, or intolerance to treatment options. | **No:** Pass to RPh; Deny; medical appropriateness.<br><br>Recommend adequate trial of first-line therapies.<br><br>If provider requests short-term approval with a plan to start additional therapy, approval may be granted for up to 3 months. Subsequent requests must document experience with first-line treatment options. |
| 12. Is the patient on a concurrent sedative, hypnotic, muscle relaxant, or opioid? | **Yes:** Go to #13 | **No:** Go to #14 |
| 13. Is concurrent sedative therapy part of a plan to switch and taper off a long-acting benzodiazepine (such as diazepam, clonazepam, or chlordiazepoxide) AND has the provider included a detailed strategy to taper?<br><br>Note: a documented taper strategy should include planned dose reductions and length of time between each dose modification for at least the next few weeks. It should also include a documented follow-up plan to monitor progress and manage withdrawal symptoms (regular check-ins are essential for a successful taper). Triazolam may be discontinued without a taper in most cases (2-hour half-life prevents physical dependence). | **Yes:** Approve duplicate benzodiazepine therapy for the duration specified in the taper plan (not to exceed 6 months). | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 14. RPh only: Is there appropriate rationale to support long-term benzodiazepine use for this indication?<br>For anxiety, panic disorder, or schizophrenia, provider rationale should include information from relevant chart notes.<br><br>For other diagnoses, provider must document supporting medical literature. | **Yes:** Approve for up to 6 months. | **No:** Deny; medical appropriateness. |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the request for a decrease in daily dose OR a change in drug with the intent to taper the dose? | **Yes:** Approve for up to 6 months or length of taper, whichever is less. | **No:** Go to #2 |
| 2. Is the request for an increase in dose? | **Yes:** Go to #3 | **No:** Go to #4 |
| 3. Has the patient failed all clinically appropriate first-line adjunct treatment options OR, when applicable, is the patient adherent to recommended first-line treatment options for their condition? | **Yes:** Go to #4 | **No:** Pass to RPh; Deny; medical appropriateness.<br><br>Recommend trial of alternative therapies.<br><br>If provider requests short-term approval with a plan to start additional therapy, approval may be granted for up to 3 months. Subsequent requests must document experience with first-line treatment options. |

| Renewal Criteria | | |
|---|---|---|
| 4. Is there documentation based on medical records that provider and patient have discussed whether benefits of long-term therapy (e.g. symptom improvement, social function, number of hospitalizations, etc) continue to outweigh risks of therapy (e.g. sedation, dependence, cognitive dysfunction and/or psychiatric instability)? | **Yes:** Approve for up to 12 months. | **No:** Pass to RPh; Deny; medical appropriateness.<br><br>Recommend trial of gradual taper plan. Approval may be granted for up to 3 months to allow time to develop a taper plan. Subsequent requests must document progress toward taper. |

*P&T Review:* *8/22; 3/19 (SS); 9/18, 3/14*
*Implementation:* *10/1/22; 5/1/19; 11/1/2018; 5/1/16*

# Betibeglogene Autotemcel

**Goal(s):**
- Approve Betibeglogene Autotemcel (ZYNTEGLO) for conditions supported by evidence of benefit

**Length of Authorization:**
- Once in a lifetime dose.

**Requires PA:**
- Betibeglogene Autotemcel (billed as pharmacy or provider administered claim)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this an FDA approved indication? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is there documentation that the patient has never received another gene therapy for any diagnosis? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Does patient have confirmed Beta-thalassemia? | **Yes**: Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the genotype documented? | **Yes:** Go to #6<br>Genotype_____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is the patient transfusion dependent, defined as requiring in each of the past 2 years:<br>• 100 mL/kg/year or more of packed red blood cells (any patient age) OR<br>• 8 transfusions or more of packed red blood cells per year (patients 12 years and older) | **Yes**: Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is the patient 5 years old or older? | **Yes**: Go to #9 | **No:** Go to #8 |

| Approval Criteria | | |
|---|---|---|
| 8. Does the patient weigh at least 6 kg? | **Yes**: Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Does the patient have cirrhosis or advanced liver disease? | **Yes**: Pass to RPh. Deny; medical appropriateness | **No:** Go to #10 |
| 10. Is there documentation that the patient does not have active or chronic infections of HIV, hepatitis B, or hepatitis C? | **Yes**: Go to #11 | **No:** Pass to RPh. Deny; medical appropriateness |
| 11. Does the prescriber attest that the patient's general health and comorbidities have been assessed and that the patient is expected to safely tolerate myeloablation? | **Yes**: Go to #12 | **No:** Pass to RPh. Deny; medical appropriateness |
| 12. Has the patient (and/or guardian, if applicable) been educated on the risk of insertional oncogenesis and need for lifelong monitoring (bloodwork) at least annually? | **Yes**: Go to #13 | **No**: Pass to RPh. Deny; medical appropriateness |
| 13. Is the patient of childbearing potential OR capable of fathering a child? | **Yes:** Go to #14 | **No:** Approve one lifetime dose. |
| 14. Is the patient pregnant, actively trying to conceive, or trying to father a child? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #15 |
| 15. Is there documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant or father a child during treatment and for at least 6 months after administration of the gene therapy? | **Yes:** Approve for one lifetime dose | |

*P&T/DUR Review: 10/23 (SF)*
*Implementation: 11/1/23*

# Bone Metabolism Agents

**Goal(s):**

- To ensure appropriate and safety use of bone metabolism agents by authorizing utilization in specified patient populations.

**Length of Authorization:**

- 12 to 24 months

**Requires PA:**

- Non-preferred drugs for pharmacy claims
- Provider administered claims for romosozumab

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. Definition for Very High Risk of Fracture**

| |
|---|
| Osteoporosis in post-menopausal women and men at very high risk of fracture with:<br>• Multiple fragility fractures OR<br>• T score ≤ - 2.0 plus a fragility fracture OR<br>• T-score ≤ - 3.0 in the absence of fractures OR<br>• Fractures sustained while on approved osteoporosis therapy OR<br>• Fractures while on medications causing skeletal harm (e.g. long-term glucocorticoids) OR<br>• High risk for falls or history of injurious falls and very high fracture probability with a FRAX Score > 30% for major osteoporosis fracture or > 4.5% |
| Abbreviation: FRAX = Fracture Risk Assessment Tool |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for treatment of cancer-related issues? | **Yes:** Approve for 12 months | **No:** Go to #3 |
| 3. Is this a request for continuation of therapy for those previously approved by the FFS program for abaloparatide, teriparatide, or romosozumab? | **Yes**: Go to **Renewal Criteria** | **No:** Go to #4 |
| 4. Has the patient tried and failed to receive benefit from an oral bisphosphonate (alendronate, risedronate, or ibandronate), have contraindications to these treatments, or have very high risk of fracture (Table 1)?<br><br>(document contraindication, if any) | **Yes:** Go to #7 | **No:** Go to #5 |

| Approval Criteria | | |
|---|---|---|
| 5. Is the request for a non-preferred bisphosphonate, calcitonin or zoledronic acid? | **Yes:** Go to #6 | **No:** Pass to RPh; Deny; medical appropriateness.<br><br>Recommend trial of oral bisphosphonate. |
| 6. Will the prescriber consider a change to a preferred product?<br><br>Note:<br>• Preferred products do not require a PA. Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee | **Yes:** Inform prescriber of covered alternatives in class | **No:** Approve for up to 12 months. |
| 7. Is the request for denosumab? | **Yes:** Go to #8 | **No:** Go to #11 |
| 8. Is denosumab being prescribed for one of the following reasons:<br>• Treatment of postmenopausal women with osteoporosis at high risk for fracture<br>• Treatment to increase bone mass in men with osteoporosis at high risk for fracture<br>• Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture<br>• Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer<br>• Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer | **Yes:** Go to #9 | **No:** Pass to RPh; Deny; medical appropriateness |
| 9. Have labs been obtained to assess renal function? | **Yes:** Document date and results here_____<br><br>Go to #10 | **No:** Pass to RPh; Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 10. If estimated glomerular filtration rate (eGFR) is less than 30 mL/min is there documentation of a calcium monitoring plan?<br><br>Note: Denosumab has a black box warning regarding the risk of severe hypocalcemia following denosumab administration in patients with advanced chronic kidney disease (eGFR <30 mL/min), including dialysis-dependent patients. Treatment with denosumab in these patients should be supervised by a healthcare provider with expertise in the diagnosis and management of chronic kidney disease. | **Yes:** Approve for up to 12 months. | **No:** Pass to RPh; Deny; medical appropriateness |
| 11. Is the request for raloxifene in a postmenopausal woman with osteoporosis? | **Yes:** Go to #12 | **No:** Go to #13 |
| 12. Is the patient at increased risk for thromboembolism (DVT or PE) or stroke due to coronary heart disease? | **Yes:** Pass to RPh. Deny; medical appropriateness.<br><br>Note: Inform prescriber boxed warning for venous thromboembolism and stroke. | **No:** Approve for up to 12 months |
| 13. Is the request for teriparatide or abaloparatide? | **Yes:** Go to #14 | **No:** Go to #16 |
| 14. Is the is the patient at very high risk for fracture (see **Table 1**)? | **Yes:** Go to #15 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 15. Does the patient meet one of the following conditions:<br><br>a. Concomitant bisphosphonate; or<br>b. Pediatric or young adult with open epiphyses; or<br>c. History of osteosarcoma or skeletal malignancies; or<br>d. Metabolic bone disease other than osteoporosis, such as Paget's disease; or<br>e. Underlying hypercalcemic disorders; or<br>f. Unexplained elevated alkaline phosphatase levels? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Approve for up to 24 months (depending on when therapy was initiated.)<br><br>Note: Teriparatide and abaloparatide are only FDA approved for a total duration of therapy of 2 years but use for more than 2 years during a patient's lifetime can be considered if the patient remains at or has returned to having a high risk for fracture. |
| 16. Is the request for romosozumab and is the patient a postmenopausal woman with osteoporosis and T-score ≤ -2.5 or a history of fracture? | **Yes:** Go to #17 | **No:** Pass to RPh; Deny; medical appropriateness |
| 17. Has the patient had a myocardial infarction or stroke within the past year? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Approve for up to 12 months maximum.<br><br>Note: FDA has only approved use of romosozumab for a total of 12 months. If continued osteoporosis therapy is warranted, continue therapy with an anti-resorptive agent (e.g. bisphosphonates or denosumab). |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the request to continue romosozumab beyond 1 year of total therapy? | **Yes**: Pass to RPh; Deny; medical appropriateness. | **No**: Go to # 2 |
| 2. Is the request to continue abaloparatide or teriparatide beyond 2 years of total therapy? | **Yes:** Go to #3 | **No:** Pass to RPh; Deny; medical appropriateness. |

| Renewal Criteria | | |
|---|---|---|
| 3. Does the prescriber attest that the patient remains at or has returned to having a high risk for fracture? | **Yes:** Approve for 12 months. Document provider attestation received. | **No:** Pass to RPh; Deny; medical appropriateness. |

*P&T Review:* *12/24 (DM); 7/19; 3/18; 7/16; 9/10*
*Implementation:* *1/1/25; 11/1/19; 4/16/18; 8/16, 1/1/11*

# Botulinum Toxins

**Goal(s):**
- Approve use of botulinum toxins for conditions funded under the Oregon Health Plan (OHP) and supported by evidence of benefit.
- Require positive response to therapy for continued use to manage chronic migraine headaches or overactive bladder.
- Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**
- From 90 days to 12 months

**Requires PA:**
- Use of botulinum toxins (billed as a physician administered or pharmacy claim) without associated dystonia or neurological disease diagnosis in last 12 months.

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. Is this a request for renewal of a previously approved prior authorization for management of migraine headache or detrusor muscle over-activity ("overactive bladder") or hyperhidrosis? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #2 |
| 2. What diagnosis is being treated? | Record ICD10 code | |
| 3. Is botulinum toxin treatment for any of the following?<br>a. Upper or lower limb spasticity (G24.02, G24.1, G35, G36.0, I69.03- I69.06 and categories G71, and G80-G83)<br>b. Strabismus due to a neurological disorder (H50.89)<br>c. Blepharospasm (G24.5)<br>d. Spasmodic torticollis (G24.3)<br>e. Torsion dystonia (G24.9)<br>f. Achalasia (K22.0) | **Yes:** Approve for up to 12 months | **No:** Go to #4 |
| 4. Is botulinum toxin treatment for chronic migraine, with ≥15 headache days per month, of which ≥8 days are with migraine? | **Yes:** Go to #5<br>Baseline headaches per month: _____ | **No:** Go to #8 |

| Approval Criteria | | |
|---|---|---|
| 5. Is the botulinum toxin administered by, or in consultation with, a neurologist or headache specialist? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 6. Has the patient had an adequate trial (2-6 months) without response, or has contraindications, to at least 3 of the following OHP preferred drugs (in the same or different drug classes)?<br>• Propranolol immediate-release, metoprolol, or atenolol<br>• Topiramate, valproic acid, or divalproex sodium<br>• Amitriptyline, nortriptyline, or venlafaxine<br>• Candesartan or telmisartan | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of preferred alternatives at www.orpdl.org/drugs/ |
| 7. Do chart notes indicate headaches are due to medication overuse? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Approve no more than 2 injections given ≥3 months apart within a 12 month time period.<br><br>Additional treatment requires documented positive response to therapy from baseline (see Renewal Criteria). |
| 8. Is botulinum toxin treatment for detrusor muscle over-activity (“overactive bladder”)? | **Yes:** Go to #9 | **No:** Go to #10 |

| Approval Criteria | | |
|---|---|---|
| 9. Has the patient had an inadequate response to, or is intolerant to at least two urinary incontinence antimuscarinic or beta-3 adrenergic therapies, such as those listed below?<br>a. Fesoterodine (OHP preferred)<br>b. Oxybutynin (OHP preferred)<br>c. Solifenacin (OHP preferred)<br>d. Darifenacin<br>e. Flavoxate<br>f. Mirabegron<br>g. Tolterodine<br>h. Trospium<br>i. Vibegron | **Yes:**<br>• Baseline urine frequency/day: _____.<br>• Baseline urine incontinence episodes/day: _____.<br><br>Approve for up to 90 days.<br><br>Additional treatment requires documented positive response to therapy from baseline (see Renewal Criteria). | **No:** Pass to RPh. Deny; medical appropriateness. |
| 10. Is botulinum toxin treatment for use in patient with chronic anal fissure documented to have lasted longer than 6 weeks? | **Yes:** Approve one-time dose for 6 months (may be injected into multiple sites on same day) | **No:** Go to #11 |
| 11. Is botulinum toxin treatment of primary axillary hyperhidrosis?<br><br>Note: secondary axillary hyperhidrosis related to comorbid conditions and non-axillary hyperhidrosis are not FDA-approved. | **Yes**: If not eligible for EPSDT review: Pass to RPh. Go to #16<br><br>If eligible for EPSDT review: Go to #12 | **No:** Pass to RPh. Go to #16 |
| 12. Is the requested product prescribed by, or in consultation with, a neurologist or dermatologist? | **Yes:** Go to #13 | **No**: Pass to RPh. Deny; medical appropriateness |
| 13. Is there documentation that the diagnosis detrimentally impacts at least one of the following?<br>e. disability or health impairment (e.g., complications, comorbidities, etc)<br>f. age-appropriate growth or development<br>g. independence in self-care or activities of daily living<br>h. ability to live and work in the setting of the patient's choice | **Yes:** Go to #14 | **No:** Pass to RPh; Deny; medical necessity |

| Approval Criteria | | |
|---|---|---|
| 14. Is there documentation of severe symptoms which interfere with daily activities more than once per week as indicated by one of the following:<br>• Hyperhidrosis Disease Severity Scale (HDSS) ≥ 3<br>• Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax) ≥ 3<br>• Axillary Sweating Daily Diary – item 2 (sweating severity) ≥ 4 on a 0-10 point scale<br><br>Note: these same assessments should be evaluated for continuation of treatment. | **Yes:** Go to #15 | **No:** Pass to RPh. Deny; medical necessity. |
| 15. Is there documentation indicating lack of adequate treatment with non-pharmacologic management (e.g., trigger identification and avoidance, clothing modification, use of topical antiperspirants)? | **Yes**: Approve no more than 2 injections given ≥8 weeks apart within a 12-month time period. | **No:** Pass to RPh. Deny; medical appropriateness |

16. Review treating condition, age, and ICD-10 code. ICD-10 codes included in the tables below are denied. If ICD-10 code is not included in the tables below, medical literature with evidence for use in funded conditions must be submitted by the prescriber. RPh may approve for up to 12 months for funded conditions with evidence of benefit.

| **If not eligible for EPSDT review: Deny for the following conditions; not funded by the OHP**<br>**If eligible for EPSDT review, evaluate FDA-approved indications and disease severity. If the drug is FDA approved for the condition AND prescriber submits documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.), RPh may approve for up to 12 months.** |
|---|
| ▪ Axillary hyperhidrosis (L74.510)<br>▪ Neurologic conditions with none or minimally effective treatment or treatment not necessary (G244; G2589; G2581; G2589; G259)<br>▪ Facial nerve disorders (G510-G519)<br>▪ Spastic dysphonia (J387)<br>▪ Other disorders of cervical region (M436; M4802; M530; M531; M5382; M5402; M5412; M542; M6788)<br>▪ Acute and chronic disorders of the spine without neurologic impairment (M546; M545; M4327; M4328; M532X7; M532X8; M533; M438X9; M539; M5408; M545; M5430; M5414-M5417; M5489; M549)<br>▪ Disorders of soft tissue (M5410; M609; M790-M792; M797)<br>▪ Headaches (G44209; G44009; G44019; G44029; G44039; G44049; G44059; G44099; G44209; G44219; G44221; G44229; G44309; G44319; G44329; G4441; G4451-G4453; G4459; G4481-G4489; G441; R51)<br>▪ Gastroparesis (K3184)<br>▪ Lateral epicondylitis (tennis elbow) (M7710-M7712)<br>▪ Unspecified diseases of the salivary glands (sialorrhea) (K11.5-K11.9,R68.2) |
| **Deny for medical appropriateness because evidence of benefit is insufficient** |
| ▪ Dysphagia (R130; R1310-R1319)<br>▪ Secondary and non-axillary focal hyperhidrosis (L74511-L7452)<br>▪ Other disorders of sweat glands (L301; L740-L744; L748-L749; R61)<br>▪ Other extrapyramidal disease and abnormal movement disorders (G10; G230-GG238; G2401; G244; G250-G26)<br>▪ Other disorders of binocular eye movements (e.g., esotropia, exotropia, mechanical strabismus, etc.) (H4900-H518)<br>▪ Tics (F950-F952; F959)<br>▪ Laryngeal spasm (J385)<br>▪ Spinal stenosis in cervical region or brachial neuritis or radiculitis NOS (M4802; M5412-M5413)<br>▪ Spasm of muscle in absence of neurological diagnoses (M6240-M62838)<br>▪ Contracture of tendon (sheath) in absence of neurological diagnoses (M6240; M62838)<br>▪ Amyotrophic sclerosis (G1221)<br>▪ Clinically significant spinal deformity or disorders of spine with neurological impairment (M4800; M4804; M4806; M4808; M5414-M5417)<br>▪ Essential tremor (G25.0)<br>▪ Hemifacial spasm (G513)<br>▪ Occupational dystonia (e.g., "Writer's cramp") (G248, G249)<br>▪ Hyperplasia of the prostate (N400-403; N4283)<br>▪ Conditions of the back and spine for the treatment of conditions on lines 346 and 527, including cervical, thoracic, lumbar and sacral conditions. See Guideline Note 37. |

| Renewal Criteria | | |
|---|---|---|
| 1. Is this a request for renewal of a previously approved prior authorization for management of migraine headache? | **Yes:** Go to #2 | **No:** Go to #3 |
| 2. Is there documentation of a reduction of ≥7 migraine headache days per month compared to baseline migraine headache frequency? | **Yes:** Approve no more than 2 injections given ≥3 months apart.<br><br>Baseline:____ migraine headaches/month<br>Current:____ migraine headaches/month | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is this a request for renewal of a previously approved prior authorization for management of detrusor muscle over-activity ("overactive bladder")? | **Yes:** Go to #4 | **No:** Go to #5 |
| 4. Is there a reduction of urinary frequency of ≥8 episodes per day or urinary incontinence of ≥2 episodes per day compared to baseline frequency? | **Yes:** Approve for up to 12 months<br><br>• Baseline:____ urine frequency/day<br>• Current:____ urine frequency/day<br>-or-<br>• Baseline:____ urine incontinence episodes/day<br>• Current:____ urine incontinence episodes/day | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the request for renewal of a previously approved prior authorization for axillary hyperhidrosis? | **Yes:** Go to #6 | **No:** Go to **Approval Criteria** |

| Renewal Criteria | | |
|---|---|---|
| 6. Is there documentation of symptom improvement from baseline as assessed by the prescribing provider?<br><br>Note: the following are described as clinically relevant responses to therapy:<br>• Total score ≤ 2 on the Hyperhidrosis Disease Severity Scale (HDSS) or Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax)<br>• ≥ 4 point improvement on the Axillary Sweating Daily Diary – item 2 (sweating severity) | **Yes:** Approve for 12 months | **No:** Pass to RPh; Deny; medical appropriateness |

*P&T / DUR Review:* *4/25 (SF/SS); 6/23 (KS),4/22 (AG); 5/19 (KS); 9/18; 5/18; 11/15; 9/14; 7/14*
*Implementation:* *5/12/25; 7/1/23; 5/1/22; 11/1/2018; 7/1/18; 10/13/16; 1/1/16*

# Budesonide Oral Suspension (Eohilia™)

**Goal(s):**
- Promote use that is consistent with national clinical practice guidelines and medical evidence.
- Promote use of cost-effective products.

**Length of Authorization:**
- Up to 12 weeks

**Requires PA:**
- Budesonide (Eohilia™) oral suspension for pharmacy claims.

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for an FDA-approved age and indication? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is there documentation of failure to have benefit with, or contraindication to:<br>• Proton pump inhibitor therapy for at least 8 weeks AND<br>• Corticosteroid therapy with local administration of fluticasone nasal inhaler for at least 8 weeks (use inhaler and swallow contents of the spray). | **Yes:** Approve for 12 weeks of therapy for one course of treatment.<br><br>Note: Budesonide oral suspension has not been shown to be safe and effective for the treatment of erosive esophagitis for longer than 12 weeks. | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T Review:* *10/24 (DM)*
*Implementation:* *12/1/2024*

# Buprenorphine and Buprenorphine/Naloxone

**Goals:**

- Prevent use of high-dose transmucosal buprenorphine products for off-label indications.

**Length of Authorization:**

- Up to 6 months

**Requires PA:**

- Transmucosal buprenorphine products that exceed an average daily dose of 32 mg per day

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. Is the prescription for opioid use disorder (opioid dependence or addiction)? | **Yes:** Go to #2 | **No:** Pass to RPh. Deny; medical appropriateness |
| 2. Is the prescription for a transmucosal formulation of buprenorphine (film, tablet) with an average daily dose of more than 32 mg (e.g., >32 mg/day or >64 mg every other day)? | **Yes:** Go to #3 | **No:** Go to #7 |
| 3. Is there documentation of inadequate symptom improvement with 32 mg daily? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is there recent documentation (within past month) from a urine drug screen indicating that buprenorphine is being taken? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Has the prescriber evaluated the PDMP in the past 3 months? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 6. Does the member have access to naloxone? | **Yes:** Approve for 30 days.<br><br>Subsequent requests for continuation of therapy will require documentation of objective clinical benefit with higher doses (e.g. improved management of OUD), documentation of a comprehensive treatment plan for OUD, and ongoing monitoring plan for safety risks. | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is the requested medication a preferred agent? | **Yes:** Approve for 6 months.<br><br>Note: Notify prescriber concomitant naloxone is recommended if not present in claims history. | **No:** Go to #8 |
| 8. Will the prescriber switch to a preferred product?<br><br>Note: Preferred products are reviewed for comparative safety and efficacy by the Oregon Pharmacy and Therapeutics Committee. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Approve for 6 months.<br><br>Note: Notify prescriber concomitant naloxone is recommended if not present in claims history. |

*P&T/DUR Review:* *8/25 (TW); 10/23; 8/23 (SS); 2/23; 12/22; 12/20;11/19; 1/19; 1/17; 9/16; 1/15; 9/09; 5/09*
*Implementation:* *9/1/23; 1/1/2020; 3/1/2019; 4/1/2017; 9/1/13; 1/1/10*

# Butalbital Containing Products

**Goal(s):**
- Decrease potential for dependence and medication overuse headache through quantity limits.

**Length of Authorization:**
- Up to 6 months

**Requires PA:**
- All butalbital products

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Check the Reason for PA:**
- All butalbital products are non-preferred

**Table 1. Quantity Limits per Labeling.**

| Generic | Max Daily Dose | Quantity Limit Per 30 days |
|---|---|---|
| Butalbital containing formulations | 6 capsules or tablets | 30 capsules or tablets |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Does the patient have a diagnosis of migraine headaches? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #3 |
| 3. Does the patient have medication overuse headache? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #4 |
| 4. Does the patients have a diagnosis of tension headache? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 5. Has the patient had an adequate trial, without response, or has contraindications, to at least 2 of the following OHP preferred drugs for tension headache:<br>• Ibuprofen<br>• Acetaminophen<br>• Amitriptyline | **Yes:** Approve for up to 6 months. Quantities to not exceed limits provided in Table 1 above. | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T Review:* *04/25 (KS)*
*Implementation:* *5/12/25*

# Calcitonin Gene-Related Peptide (CGRP) antagonists

**Goal(s):**
- Promote safe use of CGRP inhibitors in adult patients.
- Promote use that is consistent with medical evidence and product labeling for migraine prevention, acute migraine treatment and cluster headache prevention (Table 1).

**Length of Authorization:**
- Initial: Up to 3 months
- Renewal: Up to 6 months

**Requires PA:**
- All calcitonin gene-related peptide (CGRP) antagonist pharmacy and practitioner administered claims

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. FDA Approved Indications for CGRP antagonists**

| Drug | FDA Approved Indication |
|---|---|
| Atogepant | Preventative migraine treatment |
| Eptinezumab | Preventative migraine treatment |
| Erenumab | Preventative migraine treatment |
| Fremanezumab | Preventative migraine treatment |
| Galcanezumab | Preventative migraine treatment and cluster headache prevention |
| Rimegepant sulfate | Acute migraine treatment and preventative treatment of episodic migraine |
| Ubrogepant | Acute migraine treatment |
| Zavegepant | Acute migraine treatment |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this an FDA-approved indication (Table 1)? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is this a request for renewal of a previously approved Fee-For-Service prior authorization of a CGRP antagonist for management of migraine headache? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #4 |
| 4. Is the medication being prescribed by or in consultation with a neurologist or headache specialist? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 5. Do chart notes indicate headaches are due to medication overuse? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to # 6 |
| 6. Is the request for acute (abortive) migraine treatment AND the patient is an adult (18 years or older)? | **Yes:** Go to #11 | **No:** Go to #7 |
| 7. Is the request for the prevention of cluster headache AND the patient is an adult (18 years or older)? | **Yes:** Go to #14 | **No:** Go to #8 |
| 8. Is the request for prophylactic therapy and there is documentation that the patient has experienced 4 or more migraine days in the previous month AND the patient is an adult (18 years or older)? | **Yes:** Document migraine days per month _____ Go to # 9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Has the patient had an adequate trial (2-6 months) without response, or has contraindications, to at least 3 of the following OHP preferred drugs (in the same or different classes)?<br>• Propranolol immediate-release, metoprolol, or atenolol<br>• Topiramate, valproic acid, or divalproex sodium<br>• Amitriptyline, nortriptyline, or venlafaxine<br>• Candesartan or telmisartan<br><br>OR<br><br>Does the patient have a documented intolerance, FDA-labeled contraindication, or hypersensitivity to the above migraine prophylaxis agents? | **Yes:** Document agents used and dates<br><br>_____<br><br>_____<br><br>Go to # 10 | **No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of preferred alternatives at www.orpdl.org/drugs/ |
| 10. Has the patient received an injection with botulinum toxin for headache treatment once in the previous 2 months? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Approve for up to 3 months |
| 11. In a patient with acute migraines, has the patient failed to receive benefit from adequate trials of abortive therapy (2 or more different triptans) or have contraindications to triptans? | **Yes:** Go to #12 | **No:** Pass to RPh. Deny; medical appropriateness. Recommend triptan trial. |

| Approval Criteria | | |
|---|---|---|
| 12. Does the patient have chronic migraines? | **Yes**: Go to #13 | **No**: Approve for 3 months |
| 13. Does the patient have a history of at least 4 migraines a month AND is on preventative migraine therapy (excluding other CGRP inhibitors)? | **Yes:** Approve for up to 3 months | **No:** Pass to RPh. Deny; medical appropriateness |
| 14. Has the patient had an adequate trial (2-6 months) without response, or has contraindications, to at least 2 of the following OHP preferred drugs:<br>• Lithium<br>• Verapamil<br>• Suboccipital steroid injection<br>• Sumatriptan subcutaneous<br>• Zolmitriptan nasal spray | **Yes**: Approve for up to 3 months | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Do chart notes indicate headaches are due to medication overuse? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #2 |
| 2. Is the renewal request for acute migraine treatment? | **Yes:** Go to #5 | **No:** Go to #3 |
| 3. Is the renewal request for migraine prevention? | **Yes:** Go to #4 | **No:** Go to # 6 |
| 4. Has the patient experienced a documented positive response to therapy, as demonstrated by a reduction in migraine headache frequency and/or intensity from baseline? | **Yes:** Approve for up to 6 months. Document response. | **No:** Pass to RPh. Deny; medical Appropriateness |
| 5. Has the patient demonstrated a response to therapy as indicated by a reduction in headache frequency and/or intensity? | **Yes:** Approve for up to 6 months. Document response. | **No:** Pass to RPh. Deny; medical Appropriateness |
| 6. Is the renewal request for cluster headache prevention? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical Appropriateness |

| | | |
|---|---|---|
| 7. Has the provider documented a positive patient response as indicated by a reduction in the number of cluster headaches per month? | **Yes:** Approve for up to 6 months. Document response. | **No:** Pass to RPh. Deny; medical Appropriateness |

*P&T/DUR Review: 4/25 (KS), 6/23 (DE); 10/21, 8/20; 5/19; 9/18*
*Implementation: 5/12/25; 7/1/23; 1/1/2022; 11/1/2018*

# Calcium and Vitamin D Supplements

**Goal(s):**

- Restrict use of calcium and vitamin D supplements to patients who are pregnant; have a documented nutritional deficiency; have a diagnosis of osteopenia or osteoporosis; infants 0-24 months or elderly patients at risk for falls.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Non-preferred calcium and vitamin D products

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is this an OHP-funded diagnosis? | **Yes:** Go to #3 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #4 |
| 3. Does the patient meet any of the following criteria:<br>• Pregnancy;<br>• Documented nutrient deficiency;<br>• Diagnosis of osteopenia or osteoporosis;<br>• Infants 0-24 months of age<br>**OR**<br>• Age 65 years or older and at risk for falls | **Yes:** Approve for up to 12 months. Request that a 90 day's supply be filled at a time. | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical necessity. |

| Approval Criteria | | |
|---|---|---|
| 5. Is the request for an FDA approved indication AND as the patient failed to have benefit with, or have contraindications or intolerance to, at least 2 preferred products?<br><br>Message: Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Inform prescriber of covered alternatives in class and process appropriate PA. |

*P&T Review:* *3/19 (KS), 3/16 (KS)*
*Implementation:* *5/1/19; 5/1/16*

# Cannabidiol

**Goal(s):**
- To ensure appropriate drug use and restrict to indications supported by medical literature.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Cannabidiol

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for renewal of therapy previously approved by the FFS system? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Is this an FDA approved indication? | **Yes**: Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the patient uncontrolled on current baseline therapy with at least one other antiepileptic medication AND is cannabidiol intended to be prescribed as adjuvant antiepileptic therapy? | **Yes:** Go to #5<br><br>Document current seizure frequency_____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the prescribed dose greater than 25 mg/kg/day? | **Yes**: Pass to RPh. Deny; medical appropriateness | **No**: Go to # 6 |

| Approval Criteria | | |
|---|---|---|
| 6. Are baseline liver function tests (LFTs) on file (serum transaminases and total bilirubin levels)?<br>AND<br>If LFTs are not within normal limits, has the cannabidiol dose been adjusted per guidance for moderate to severe hepatic impairment in Table 1?<br><br>LFTs should be obtained at 1 month, 3 months, and 6 months after starting treatment with cannabidiol and periodically thereafter as clinically indicated, after cannabidiol dose changes, or addition of other medications that are known to impact the liver. | **Yes:** Approve for 12 months<br><br>Document results here:<br>Date of lab work_____<br>AST_____<br>ALT_____<br>Total Bilirubin_____ | **No**: Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Are recent LFT's documented in patient records?<br>AND<br>If LFTs are not within normal limits has the cannabidiol dose been adjusted per guidance for moderate to severe hepatic impairment in Table 1? | **Yes:** Go to # 2<br><br>Document results here:<br>Date of lab work_____<br>AST_____<br>ALT_____<br>Total Bilirubin_____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 2. Has seizure frequency decreased since beginning therapy? | **Yes:** Go to #3<br><br>Document baseline & current seizure frequency | **No:** Pass to RPh. Deny for lack of treatment response. |
| 3. Is the prescribed dose greater than 25mg/kg/day? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to # 4 |
| 4. Is cannabidiol intended to be prescribed as adjuvant antiepileptic therapy? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

**Table 1:** Dose Adjustments of Cannabidiol in Patients with Hepatic Impairment[1]

| Hepatic Impairment | Starting Dosage | Maintenance Dosage Range in Patients with Lennox-Gastaut Syndrome (LGS) or Dravet Syndrome (DS) | Maintenance Dosage in Patients with Tuberous Sclerosis Complex (TSC) |
|---|---|---|---|
| **Mild** | 2.5 mg/kg twice daily (5 mg/kg/day) | 5 to 10 mg/kg twice daily (10 to 20 mg/kg/day) | 12.5 mg/kg twice daily (25 mg/kg/day) |

| | | | |
|---|---|---|---|
| **Moderate** | 1.25 mg/kg twice daily (2.5 mg/kg/day) | 2.5 to 5 mg/kg twice daily (5 to 10 mg/kg/day) | 6.25 mg/kg twice daily (12.5 mg/kg/day) |
| **Severe** | 0.5 mg/kg twice daily (1 mg/kg/day) | 1 to 2 mg/kg twice daily (2 to 4 mg/kg/day) | 2.5 mg/kg twice daily (5 mg/kg/day) |

1. Epidolex (cannabidiol) Oral Solution Prescribing Information. Carlsbad, CA; Greenwich Biosciences, Inc. July 2020.

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*P&T/DUR Review: 4/25 (DM); 10/22 (SF); 10/21; 10/20; 6/20; 3/19; 1/19*
*Implementation: 11/1/20; 5/1/19; 3/1/19*

# Cenegermin-bkbj (Oxervate™)

**Goal(s):**
- Ensure medically appropriate use of cenegermin

**Length of Authorization:**
- 8 weeks

**Requires PA:**
- Cenegermin-bkbj (Oxervate™)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this a request for continuation of therapy? | **Yes**: Pass to RPh. Deny; medical appropriateness<br><br>Cenegermin is only approved for 8 weeks of therapy | **No:** Go to #3 |
| 3. Is this for the treatment of Stage 2 or 3 neurotrophic keratitis? | **Yes**: Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is it prescribed by or in consultation with an ophthalmologist? | **Yes:** Approve for 8 weeks | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 12/2020 (MH)*
*Implementation: 1/1/2021*

# Cholic Acid (Cholbam™)

**Goal(s):**
- To ensure appropriate use of cholic acid in patients with bile acid synthesis disorders (BASDs) due to a single enzyme defects (SEDs) or as an adjunct to patients with peroxisomal disorders (PD), including Zellweger spectrum disorders, who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Cholic acid

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this an FDA approved indication? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is this a request for continuation of therapy? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #4 |
| 4. Is cholic acid prescribed by a hepatologist or pediatric gastroenterologist? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 5. Has baseline hepatic function been assessed?<br><br>*The manufacturer recommends providers to monitor aspartate transaminase (AST), alanine aminotransferase (ALT), gamma-glutamyl transpeptidase (GGT), alkaline phosphatase (ALP), bilirubin, and international normalized ratio (INR) every month for the first 3 months of therapy, every 3 months for the next 9 months, every 6 months during the next 3 years and annually thereafter.[1] | **Yes:** Approve for 3 months.<br><br>Document baseline hepatic function values (AST,ALT, Alk Phos, bilirubin) and date obtained:_____ | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is there evidence of improvement of primary biliary cholangitis, defined as:<br>a. ALP <1.67-times the ULN; AND<br>b. Decrease of ALP >15% from baseline: AND<br>c. Normal total bilirubin level? | **Yes:** Document ALP and total bilirubin level. Go to #2<br><br>ALP:_____units/L<br>Total Bilirubin ___ mg/dL | **No:** Pass to RPh. Deny; medical appropriateness |
| 2. Has the patient's condition stabilized or improved as assessed by the prescribing provider? | **Yes:** Approve for 12 months. | **No**: Pass to RPh. Deny; medical appropriateness |

1. Cholbam (cholic acid) capsules [Full Prescribing Information]. San Diego, CA: Retrophin, Inc. March 2015.

*P&T/DUR Review: 12/21 (DM); 11/19 (DM)*
*Implementation: 1/1/22; 1/1/2020*

## *Clostridioides difficile*-Associated Infection, Prevention of Recurrence

**Goal(s):**

- To optimize appropriate prevention of recurrent *Clostridioides difficile*-associated infection (CDI). Recurrent CDI is defined by Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) as an episode of CDI that occurs less than 8 weeks after the onset of a previous CDI episode, if CDI symptoms from the previous episode were resolved.

**Length of Authorization:**

- Bezlotoxumab (ZINPLAVA): One-time infusion
- Fecal microbiota, live-jslm (REBYOTA): One-time rectal administration
- Oral fecal microbiota spores, live-brpk (VOWST): 4 capsules once daily x 3 days (12 capsules total)

**Requires PA:**

- Drugs approved to prevent recurrence of CDI:
  - Bezlotoxumab for intravenous infusion (provider administered and pharmacy claims)
  - Fecal microbiota, live-jslm suspension for rectal administration (provider administered and pharmacy claims)
  - Oral fecal microbiota spores, live-brpk (pharmacy claims)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Does the indication match the FDA-approved indication? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the request for an FDA approved-age? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the request for bezlotoxumab? | **Yes**: Go to #5 | **No:** Go to #8 |

| Approval Criteria | | |
|---|---|---|
| 5. Is this recurrent of *Clostridioides difficile*-associated infection (CDI) within 6 months of CDI<br>**OR**<br>Is the patients presenting with a primary CDI episode and has other risk factors for CDI recurrence (such as age ≥65 years, immunocompromised host, or severe CDI on presentation)? *<br><br>*Per 2021 IDSA/SHEA guidance[1] | **Yes**: Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Has the patient received either the fecal microbiota rectal suspension or a 3 day-course of the oral fecal microbiota spores? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is the patient currently receiving vancomycin or fidaxomicin? | **Yes**: Approve one dose | **No**: Pass to RPh. Deny; medical appropriateness |
| 8. Is this the second or more recurrence of a Clostridioides difficile-associated infection?*<br><br>*Per 2021 ACG and 2022 NICE guidance[2,3] | **Yes:** Go to #9 | **No**: Pass to RPh. Deny; medical appropriateness |
| 9. Will the patient have recently completed a 10-day course of vancomycin or fidaxomicin prior to starting therapy? | **Yes**: Approve for 1 course of treatment (see Length of Authorization) | **No**: Pass to RPh. Deny; medical appropriateness |


1. 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(51029-e1044.
2. Kelly CR, Fischer M, Allegretti JR, et al. American College of Gastroenterology Clinical Guidelines: Prevention, Diagnosis, and Treatment of Clostridioides difficile Infections. The American Journal of Gastroenterology. 2021; 116(6):1124-1147.
3. National Institute for Health and Care Excellence (NICE): Fecal microbiota transplant for recurrent Clostridioides difficile infection. August 31, 2022. https://www.nice.org.uk/guidance/mtg71 Accessed February 27, 2023.


*P&T / DUR Review:* *8/23 (DM); 6/23*
*Implementation:* *9/1/23; 7/1/23*

# Conjugated Estrogens/Bazedoxifene (Duavee®)

**Goal(s):**

- Approve conjugated estrogens/bazedoxifene only for indications where there is evidence to support its use and safety.
- Support the use of agents with clinical efficacy and safety supported by the medical literature and guidelines.

**Length of Authorization:**

- 6-12 months

**Requires PA:**

- Conjugated estrogens/bazedoxifene

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Step Therapy Required Prior to Coverage:**

- Prevention of vasomotor symptoms: conventional hormone therapy (see preferred drug list options at (www.orpdl.org)
- Prevention of osteoporosis: bisphosphonates (see preferred drug list options at www.orpdl.org).

| Approval Criteria | | |
|---|---|---|
| 1. What is the diagnosis? | Record ICD10 code | |
| 2. Is patient a postmenopausal woman within 10 years of menopause? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is the patient <60 years of age with an intact uterus? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products do not require a co-pay. Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics (P&T) Committee. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Go to #5 |
| 5. Is the patient being prescribed the medication for the prevention of osteoporosis? | **Yes:** Go to #6 | **No:** Go to #7 |

| Approval Criteria | | |
|---|---|---|
| 6. Has the patient tried and failed, or is there a contraindication to, bisphosphonates? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is the medication being prescribed for the prevention of vasomotor symptoms? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Has the patient tried and failed or has a contraindication to conventional hormone therapy? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T Review:* *1/17 (SS), 11/14*
*Implementation:* *4/1/17; 1/1/15*

# Drugs for Constipation

**Goal(s):**
- Promote use that is consistent with medical evidence and product labeling.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Non-preferred drugs (pharmacy point of sale)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. Gastrointestinal Drugs FDA-Approved for Treatment of Constipation in an Outpatient Setting**

| Generic (Brand Name) | Indications |
|---|---|
| Linaclotide (LINZESS) | • CIC in adults<br>• IBS-C in adults<br>• FC in pediatric patients aged 6 to 17 yo |
| Lubiprostone (AMITIZA) | • CIC in adults<br>• IBS-C in females > 18 yo<br>• OIC in adults: chronic, non-cancer pain including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation |
| Methylnaltrexone (RELISTOR) | • OIC in adults with advanced illness (injection only)<br>• OIC in adults with chronic, non-cancer pain (tablets and injection) |
| Naldemedine (SYMPROIC) | OIC in adults with chronic, non-cancer pain |
| Naloxegol (MOVANTIK) | OIC in adults with chronic, non-cancer pain |
| Plecanatide (TRULANCE) | • CIC in adults<br>• IBS-C in adults |
| Prucalopride (MOTEGRITY) | CIC in adults |
| Tenapanor (IBSRELA) | IBS-C in adults |
| Abbreviations: CIC = chronic idiopathic constipation; FC = functional constipation; IBS-C = irritable bowel syndrome with constipation; IBS-D = irritable bowel syndrome with diarrhea; OIC = opioid-induced constipation; yo = years old | |

**Table 2.** Initial Management Strategies for Constipation

| | |
|---|---|
| Dietary Modification | Increased dietary fiber (25 grams/day) and increased fluid consumption |
| Bulk-forming Laxatives | Psyllium (not recommended for opioid-induced constipation) |
| Osmotic Laxatives | Polyethylene glycol, lactulose, magnesium hydroxide, milk of magnesia |
| Stool Softener | Docusate |
| Stimulant Laxatives | Senna, bisacodyl |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the diagnosis funded by the OHP? | **Yes:** Go to #3 | **No:** Not eligible for EPSDT review: Pass to RPh. Deny; diagnosis not covered by OHP.<br><br>Eligible for EPSDT review: Go to #3 |
| 3. Is the request for an FDA-approved age and indication (**Table 1**)? | **Yes**: Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 4. Is there documentation of failure to have benefit with, or contraindication to, at least 2 of the recommended conventional first-line treatments including dietary modifications for at least 4 weeks (**Table 2**)? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny for funding<br><br>Constipation is not funded under the OHP. Therefore, funding for drugs that treat constipation are dependent whether the constipation adversely affects, or is secondary to, the underlying medical condition covered by the Prioritized List.<br><br>Chronic constipation caused by a funded condition or adversely affecting a funded condition is approvable if medically appropriate and justification is provided for not meeting criterion #4. |
| 5. Is the drug prescribed by one of the following:<br>-gastroenterologist OR<br>-other provider after patient consultation with a dietician OR<br>-if patient has PA approval for long-term opioid therapy OR<br>-pain management specialist? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny for medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 6. Is the request to treat irritable bowel syndrome with constipation in an adult female assigned at birth with lubiprostone? | **Yes**: Approve for 12 months | **No:** Go to #7 |
| 7. Is the request to treat opioid-induced constipation in an adult with lubiprostone? | **Yes**: Go to #8 | **No:** Approve for 12 months |
| 8. Is request for lubiprostone in a patient that has been prescribed methadone? | **Yes:** Pass to RPh. Deny; medical appropriateness. The efficacy of lubiprostone in patients taking methadone has not been established. | **No:** Approve for 12 months |

*P&T Review:* *2/25 (DM): 6/20 (DM), 7/17 (DM); 3/15; 3/09*
*Implementation:* *3/10/25;7/1/20; 9/1/17; 5/1/16; 10/15, 4/18/15*

# Continuous Glucose Monitoring (CGM)

**Goal(s):**
- Restrict use of CGM to medically appropriate conditions funded under the Oregon Health Plan
- Promote use that is consistent with the Health Evidence Review Commission guideline note 108

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- All continuous glucose monitoring supplies

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1. Quantity limits for continuous glucose monitoring

| Product | Receiver/Reader* | Transmitter | Sensors |
|---|---|---|---|
| Cost-effective CGM | | | |
| Dexcom 6 or 7 | 1 receiver every 5 years | G6: 1 transmitter every 90 days<br>G7: NA | 1 sensor every 10 days |
| Freestyle Libre | 1 reader every 5 years | NA | 1 sensor every 14 days |

*Receivers and readers may not be needed if the member is able to use a compatible smartphone

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for diabetic supplies in excess of amounts outlined in Table 1? | **Yes:** Pass to RPh. Deny; DME in excess of quantity limit. | **No:** Go to #3 |
| 3. Is the request for continuation of therapy previously approved by FFS? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #4 |
| 4. Has the patient received (or will receive) diabetes education specific to the use of CGM? | **Yes:** Go to #5<br><br>Document provider attestation | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the request for type 1 diabetes mellitus? | **Yes**: Go to #6 | **No:** Go to #7 |

| Approval Criteria | | |
|---|---|---|
| 6. Is there documentation for any of the following:<br>a. age of 21 years or less<br>b. current pregnancy or plans to become pregnant within 6 months<br>c. current use of an insulin pump<br>d. HbA1c ≥ 8.0% (in the past 3 months or prior to CGM use) OR<br>e. Frequent, severe, or impaired awareness of hypoglycemia | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is the request for gestational or type 2 diabetes AND is the patient using short or intermediate acting insulin? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Is there documentation for any of the following:<br>a. HbA1c ≥ 8% (in the past 3 months or prior to CGM use)<br>b. Frequent, severe, or impaired awareness of hypoglycemia OR<br>c. Diabetes-related complications (e.g., peripheral neuropathy, cardiovascular disease, end-organ damage, etc) | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Is the request for a cost-effective product OR will the prescriber switch to a cost-effective product (Table 1)? | **Yes:** Approve necessary supplies for the preferred product for 6 months or for the duration of the pregnancy (up to 12 months) | **No:** Pass to RPh. Deny; cost-effectiveness for DME. |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the request for continuation of CGM *after* a pregnancy? | **Yes:** Go to #2 | **No:** Go to #3 |
| 2. Does the patient meet any other criteria for approval?<br><br>Note: continuation after a pregnancy is only considered medically appropriate for members who meet other criteria for approval (see above). | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 3. Has the member used the device for at least 50% of the time at their first follow-up visit? | **Yes:** Approve for 12 months<br><br>Document use based on CGM metrics | **No:** Pass to RPh. Deny; medical appropriateness |

*Implementation: 1/1/24*

# Cough and Cold Preparations

**Goal(s):**

- Limit use of cough and cold preparations to OHP-funded diagnoses.
- Symptomatic treatment of upper respiratory tract infections is not funded by the OHP.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- All drugs (expectorants, antitussives, oral decongestants and combinations) in TC = 16, 17 except those listed below.
- All products for patients under 13 years of age.
- All codeine-containing products for patients under 19 years of age (see Codeine PA criteria).

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| HSN | Generic Drug Name |
|---|---|
| 000206 | Guaifenesin/codeine |
| 000223 | Guaifenesin/Dextromethorphan |
| 002091 | Pseudoephedrine |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the diagnosis an OHP-funded diagnosis? All indications need to be evaluated to see if funded on the Oregon Health Plan list of prioritized services. | **Yes:** Go to #4 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #3 |
| 3. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical necessity. |
| 4. Has the patient tried and failed, or have contraindications to, one of the covered alternatives listed above? | **Yes:** document failure. Approve for up to 12 months. | **No:** Pass to RPh. Deny; cost-effectiveness |

*P&T Review:* *5/16 (KK); 5/13; 2/06*
*Implementation:* *7/1/16; 1/10/08*

# Cysteamine Delayed-release (PROCYSBI®)

**Goal(s):**
- To restrict use of costly agents to appropriate patient populations.

**Length of Authorization:**
- Up to 6 months

**Requires PA:**
- Cysteamine delayed-release capsules (PROCYSBI)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is the diagnosis nephropathic cystinosis? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is the patient receiving medications through a gastrostomy tube? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #4 |
| 4. Has the patient had an adequate trial of cysteamine immediate-release (IR) capsules (CYSTAGON); AND<br>Is the prescriber experienced in managing metabolic diseases such as nephropathic cystinosis; AND<br>Is there documentation of justified patient non-adherence to cysteamine IR that prevents the patient from achieving WBC cysteine levels (<1 nmol ½ cysteine per mg protein)? | **Yes:** Approve for up to 6 months. | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T/DUR Review:* *11/16 (DM); 3/14*
*Implementation:* *1/1/17; 5/1/14*

# Cystic Fibrosis Modulators, Oral

**Goals:**

- To ensure appropriate drug use and limit to patient populations in which they have demonstrated to be effective and safe.
- To monitor for clinical response for appropriate continuation of therapy.

**Length of Authorization:**

- 6 months

**Requires PA:**

- Ivacaftor (Kalydeco®)
- Lumacaftor/Ivacaftor (Orkambi®)
- Tezacaftor/Ivacaftor (Symdeko®)
- Elexacaftor/Tezacaftor/Ivacaftor (Trikafta™)

**Preferred Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1: Approved and Funded Indications for Oral Cystic Fibrosis Modulators**

| Drug Name | FDA approved CFTR mutation | Age |
|---|---|---|
| **Deutivacaftor/tezacaftor/ vanzacaftor (Alyftrek)** | At least one F508del mutation or another responsive mutation in the CFTR gene. See drug labeling for a comprehensive list of mutations: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=218730 | ≥ 6 years |
| **Ivacaftor (Kalydeco)** | E56K, G178R, S549R K1060T, G1244E, P67L, E193K, G551D, A1067T, S1251N<br>R74W, L206W, G551S, G1069R, S1255P, D110E, R347H, D579G, R1070Q, D1270N, D110H, R352Q, S945L, R1070W G1349D, R117C, A455E, S977F, F1074L, R117H, S549N, F1052V, D1152H 3849 + 10kbC –T, 2789 +5G>A, 3272-26A-G, 711+3A-G, E831X, R117H or a mutation in the CFTR gene that is responsive based on in vitro data. See drug labeling for a comprehensive list of approved mutations: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203188 | 4 months to < 6 months AND ≥ 5 kg<br><br>≥ 6 months |
| **Lumacaftor/ivacaftor (Orkambi)** | Homozygous Phe508del | ≥ 1 year |
| **Tezacaftor/Ivacaftor (Symdeko)** | Homozygous Phe508del, A455E, A1067T, D110E, D110H, D579G, D1152H, D1270N, E56K, E193K, E831X, F1052V, F1074L, K1060T, L206W, P67L, R74W, R1070W, R117C, R347H, R352Q, S945L, S977F, 711+3A→G, 2789+5G→A, 3272-26A→G, 3849+10kbC→T or a mutation in the CFTR gene that is responsive based on in vitro data. See drug labeling for a comprehensive list of approved mutations: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210491 | ≥ 6 years |
| **Elexacaftor/tezacaftor/ ivacaftor (Trikafta)** | At least one Phe508del mutation (homozygous or heterozygous) or a mutation in the CFTR gene that is responsive based on in vitro data. See drug labeling for a comprehensive list of mutations: | ≥ 2 years |

| | | |
|---|---|---|
| | https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212273 | |

| Approval Criteria | | |
|---|---|---|
| 1. Is this a request for continuation of therapy previously approved by the FFS program (patient already on ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, or elexacaftor/tezacaftor/ivacaftor)? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #2 |
| 2. Does the patient have a diagnosis of Cystic Fibrosis? | **Yes:** Record ICD10 code. Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the request from a practitioner at an accredited Cystic Fibrosis Center or a pulmonologist? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the request for an FDA approved age and CFTR gene mutation as defined in Table 1? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness<br><br>If unknown, there needs to be a CF mutation test to detect the presence of the CFTR mutation prior to use. |
| 5. How many exacerbations and/or hospitalizations in the past 12 months has the patient had? | Prescriber must provide documentation before approval. Document baseline value.<br>Go to #6 | |
| 6. Is the request for ivacaftor? | **Yes:** Go to #7 | **No:** Go to #8 |
| 7. Does the patient have a documented R117H mutation in the CFTR gene detected by a CF mutation test? | **Yes:** Pass to RPh. Refer request to Medical Director for manual review and assessment of clinical severity of disease for approval. | **No:** Go to #8<br><br>If unknown, there needs to be a CF mutation test to detect the presence of the CFTR mutation prior to use.<br><br>CF due to other CFTR gene mutations are not approved indications (including the F508del mutation). |

| Approval Criteria | | |
|---|---|---|
| 8. Is the patient on ALL the following drugs, or has had an adequate trial of each drug, unless contraindicated or not appropriate based on age <6 years and normal lung function?<br>• Dornase alfa; AND<br>• Hypertonic saline; AND<br>• Inhaled or oral antibiotics (if appropriate)? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Is the patient on concomitant therapy with a strong CYP3A4 inducer (see Table 2)? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #10 |
| 10. What are the baseline liver function (AST/ALT) and bilirubin levels (within previous 3 months)? | Document labs. Go to #11<br><br>If unknown, these labs need to be collected prior to approval. | |
| 11. Is medication dosed appropriately based on age, weight, and co-administered drugs (see dosing and administration below)? | **Yes:** Approve for 6 months.<br>If approved, a referral will be made to case management by the Oregon Health Authority. | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is there evidence of adherence and tolerance to therapy through pharmacy claims/refill history and provider assessment? | **Yes:** Go to #2 | **No:** Pass to RPh; Deny (medical appropriateness) |

| Renewal Criteria | | |
|---|---|---|
| 2. Does the patient have documented response to therapy as defined as below :<br>For patients age ≥6 years:<br>• An improvement or lack of decline in lung function as measured by the FEV1 when the patient is clinically stable; OR<br>• A reduction in the incidence of pulmonary exacerbations; OR<br>• A significant improvement in BMI by 10% from baseline?<br>For patients age 2-5 years (cannot complete lung function tests)<br>• Significant improvement in BMI by 10% from baseline; OR<br>• Improvement in exacerbation frequency or severity | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Have liver function tests been appropriately monitored? What are the most recent liver function tests (AST, ALT, and bilirubin)?<br><br>Note: Monitoring LFTs is recommended every 3 months for the first year, followed by once a year. | Document. Go to #4<br><br>Note: Therapy should be interrupted in patients with AST or ALT >5x the upper limit of normal (ULN), or ALT or AST >3x ULN with bilirubin >2x ULN. | |
| 4. Is the CFTR modulator dosed appropriately based on age, weight, and co-administered drugs (see dosing and administration below)? | **Yes:** Approve for additional 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

**Dosage and Administration:**

<u>Ivacaftor:</u>

- Adults and pediatrics age ≥6 years: 150 mg orally every 12 hours with fat-containing foods
- Children age 6 months to <6 years:
  - 5 kg to < 7 kg: 25 mg packet every 12 hours
  - 7 kg to < 14 kg: 50 mg packet every 12 hours
  - ≥ 14 kg: 75 mg packet every 12 hours
- Hepatic Impairment
  - Moderate Impairment (Child-Pugh class B):
    - Age ≥6 years: one 150 mg tablet once daily
    - Age 6 months to < 6 years
      - with body weight < 14 kg: 50 mg packet once daily
      - with body weight ≥ 14 kg : 75 mg packet of granules once daily
  - Severe impairment (Child-Pugh class C): Use with caution at a dose of 1 tablet or 1 packet of oral granules once daily or less frequently. For infants, children and adolescents: administer usual dose once daily or less frequently. Use with caution.
- Dose adjustment with concomitant medications:

Table 2. Examples of CYP3A4 inhibitors and inducers.

| Drug co-administered with IVA | Co-administered drug category | Recommended dosage adjustment for IVA |
|---|---|---|
| Ketoconazole<br>Itraconazole<br>Posaconazole<br>Voriconazole<br>Clarithromycin<br>Telithromycin | CYP3A4 strong inhibitors | Reduce IVA dose to 1 tablet or 1 packet of oral granules **twice weekly** (one-seventh of normal initial dose) |
| Fluconazole<br>Erythromycin<br>Clofazimine | CYP3A4 moderate inhibitors | Reduce IVA dose to 1 tablet or 1 packet of oral granules **once daily** (half of normal dose) |
| Rifampin<br>Rifabutin<br>Phenobarbital<br>Phenytoin<br>Carbamazepine<br>St. John's wort | CYP3A4 strong inducers | Concurrent use is **NOT** recommended |
| Grapefruit Juice | CYP3A4 moderate inhibitors | |

Lumacaftor/ivacaftor

- Adults and pediatrics age ≥12 years: 2 tablets (LUM 200 mg/IVA 125 mg) every 12 hours
- Pediatric patients age 6 through 11 years: 2 tablets (LUM 100mg/IVA 125 mg) every 12 hours
- Children age 2 to <6 years:
  - < 14 kg: 1 packet (LUM 100mg/IVA125mg) every 12 hours
  - ≥ 14 kg: 1 packet (LUM 150mg/IVA 188mg) every 12 hours
- Hepatic impairment
  - Moderate impairment (Child-Pugh class B):
    - Age ≥ 6 years: 2 tablets in the morning and 1 tablet in the evening
    - Age 2 to <6 years: 1 packet in the morning and 1 packet every other day in the evening
  - Severe impairment (Child-Pugh class C): Use with caution after weighing the risks and benefits of treatment.
    - Age ≥ 6 years: 1 tablet twice daily, or less
    - Age 2 to <6 years: 1 packet once daily, or less
- Dose adjustment with concomitant medications:
  - When initiating therapy in patients taking strong CYP3A inhibitors (see table above), reduce dose to 1 tablet daily for the first week of treatment. Following this period, continue with the recommended daily dose.

Tezacaftor/ivacaftor:

- Adults and pediatrics age ≥6 years weighing ≥30 kg : 1 tablet (TEZ 100 mg/IVA 150 mg) in the morning and IVA 150 mg in the evening
- Pediatrics age ≥ 6 years weighing < 30 kg: TEZ 50mg/IVA 75 mg in the morning and IVA 75 mg in the evening
- Hepatic impairment
  - Moderate impairment (Child-Pugh class B):
    - 1 tablet (TEZ 100 mg/IVA 150 mg) in the morning. The evening IVA dose should not be administered.
  - Severe impairment (Child-Pugh class C):
    - 1 tablet (TEZ 100 mg/IVA 150 mg) in the morning (or less frequently). The evening IVA dose should not be administered.
- Dose adjustment with concomitant medications:

- When initiating therapy in patients taking moderate CYP3A inhibitors (see table above), reduce dose to:
  - On day 1, TEZ 100/IVA 150 once daily in the morning, and on day 2, IVA 150 mg once daily in the morning; continue this dosing schedule.
- When initiating therapy in patients taking strong CYP3A4 inhibitors (See table above), reduce dose to:
  - TEZ 100 mg/IVA 150 mg twice a week, administered 3 to 4 days apart. The evening dose of IVA 150 mg should not be administered.

Elexacaftor/tezacaftor/ivacaftor:

- Adults and pediatrics age ≥12 years: 2 tablets (ELX 100mg/TEZ 50 mg/IVA 75 mg) in the morning and IVA 150 mg in the evening
- Hepatic impairment
  - Moderate impairment (Child-Pugh class B): Use only if the benefits outweigh the risks.
    - 2 tablet (ELX 100 mg/TEZ 50 mg/IVA 75 mg) in the morning. The evening IVA dose should not be administered.
  - Severe impairment (Child-Pugh class C): Use not recommended
- Dose adjustment with concomitant medications:
  - Dosage adjustment for concomitant therapy with moderate CYP3A inhibitors (see table above):
    - 2 tablets (ELX 100 mg/ TEZ 50 mg/IVA 75 mg once daily in the morning, alternating with one IVA 150 mg tablet in the morning every other day.
  - Dosage adjustment for concomitant therapy with strong CYP3A4 inhibitors (See table above), reduce dose to:
    - 2 tablets (ELX 100 mg/TEZ 50 mg/IVA 75 mg twice a week, administered 3 to 4 days apart. The evening dose of IVA 150 mg should not be administered.

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*P&T Review:* *6/21(MH); 6/20; 9/19; 9/18; 7/18; 11/16; 11/15; 7/15; 5/15; 5/14; 6/12*
*Implementation:* *7/1/21; 7/1/20; 11/1/19; 11/1/2018; 1/1/16; 8/25/15; 8/12*

# Dalfampridine

**Goal(s):**

- To ensure appropriate drug use and limit to patient populations in which the drug has been shown to be effective and safe.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Dalfampridine

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Does the patient have a diagnosis of Multiple Sclerosis? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the medication being prescribed by or in consultation with a neurologist? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the request for continuation of therapy previously approved by the FFS program (patient has completed 2-month trial)? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #5 |
| 5. Does the patient have a history of seizures? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #6 |
| 6. Is a documented estimated glomerular filtration rate (eGFR) showing the product is not contraindicated?<br><br>Note: Dalfampridine is contraindicated in patients with moderate or severe renal impairment (CrCl ≤ 50 mL/min) | **Yes:** Go to # 7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is the patient ambulatory with a walking disability requiring use of a walking aid **OR;**<br>have moderate ambulatory dysfunction and does not require a walking aid AND able to complete the baseline timed 25-foot walk test between 8 and 45 seconds? | **Yes:** Approve initial fill for 2-month trial. | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Has the patient been taking dalfampridine for ≥2 months with documented improvement in walking speed while on dalfampridine (≥20% improvement in timed 25-foot walk test)? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

**Clinical Notes:**

- Because fewer than 50% of MS patients respond to therapy and therapy has risks, a trial of therapy should be used prior to beginning ongoing therapy.
- The patient should be evaluated prior to therapy and then 4 weeks to determine whether objective improvements which justify continued therapy are present (i.e. at least a 20% improvement from baseline in timed walking speed).
- Dalfampridine is contraindicated in patients with moderate to severe renal impairment.
- Dalfampridine can increase the risk of seizures; caution should be exercised when using concomitant drug therapies known to lower the seizure threshold.

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*P&T Review:* *10/24 (DM); 10/22 (DM); 6/21(DM); 8/20 (DM); 6/20; 11/17; 5/16; 3/12*
*Implementation:* *1/1/23, 8/16, 9/1/13*

# Dispense as Written-1 (DAW-1) Reimbursement Rate

**Brand Name and Multi-Source**

**Goal(s):**

- State compliance with US CFR 42 Ch.IV §447.512
- Encourage use of generics.
- Cover multi-source brand drugs at the higher reimbursement rate (DAW-1) only when diagnosis is covered by OHP and medically necessary.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- All brand multi-source drugs dispensed with a DAW-1 code (except narrow therapeutic index drugs listed below) as defined in ORS 414.325.

**Covered Alternatives:**

- Preferred alternatives listed at www.orpdl.org
- Prior Authorization is NOT required when multi-source brands are dispensed with DAW codes other than DAW-1 and thus pay at generic AAAC (Average Actual Acquisition Cost).
- AAAC prices and dispute forms are listed at: http://www.oregon.gov/oha/pharmacy/Pages/aaac-rates.aspx

| Narrow-therapeutic Index Drugs that WILL PAY Without Prior Authorization | | |
|---|---|---|
| **HSN** | **Generic Name** | **Brand Name** |
| 001893 | Carbamazepine | Tegretol |
| 004834 | Clozapine | Clozaril |
| 004524 | Cyclosporine | Sandimmune |
| 010086 | Cyclosporine, modified | Neoral |
| 000004 | Digoxin | Lanoxin |
| 002849 | Levothyroxine | Levothroid, Synthroid |
| 008060 | Pancrelipase | Pancrease |
| 001879 | Phenytoin | Dilantin |
| 002812 | Warfarin | Coumadin |
| 008974 | Tacrolimus | Prograf |
| 000025 | Theophylline controlled-release | Various |
| HIC3-C4G | Insulin(s) | Various |

| Approval Criteria | | |
|---|---|---|
| 1. Is the diagnosis an OHP (DMAP) above the line diagnosis? | **Yes:** Go to #2. | **No:** If not eligible for EPSDT review: Pass to RPH; Deny (Not Covered by the OHP). Offer alternative of using generic or pharmacy accepting generic price (no DAW-1)<br><br>If eligible for EPSDT review: Go to #2 |
| 2. Is the drug requested an antiepileptic in Std TC 48 (e.g. Lamotrigine) or immunosuppressant in Spec TC Z2E (e.g. Cellcept) and is the client stabilized on the branded product? | **Yes:** Document prior use and approve for one year. | **No:** Go to #3. |
| 3. Does client have documented failure (either therapeutic or contraindications) on an AB-rated generic? (usually 2 weeks is acceptable) | **Yes:** Document date used and results of trial. Approve for one year. | **No:** Pass to RPH; Deny, (Cost Effectiveness) |

*P&T / DUR Action:* *2/23/06, 3/19/09, 12/3/09 (KK)*
*Implementation:* *10/15, 7/1/06, 9/08, 7/1/09 (KK), 1/1/10 (KK)*

# Delandistrogene moxeparvovec

**Goal(s):**
- Restrict use of this gene therapy to patients with the FDA-labeled indication.

**Length of Authorization:**
- 1 lifetime dose

**Requires PA:**
- Delandistrogene moxeparvovec (pharmacy and provider administered claims)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for treatment of genetically-confirmed Duchenne Muscular Dystrophy? | **Yes:** Go to #3<br><br>Results of genetic testing are required for approval. | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Note: Therapies are not indicated for other forms of muscular dystrophy or other diagnoses. |
| 3. Is the medication prescribed by a neuromuscular specialist? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 4. Is the request for an FDA approved age (i.e., 4 years or older)? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 5. Does the patient have deletions of exon 8 or 9? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #6 |
| 6. For patients with deletions of exons 1 to 17 or exons 59 to 71, is there documentation that the provider and patient have discussed potential risks of treatment?<br><br>Note: these populations were excluded from clinical studies and may have increased risk for severe immune-mediated myositis reactions. | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 7. Has baseline testing been completed and is within normal limits?<br><br>Recommended baseline testing includes testing for anti-AAVrh74 antibodies (by ELISA), troponin-I, platelets, and liver function tests. | **Yes:** Go to #8<br><br>For any testing that is not within normal limits, refer to medical director for review. Liver function tests should be <3x the upper limit of normal. | **No:** Pass to RPh. Deny; medical appropriateness. |
| 8. Has the patient received, or have contraindications to, all routine immunizations recommended for their age?<br><br>Note: Routine vaccinations for patients at least 4 years of age typically include hepatitis B, hepatitis A, diphtheria, tetanus, pertussis, pneumococcal conjugate, inactivated poliovirus, influenza, COVID-19, and at least 2 doses of measles, mumps, rubella, and varicella. | **Yes:** Go to #9<br><br>Document provider attestation of immunization history. | **No:** Pass to RPh. Deny; medical appropriateness. |
| 9. Is the patient able to tolerate an elevated dose of prednisone for at least 60 days and complete necessary ongoing monitoring? | **Yes:** Go to #10<br><br>Document provider attestation. | **No:** Pass to RPh. Deny; medical appropriateness. |
| 10. Is there documentation that the provider and member have discussed potential risks of treatment?<br><br>Note: Informed consent is recommended as this therapy has shown that it does not change global motor function in 2 clinical trials. It is associated with serious side effects including injury to the liver and heart and it may prevent use of any future adeno-based gene therapy. | **Yes**: Go to #11 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 11. Has the patient received a prior dose of an adeno-based gene therapy? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Approve single infusion (max 1 dose per lifetime) |

*P&T/DUR Review:* *10/24, 2/24 (SS)*
*Implementation:* *12/1/2024; 4/1/24*

# Dextromethorphan/Quinidine (NUEDEXTA)

**Goal(s):**
- To ensure appropriate drug use and restrict to indications supported by medical literature.
- Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- NUEDEXTA (Combination of dextromethorphan 20 mg and quinidine 10 mg capsule)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this for a patient with pseudobulbar affect (involuntary outbursts of laughing or crying that are inappropriate to the patient's emotional state) associated with a chronic neurological condition (e.g., amyotrophic lateral sclerosis, multiple sclerosis, stroke, dementia, Parkinson's disease, traumatic brain injury)? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the patient eligible for EPSDT review? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; not funded by the OHP |
| 4. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.)? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical necessity. |
| 5. Is the medication prescribed by or in consultation with a neurologist? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 6. Is there documentation of the number of baseline laughing or crying episodes? | **Yes:** Approve for 6 months.<br><br>Document results here:<br>Number of crying or laughing episodes per day_____<br>Date:_____ | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is there documentation of improvement in frequency of laughing or crying episodes from baseline as assessed by the prescribing provider? | **Yes**: Approve for 60 months. | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 6/25 (DM)*
*Implementation: 8/1/25*

# Drugs for Diarrhea

**Goal(s):**
- Promote use that is consistent with medical evidence and product labeling.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Eluxadoline (Viberzi), Alosetron (Lotronex) and Loperamide at doses > 16 mg/day

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the diagnosis funded by the OHP? | **Yes:** Go to #3 | **No:** Not eligible for EPSDT review: Pass to RPh. Deny; diagnosis not covered by OHP.<br><br>Eligible for EPSDT review: Go to #3 |
| 3. Is this a request for continuation of therapy previously approved by the FFS program? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #4 |
| 4. Is the diagnosis irritable bowel syndrome (IBS) with diarrhea with the following symptoms for the past 3 months:<br>• Frequent and severe abdominal pain and discomfort AND<br>• Frequent bowel urgency or fecal incontinence AND<br>• Disability or restriction of daily activities due to IBS | **Yes:** Go to #5 | **No:** Pass to RPh. Deny for medical appropriateness |
| 5. Is the request for eluxadoline in an adult? | **Yes:** Go to #6 | **No:** Go to #9 |
| 6. Have baseline liver function tests been obtained? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny for medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 7. Is there documentation of sphincter of Oddi problems, cholecystectomy, alcohol dependence, pancreatitis or severe liver impairment? | **Yes:** Pass to RPh. Deny for medical appropriateness | **No:** Go to #8 |
| 8. Does the patient have normal hepatic function or if they have mild or moderate hepatic function has the eluxadoline dose been adjusted to 75 mg twice daily? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny for medical appropriateness |
| 9. Is the request for alosetron in an adult woman who has chronic IBS-D symptoms (e.g., last longer than 6 months)? | **Yes:** Go to #10 | **No:** Pass to RPh. Deny for medical appropriateness |
| 10. Have anatomic or biochemical abnormalities of the gastrointestinal tract been excluded? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny for medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the request for irritable bowel syndrome with diarrhea? | **Yes:** Go to #2 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 2. Does the provider attest that the patient's symptoms have improved with therapy as evidenced by less frequent bowel movements compared to baseline? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T Review:* *2/25 (DM):*
*Implementation:* *3/10/25*

# Diazoxide Choline Extended-Release Tablets

**Goals:**
- Ensure appropriate utilization in people with hyperphagia due to Prader-Willi syndrome.
- Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Vykat XR (diazoxide choline extended-release tablets)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for continuation of therapy in a patient previously approved by FFS? | **Yes:** Go to Renewal Criteria | **No:** Go to #3 |
| 3. Is this an FDA-approved indication? | **Yes**: Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.) | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical necessity. |
| 5. Is the medication prescribed by an endocrinologist or in consultation with a provider that specializes in caring for patients with Prader-Willi syndrome? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 6. Has extent of baseline hyperphagia behavior been documented using the caregiver Hyperphagia Questionnaire for Clinical Trials (HQ-CT) assessment or a comparable assessment that is documented in the patient records? | **Yes:** Approve for 6 months<br><br>Document care plan and treatment goals: _____ | **No:** Pass to RPh. Deny; medical appropriateness. |

| Renewal Criteria | | |
|---|---|---|
| 1. Has hyperphagia behavior decreased since beginning therapy as assessed by improvement in the HQ-CT score or a comparable assessment that is documented in the patient record? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny for lack of treatment response. |

*P&T/DUR Review: 8/25; (DM)*
*Implementation: 9/15/25*

# Dichlorphenamide

**Goal(s):**
- Encourage appropriate use of dichlorphenamide for Hyperkalemic and Hypokalemic Periodic Paralysis.

**Length of Authorization:**
- Up to 3 months for the first authorization and first renewal. Up to 6 months for renewals thereafter.

**Requires PA:**
- Dichlorphenamide

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for continuation of dichlorphenamide treatment previously approved by Fee-For-Service? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Is the requested treatment for Andersen-Tawil Syndrome or Paramytonia congenita? | **Yes:** Pass to RPh. Deny; medical appropriateness.<br><br>Note: Dichlorphenamide is only approved for Hyperkalemic and Hypokalemic Periodic Paralyses. | **No:** Go to #4 |
| 4. Is the request for treatment of Hyperkalemic or Hypokalemic Periodic Paralysis based on genetic testing or clinical presentation? | **Yes:** Go to #5 | **No**: Pass to RPh. Deny; medical appropriateness.<br><br>Note: Dichlorphenamide is not indicated for other forms of periodic paralysis. |
| 5. Does the patient have an average baseline attack rate of ≥1 attack per week? | **Yes:** Go to #6<br><br>Document baseline attack rate. | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 6. Has the patient previously tried and failed acetazolamide? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 7. Has the patient previously experienced disease worsening upon treatment with acetazolamide? | **Yes:** Pass to RPh. Deny; medical appropriateness.<br><br>Note: Dichlorphenamide was not studied in this population due to potential for similar disease worsening effects. | **No:** Go to #8 |
| 8. Have potential precipitating factors (including lifestyle and recent medication changes) been evaluated for with documentation of continued attack rate or severity upon changes to therapy or lifestyle modifications?<br><br>Note: Medications which affect potassium levels include, but are not limited to, oral potassium, steroids, insulin, and diuretics. | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Note: Lifestyle and medication changes are generally regarded as first-line therapy. |
| 9. Is the patient currently taking ≥1000mg of aspirin daily? | **Yes:** Pass to RPh. Deny; medical appropriateness.<br><br>Note: Concurrent use of ≥1000mg aspirin daily with dichlorphenamide is contraindicated. | **No:** Go to #10 |
| 10. Is the patient ≥18 years old? | **Yes:** Go to #11 | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Note: There is insufficient evidence of safety and efficacy in the pediatric population. |

| Approval Criteria | | |
|---|---|---|
| 11. Have baseline serum potassium and bicarbonate been documented as >3.5 mmol/L and >22 mmol/L respectively? | **Yes:** Approve for up to 3 months. | **No:** Pass to RPh. Deny; medical appropriateness. |

| Renewal Criteria | | |
|---|---|---|
| 1. Has the weekly average attack rate decreased from baseline? | **Yes:** Go to #2<br><br>Document attack rate. | **No:** Pass to RPh. Deny; medical appropriateness. |
| 2. Have the serum potassium and bicarbonate been measured and documented as >3.5 mmol/L and >22 mmol/L respectively since the last approval? | **Yes:** Approve for 3 months at first renewal and up to 6 months for renewals thereafter. | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T/DUR Review: 3/18 (EH)*
*Implementation: 4/16/18*

# Donislecel (LANTIDRA)

**Goal(s):**
- To ensure appropriate use of donislecel in patients with T1DM.

**Length of Authorization:**
- Up to 3 infusions

**Covered Alternatives:**
- There are no other approved allogenic pancreatic islet cellular therapies.

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this an FDA approved indication? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is the patient 18 years or older and less than 65 years of age? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 4. Does the patient have a diagnosis of type 1 diabetes mellitus (T1DM)? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 5. Is the patient unable to meet HbA1c goal due to current repeated episodes* of severe hypoglycemia (e.g., symptoms consistent with hypoglycemia which required assistance of another person and was associated with a blood glucose of <50 mg/dL or prompt recovery after oral carbohydrate, intravenous glucose or glucagon administration) despite intensive diabetes management (e.g., self-monitoring of glucose values no less than a mean of 3 times a day averaged over each week and by administration of 3 or more insulin injections each day or insulin pump therapy) and education? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 6. Has the patient been informed that they will not be a candidate for future transplants (e.g., kidney) after receiving donislecel? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; inform patient of risk. |

| Approval Criteria | | |
|---|---|---|
| 7. Has the patient received 3 prior infusions of donislecel? | **Yes:** Pass to RPh. Deny; medical appropriateness.<br><br>Labeling recommends a maximum of 3 infusions. | **No:** Approve for up to 3 infusions<br><br>Document number of infusions. |

* Current repeated episodes identifies a patient population at risk for severe hypoglycemic events on an ongoing basis.

*P&T/DUR Review: 2/24 (KS)*
*Implementation: 4/1/24*

# Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

**Goal(s):**
- Promote cost-effective and safe step-therapy for management of type 2 diabetes mellitus (T2DM).

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- All non-preferred DPP-4 Inhibitors. Preferred products do not require PA when prescribed as second-line therapy in conjunction with metformin.

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Does the patient have a diagnosis of Type 2 diabetes mellitus? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Has the patient tried and failed metformin, or have contraindications to metformin?<br><br>(document contraindication, if any) | **Yes:** Go to #4 | **No:** Pass to RPh; deny and recommend trial of metformin. See below for metformin titration schedule. |
| 4. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics (P&T) Committee. | **Yes:** Inform prescriber of covered alternatives in class | **No:** Approve for up to 12 months |

**Initiating Metformin**

| | |
|---|---|
| 1. | Begin with low-dose metformin (500 mg) taken once or twice per day with meals (breakfast and/or dinner) or 850 mg once per day. |
| 2. | After 5-7 days, if gastrointestinal side effects have not occurred, advance dose to 850 mg, or two 500 mg tablets, twice per day (medication to be taken before breakfast and/or dinner). |
| 3. | If gastrointestinal side effects appear with increasing doses, decrease to previous lower dose and try to advance the dose at a later time. |
| 4. | The maximum effective dose can be up to 1,000 mg twice per day. Modestly greater effectiveness has been observed with doses up to about 2,500 mg/day. Gastrointestinal side effects may limit the dose that can be used. |

Nathan, et al. Medical management of hyperglycemia in Type 2 Diabetes: a consensus algorithm for the initiation and adjustment of therapy. *Diabetes Care*. 2008; 31;1-11.

*P&T/DUR Review:* *8/20 (KS), 7/18; 9/17; 9/16; 9/15; 9/14; 9/13; 4/12; 3/11*
*Implementation:* *9/1/20; 10/13/16; 10/15; 1/15; 9/14; 1/14; 2/13*

# Droxidopa (Northera®)

**Goal(s):**
- To optimize appropriate pharmacological management of symptomatic neurogenic orthostatic hypotension.

**Length of Authorization:**
- Initial: 14 days
- Renewal: 3 months

**Requires PA:**
- Non-preferred drugs

**Covered Alternatives:**
- Preferred alternatives listed at www.orpdl.org

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Does the patient have a diagnosis of symptomatic orthostatic hypotension (ICD10 I951) due to primary autonomic failure (Parkinson's disease, multiple system atrophy or pure autonomic failure), dopamine beta-hydroxylase deficiency, or nondiabetic autonomic neuropathy? (ICD10 G20; G230-232, G238; E700,E7021-7030, E705,E708,E710, E7040,E71120,E7119, E712, E7210, E7211,E7219, E7200-7201, E7204, E7209, E7220, E7222, E7223, E7229, E723, E728; G9001,G904, G909, G9009, G9059, G90519, G90529, G990) | **Yes:** Go to #3 | **No:** Pass to RPH. Deny for medical appropriateness. |
| 3. Is the patient currently receiving antihypertensive medication? | **Yes:** Pass to RPH. Deny for medical appropriateness. | **No:** Go to #4 |

| Approval Criteria | | |
|---|---|---|
| 4. Does the patient have a documented trial of appropriate therapy with both fludrocortisone and midodrine?<br><br>Message:<br>Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics Committee. | **Yes:** Approve for up to 14 days. | **No:** Inform provider fludrocortisone and midodrine are both covered alternatives. If justification provided for not trying alternatives (contraindications, concern for adverse effects, etc.), approve for up to 14 days. |

| Renewal Criteria | | |
|---|---|---|
| 1. Is this the first time the patient is requesting this renewal? | **Yes:** Go to #2. | **No:** Approve for up to 3 months. |
| 2. Does the patient have documented response to therapy (e.g., improvement in dizziness/ lightheadedness)? | **Yes:** Approve for up to 3 months. | **No:** Pass to RPH; Deny for medical appropriateness. |

*P&T / DUR Action:* *1/29/15 (AG)*
*Implementation:* *10/15*

# Drugs Selected for Manual Review by Oregon Health Plan

**Goal:**

- Require specialty drugs selected by the Oregon Pharmacy & Therapeutics (P&T) Committee to be manually reviewed and approved by the Oregon Health Plan (OHP) Medical Director.

**Length of Authorization:**

- To be determined by OHP Medical Director.

**Requires PA:**

- A drug approved by the P&T Committee to be manually reviewed by the OHP Medical Director for approval.

| Approval Criteria | |
|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code |
| 2. Pass to RPh. Deny; requires manual review and approval by the OHP Medical Director.<br><br>Message: The P&T Committee has determined this drug requires manual review by the OHP Medical Director for approval. | |

*P&T / DUR Review:* *11/15 (AG)*
*Implementation* *1/1/16*

# Drugs for Non-funded Conditions

**Goal:**

- Restrict use of drugs reviewed by the Oregon Pharmacy & Therapeutics (P&T) Committee without evidence for use in Oregon Health Plan (OHP)-funded conditions. Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**

- Up to 6 months.

**Requires PA:**

- A drug restricted by the P&T Committee due to lack of evidence for conditions funded by the OHP.

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is the drug being used to treat an OHP-funded condition? | **Yes:** Go to #4 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br>If eligible for EPSDT review: Go to #3 |
| 3. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Approve for 6 months, or for length of the prescription, whichever is less | **No:** Pass to RPh; Deny; medical necessity. |
| 4. Pass to RPh. The prescriber must provide documentation of therapeutic failure, adverse event, or contraindication alternative drugs approved by FDA for the funded condition. Otherwise, the prescriber must provide medical literature supporting use for the funded condition. RPh may use clinical judgement to approve drug for up to 6 months or deny request based on documentation provided by prescriber. | | |

*P&T / DUR Review:* *12/22; 4/22 (SS); 11/15*
*Implementation* *1/1/23; 1/1/16*

## Dry Eye Disease, Targeted Drugs

**Goal(s):**

- Allow for coverage of approved prescription therapies for dry eye disease and vernal keratoconjunctivitis when they are funded in 2027.
- Allow case-by-case review for members covered under the EPSDT program.
- Over-the-counter artificial tears do not require prior authorization.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Non-preferred prescription drugs for dry eye and vernal keratoconjunctivitis

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this an FDA approved indication? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is this a request for renewal of a prescription dry eye product or product for vernal keratoconjunctivitis? | **Yes**: Go to Renewal Criteria below | **No:** Go to #4 |
| 4. Is the request for a patient with dry eye? | **Yes:** Go to #5 | **No:** Go to #10 |
| 5. Is the diagnosis funded by OHP? | **Yes:** Go to #8 | **No:** Go to #6 |
| 6. Does the patient have dry eye resulting in blurred vision or other visual impairment as a result of a chronic eye condition or medical condition (e.g., Sjögren's syndrome, lupus, cataracts, etc.)? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; If eligible for EPSDT review go to #7 |
| 7. If the member is eligible for EPSDT review, is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.)? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical necessity |

| Approval Criteria | | |
|---|---|---|
| 8. Has the patient tried artificial tears/ocular lubricants for at least 4 weeks without improvement in symptoms? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of artificial tears |
| 9. Is there documentation of baseline dry eye symptoms based on the Ocular Surface Disease Index (OSDI) or visual analog score (VAS)? | **Yes:** Go to #14 | **No:** Pass to RPh. Deny; recommend baseline assessment of dry eye symptoms |
| 10. Does the patient have a diagnosis vernal keratoconjunctivitis? | **Yes:** Go to #11 | **No:** Pass to RPh. Deny |
| 11. Is the diagnosis funded by OHP? | **Yes:** Go to #13 | **No:** Pass to RPh. Deny; If eligible for EPSDT review go to #12. |
| 12. If the member is eligible for EPSDT review, is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.)? | **Yes:** Go to #13 | **No:** Pass to RPh. Deny; medical necessity. |
| 13. Has the patient tried at least 2 of the following therapies for a minimum of 2 weeks?<br>- Topical mast cell stabilizers<br>- Antihistamines (oral or topical)<br>- Topical nonsteroidal anti-inflammatories<br>- Topical corticosteroids | **Yes:** Go to #14 | **No:** Pass to RPh. Deny; recommend trial of suggested therapies. |
| 14. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products do not require a PA.<br>• Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Approve for a maximum of 12 months. |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the request for a renewal of a previously approved dry eye disease medication? | **Yes**: Go to #2 | **No:** Go to Approval Criteria above |
| 2. Is the request for a patient with dry eye? | **Yes**: Go to #3 | **No**: Go to #4 |
| 3. Is there documentation of improvement from baseline dry eye symptom scores (e.g., OSDI change of 4.5 units or more or VAS reduction of 30% or more) as assessed by the prescribing provider? | **Yes**: Approve for a maximum of 12 months | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the request for a patient with vernal keratoconjunctivitis and the provider reports improvement in symptoms (this is a rare disease without validated tools for symptom assessment)? | **Yes**: Approve for a maximum of 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 6/25 (KS)*
*Implementation: 8/1/25*

# Duchenne Muscular Dystrophy

**Goal(s):**
- Encourage use of corticosteroids which have demonstrated long-term efficacy.
- Restrict use of targeted oligonucleotides for exon skipping to patients with Duchenne Muscular Dystrophy (DMD).
- Limit use of non-preferred corticosteroids to patients with contraindications or serious intolerance to preferred oral corticosteroids.

**Length of Authorization:**
- 6-12 months (criteria-specific)

**Requires PA:**
- Targeted therapies for exon skipping or histone deacetylase (HDAC) inhibitors (see Table 1; pharmacy or provider administered claims)
- Corticosteroids that are FDA-approved for Duchenne muscular dystrophy (e.g., deflazacort, vamorolone, etc)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1. FDA Approved Indications for targeted therapies

| Drug | Indication | Examples of amenable mutations (list is not all inclusive) | Recommended safety monitoring |
|---|---|---|---|
| casimersen (Amondys 45®) | Duchenne muscular dystrophy with mutations amenable to exon 45 skipping | Deletion of exons 44, 46, 46 to 47, 46 to 48, 46 to 49, 46 to 51, 46 to 53, 46 to 55, or 46 to 57 | Renal function (e.g., serum cystatin C, urine dipstick, and urine protein-to-creatinine) within the past 3 months |
| eteplirsen (Exondys 51®) | Duchenne muscular dystrophy with mutations amenable to exon 51 skipping | Deletion of exons 43 to 50; 45 to 50; 47 to 50; 48 to 50; 49 to 50; 50; or 52 | None |
| golodirsen (Vyondys 53®) | Duchenne muscular dystrophy with mutations amenable to exon 53 skipping | Deletion of exons 42 to 52; 45 to 52; 47 to 52; 48 to 52; 49 to 52; 50 to 52; 52; or 54 to 58 | Renal function (e.g., serum cystatin C, urine dipstick, and urine protein-to-creatinine) within the past 3 months |
| viltolarsen (Viltepso®) | Duchenne muscular dystrophy with mutations amenable to exon 53 skipping | Deletion of exons 42 to 52; 45 to 52; 47 to 52; 48 to 52; 49 to 52; 50 to 52; 52; or 54 to 58 | |
| givinostat (Duvyzat®) | Genetically confirmed Duchenne muscular dystrophy | No specific restrictions for type of mutation | Fasting triglycerides <300 mg/dL, platelet count > 150 x$10^9$ cells/L for all patients, and ECG in people with heart disease or cardiac risk factors within the past 3 months |

Table 2. Minimum recommended givinostat doses

| Weight | Minimum recommended dose |
|---|---|
| 10 to <20 kg | 13.3 mg twice daily |
| 20 to <40 kg | 17.7 mg twice daily |
| 40 to <60 kg | 26.6 mg twice daily |
| ≥ 60 kg | 35.4 mg twice daily |

| **Approval Criteria** | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for treatment of Duchenne Muscular Dystrophy? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Note: Therapies are not indicated for other forms of muscular dystrophy or other diagnoses. |
| 3. Is the request for a corticosteroid? | **Yes:** Go to #4 | **No:** Go to #7 |
| 4. Is the patient ≥ 2 years of age? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 5. Has the patient received, or have contraindications to, all routine immunizations recommended for their age?<br><br>Note: Routine vaccinations for patients at least 2 years of age typically include hepatitis B, hepatitis A, diphtheria, tetanus, pertussis, pneumococcal conjugate, inactivated poliovirus, influenza, and at least one dose of measles, mumps, rubella, and varicella. | **Yes:** Go to #6<br><br>Document physician attestation of immunization history. | **No:** Pass to RPh. Deny; medical appropriateness. |
| 6. Does the patient have a documented contraindication or intolerance to a preferred corticosteroid, such as oral prednisone, that is not expected to crossover to the requested therapy?<br><br>Note: deflazacort may be an option for patients with clinically significant weight gain associated with prednisone use. | **Yes:** Approve for up to 12 months.<br><br>Document contraindication or intolerance reaction. | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Recommend trial of prednisone. |
| 7. Is the request for givostat? | **Yes:** Go to #8 | **No:** Go to #9 |

| Approval Criteria | | |
|---|---|---|
| 8. Is the requested dose at or above the minimum recommended FDA dose (Table 2)?<br><br>Note: Discontinuation of givostat is recommended if adverse events persist despite dose reduction. There is no evidence evaluating efficacy of lower doses. | **Yes**: Go to #9 | **No:** Pass to RPh, Deny; medical appropriateness. |
| 9. Is the request for continuation of treatment previously approved by FFS? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #10 |
| 10. Is the request for an FDA-approved indication (Table 1)? | **Yes:** Go to #11<br><br>Document genetic testing. | **No:** Pass to RPh, Deny; medical appropriateness. |
| 11. Is the request for combination treatment with 2 or more targeted therapies?<br><br>There is no data evaluating combined use of targeted treatments for Duchenne Muscular Dystrophy. | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #12 |
| 12. Has baseline testing been completed as recommended in the FDA label (Table 1)? | **Yes**: Go to #13 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 13. Has the patient been on a stable dose of corticosteroid for at least 6 months or have documented contraindication to steroids? | **Yes:** Go to #14 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 14. Has baseline functional assessment been evaluated using a validated tool (e.g., the 6-minute walk test, North Star Ambulatory Assessment, etc)? | **Yes:** Document baseline functional assessment and approve for up to 6 months | **No:** Pass to RPh. Deny; medical appropriateness. |

| Renewal Criteria | | |
|---|---|---|
| 1. Has the provider performed safety monitoring as recommended in the FDA label (Table 1)?<br><br>Recommended monitoring includes urine dipstick monthly, serum cystatin C every 3 months, and protein-to-creatine ratio every 3 months. | **Yes:** Go to #2 | **No:** Pass to RPh, Deny; medical appropriateness. |
| 2. Has the patient's baseline functional status been maintained at or above baseline level or not declined more than expected given the natural disease progression? | **Yes:** Go to #3<br><br>Document functional status and provider attestation. | **No:** Pass to RPh, Deny; medical appropriateness. |
| 3. Is there documentation based on chart notes of any serious adverse events related to treatment (e.g., acute kidney injury, infections, low platelets, high triglycerides, etc.)? | **Yes:** Go to #4 | **No:** Approve for up to 6 months |
| 4. Has the adverse event been reported to the FDA Adverse Event Reporting System (FAERS)? | **Yes:** Approve for up to 6 months<br><br>Document provider attestation | **No:** Pass to RPh, Deny; medical appropriateness. |

*P&T/DUR Review:* *10/24, 2/24; 8/21 (SS); 2/21; 6/20; 09/19; 11/17; 07/17*
*Implementation:* *12/1/2024; 4/1/24; 9/1/21; 3/1/21; 7/1/20; 11/1/19; 1/1/18; 9/1/17*

# Edaravone (Radicava® or Radicava ORS®)

**Goal(s):**

- To encourage use of riluzole which has demonstrated mortality benefits.
- To ensure appropriate use of edaravone in populations with clinically definite or probable amyotrophic lateral sclerosis
- To monitor for clinical response for appropriate continuation of therapy.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Edaravone (pharmacy and provider administered claims)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for continuation of therapy of previously approved FFS criteria (after which patient has completed 6-month trial)? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Is the diagnosis an FDA approved indication? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the patient currently on riluzole therapy, OR have a documented contraindication or intolerance to riluzole? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the medication being prescribed by or in consultation with a neurologist? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Does the patient have documented percent-predicted forced vital capacity (%FVC) ≥ 80%? | **Yes:** Record lab result. _____ Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 7. Is there a baseline documentation of the revised ALS Functional Rating Scale (ALSFRS-R) score with ≥2 points in each of the 12 items? | **Yes:** Record baseline score.<br>(0 [worst] to 48 [best])<br>_____<br>Approve for 6 months based on FDA-approved dosing (**Table 1**) | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Has the prescriber provided documentation that the use of edaravone has slowed in the decline of functional abilities as assessed by a Revised ALS Functional Rating Scale (ALSFRS-R) with no decline more than expected given the natural disease progression (5 points from baseline over 6 months)? | **Yes:** Go to #2 | **No:** Pass to RPh. Deny; medical appropriateness<br><br>Use clinical judgment to approve for 1 month to allow time for appeal.<br><br>MESSAGE: "Although the request has been denied for long-term use because it is considered medically inappropriate, it has also been APPROVED for one month to allow time for appeal." |
| 2. Does the patient have documented percent-predicted forced vital capacity (%FVC) ≥ 80%? | **Yes:** Record lab result.<br>Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is there a documentation of the revised ALS Functional Rating Scale (ALSFRS-R) score with ≥2 points in each of the 12 items? | **Yes:** Record score.<br>(0 [worst] to 48 [best])<br><br>Approve for 12 months. | **No:** Pass to RPh. Deny; medical appropriateness |

**Table 1**. FDA Approved Dosing. (Consult FDA website for prescribing information details at www.fda.gov)

| Edaravone (RADICAVA) intravenous solution | Edaravone (RADICAVA ORS) oral suspension |
|---|---|
| 60 mg (two consecutive 30 mg infusion bags) IV infusion over 60 minutes | 105 mg (5mL) taking orally or via feeding tube in the morning after overnight fasting. Food should not be consumed for 1 hour after administration except water. |
| • Initial treatment cycle: daily dosing for 14 days followed by a 14-day drug-free period<br>• Subsequent treatment cycles: daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free period | |

*P&T/DUR Review: 4/23 (SF); 7/18 (DE)*
*Implementation: 8/15/18*

# Efgartigimod (VYVGART, VYVGART HYTRULO)

**Goal(s):**
- Restrict use to OHP-funded conditions.
- Promote use that is consistent with medical evidence.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Efgartigimod alfa-fcab (VYVGART) and efgartigimod alfa-hyaluronidase-qvfc (VYVGART HYTRULO) pharmacy and provider administered claims.

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the diagnosis funded by OHP? | **Yes:** Go to #4 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #3. |
| 3. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical necessity. |
| 4. Is this an FDA approved indication? | **Yes**: Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is this a request for continuation of therapy? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #6 |
| 6. Does the patient have an active infection? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #7 |

| Approval Criteria | | |
|---|---|---|
| 7. Has the patient received, or have contraindications to, all routine immunizations recommended for their age?<br><br>Note: Routine vaccinations for patients at least 2 years of age typically included hepatitis B, hepatitis A, diphtheria, tetanus, pertussis, pneumococcal conjugate, inactivated poliovirus, influenza, and at least 2 doses of measles, mumps, rubella, and varicella. Immunization with live vaccines is not recommended during efgartigimod treatment. | **Yes:** Go to #8.<br><br>Document physician attestation of immunization history | **No:** Pass to RPh. Deny; medical appropriateness. Administer vaccines before initiation of a new treatment cycle of efgartigimod |
| 8. Does the patient have a positive serological test for anti-acetylcholine receptor (AchR) antibodies? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Does the patient have a Myasthenia Gravis Foundation of America Clinical Classification of class II, III or IV? | **Yes:** Go to #10 | **No:** Pass to RPh. Deny; medical appropriateness |
| 10. Does the patient have a myasthenia gravis-specific activities of daily living scale (MG-ADL) total score of 5 points or more? | **Yes:** Go to #11<br><br>Record baseline MG-ADL score | **No:** Pass to RPh. Deny; medical appropriateness |
| 11. Has the patient received or is currently receiving two immunosuppressant therapies (as monotherapy or in combination) for at least one year without adequate symptom control or do they have contraindications to these therapies?<br><br>Example immunosuppressant therapies:<br>- Azathioprine<br>- Cyclosporine<br>- Mycophenolate mofetil<br>- Tacrolimus<br>- Methotrexate<br>- Cyclophosphamide | **Yes:** Go to #12 | **No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of immunosuppressant therapy |

| Approval Criteria | | |
|---|---|---|
| 12. Is the request for efgartigimod dosing that corresponds to FDA labeling?<br>• 10 mg/kg once weekly for 4 weeks<br>• For patients weighing 120 kg or more, the recommended dose is 1200 mg per infusion | **Yes:** Approve for up to two cycles. Each cycle is 1 dose/week for 4 weeks. The second cycle should not be administered sooner than 50 days from start of previous cycle. | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Has it been 50 days or more from the start of the previous efgartigimod treatment cycle? | **Yes**: Go to #2 | **No:** Pass to RPh. Deny; medical appropriateness |
| 2. Is this request for the first renewal of efgartigimod? | **Yes**: Go to #3 | **No:** Go to #4 |
| 3. Has the patient experienced a reduction in symptoms of at least 2 points from MG-ADL total baseline score? | **Yes**: Approve for up to 5 cycles. Each cycle is 1 dose/week for 4 weeks. Additional cycles should not be administered sooner than 50 days from start of previous cycle.<br><br>Record MG-ADL score | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Has the patient maintained a stable MG-ADL score over the last 12 months of efgartigimod therapy? | **Yes**: Approve for up to 7 cycles. Each cycle is 1 dose/week for 4 weeks. Additional cycles should not be administered sooner than 50 days from start of previous cycle.<br><br>Record MG-ADL score | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 2/23 (DM); 4/22 (KS)*
*Implementation: 4/1/23; 5/1/22*

# Emapalumab

**Goal(s):**
- To ensure appropriate use of emapalumab in patients with primary hemophagocytic lymphohistiocytosis (pHLH).

**Length of Authorization:**
- 2 - 6 months

**Requires PA:**
- Emapalumab

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1: Diagnostic Criteria for pHLH**

| | |
|---|---|
| ≥ 5 of the following 8 criteria at baseline | Fever |
| | Splenomegaly |
| | Cytopenias (2 or more):<br>- Hemoglobin <9 g/dL (infants <4 weeks: <10 g/dL)<br>- Platelets <100 x 109/L<br>- Neutrophils <1 x 109/L |
| | Hypertriglyceridemia (fasting, >265 mg/dL) or hypofibrinogenemia (<150 mg/dL) |
| | Hemophagocytosis in spleen, bone marrow, lymph nodes or liver |
| | Low or absent NK cell activity |
| | Ferritin >500 µg/L |
| | Elevated soluble CD25 (interleukin 2 receptor alpha) ≥2,400 units/mL |
| **OR** | |
| Molecular Genetic Testing | Biallelic pathogenic gene variant (eg. *PRF1, UNC13D, STX11, or STXBP2*)<br>or family history consistent with primary HLH |

**Table 2: Dosage and Administration**

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Primary HLH | 1 mg/kg IV twice per week (every 3 to 4 days) | 10 mg/kg/dose |

| Approval Criteria | | |
|---|---|---|
| 1. Is this a request for continuation of therapy previously approved by the FFS program? | **Yes**: Go to **Renewal Criteria** | **No**: Go to #2 |
| 2. What diagnosis is being treated? | Record ICD10 code. | |

| Approval Criteria | | |
|---|---|---|
| 3. Is this agent being prescribed for treatment of refractory, recurrent, or progressive primary HLH or for those who are intolerant to conventional primary HLH therapy?<br><br>*Conventional therapy should have included an etoposide and dexamethasone-based regimen* | **Yes:** Document prior therapies or reasons for failure.<br><br>Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 4. Has the diagnosis of pHLH been confirmed by genetic testing or by diagnostic criteria listed in **Table 1**? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 5. Is the agent prescribed by or in consultation with a specialist (e.g. hematologist) with experience in treating HLH patients? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 6. Is the agent being prescribed concurrently with dexamethasone? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 7. Is there documentation that the prescriber has assessed the patient and found no evidence of active infection? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 8. Has the patient received prophylaxis for Herpes Zoster, *Pneumocystis Jirovecii*, and fungal infections? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 9. Is there documentation that the patient has been evaluated and will continue to be monitored for TB, adenovirus, EBV, and CMV every 2 weeks as clinically appropriate? | **Yes:** Go to #10 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 10. Is the agent dosed appropriately based on documentation of a recent patient weight (see **Table 2** above)? | **Yes:** Document patient weight and go to #11<br><br>Weight:_____ | **No:** Pass to RPh. Deny; medical appropriateness. |
| 11. Is there attestation that the patient and provider will comply with case management to promote the best possible outcome for the patient and adhere to monitoring requirements required by the Oregon Health Authority? | **Yes:** Approve for 2 months. | **No:** Pass to RPh. Deny; medical appropriateness. |

| Renewal Criteria | | |
|---|---|---|
| 1. Does the patient show evidence of developing any serious infections, severe infusion reactions, or unacceptable toxicity related to emapalumab treatment/administration? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No**: Go to #2 |
| 2. Is emapalumab being prescribed concurrently with dexamethasone? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the patient receiving ongoing monitoring for TB, adenovirus, EBV, and CMV every 2 weeks as clinically appropriate? | **Yes**: Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Does the provider attest that the patient has not yet received hematopoietic stem cell transplantation (HSCT)? | **Yes**: Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Has the patient's condition stabilized or improved as assessed by the prescribing provider? | **Yes**: Approve for up to 6 months. | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 6/20 (DE)*
*Implementation: 9/1/2020*

# Ensifentrine

**Goals:**

- Promote use that is consistent with national clinical practice guidelines and medical evidence in people with COPD.

**Length of Authorization:**

- Up to 12 months

**Covered Alternatives:**

- Preferred alternatives listed at http://www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is this a request for continuation of therapy previously approved by the FFS program? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Does the patient have COPD? | **Yes:** Go to #4 | No: Pass to RPh. Deny for medical appropriateness |
| 4. Does the patient have an active prescription for a long-acting bronchodilator (long-acting anticholinergic agent or long-acting beta-agonist) or an inhaled corticosteroid (ICS)? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; recommend trial of preferred long-acting bronchodilator and ICS |
| 5. Is the prescriber a specialist in respiratory medicine or is the request in consultation with a specialist? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny for medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Does the provider attest that the patient's condition improved with ensifentrine treatment? | **Yes:** Approve for 12 months. | **No:** Pass to RPh. Deny for medical appropriateness |

*P&T/DUR Review:* *12/24 (DM)*
*Implementation:* *3/10/25*

# Esketamine (Spravato)

**Goal(s):**

- To ensure safe and appropriate use of esketamine in patients with treatment-resistant depression or suicidal ideation.

**Length of Authorization:**

- Up to 6 months

**Requires PA:**

- Esketamine (pharmacy and physician administered claims).

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this an FDA approved indication? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the request for maintenance dosing of esketamine (for determining response to therapy) OR for continuation after initiation during a recent hospitalization? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #4 |
| 4. Is the patient 65 years or older? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #5 |
| 5. Is the member currently engaged in or been referred for psychotherapy? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 6. Is there prescriber attestation or documentation of treatment-resistant depression based on all the following criteria:<br>a. Diagnosis of unipolar major depressive disorder<br>b. Patient has tried at least 2 different antidepressants in which:<br>i. There has been inadequate response after at least 6 weeks of treatment at an average minimum therapeutic dose or greater; or<br>ii. The patient has not been able to continue treatment for at least 6 weeks due to intolerable side effects.<br><br>Minimum therapeutic doses can be found here: https://www.oregon.gov/oha/HPA/DSI-Pharmacy/MHCAGDocs/Switching-Between-Anti-Depressant-Medications.pdf | **Yes:** Go to #9 | **No:** Go to #7 |
| 7. Is the request for treatment of major depressive disorder in the setting of acute suicidal ideation or behavior? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Recommend an adequate trial (minimum of 6-8 weeks) of 2 or more antidepressants. |
| 8. Is there a documented plan to optimize oral antidepressant treatment in one of the following ways:<br>a. Titrating the dose of the current antidepressant to a therapeutic level<br>b. Switching to a different antidepressant OR<br>c. Adding oral augmentation therapy (e.g., a second antidepressant, an atypical antipsychotic, or mood stabilizer)? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 9. Does the patient have documentation of any of the following:<br>• Current Aneurysmal vascular disease or arterial venous malformation OR<br>• History of Intracerebral hemorrhage OR<br>• Current Pregnancy OR<br>• Current Uncontrolled hypertension (e.g., >140/90 mmHg) | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Approve up to 28 days for induction (either 56 mg and/or 84 mg for titration) not to exceed 24 units total to be covered within the approved time window.<br><br>The approved time window typically spans 60 days to accommodate scheduling visits. |

| Renewal Criteria | | |
|---|---|---|
| 1. Is there documentation that the patient demonstrated an adequate response during the 4-week induction phase (an improvement in depressive symptoms)? | **Yes:** Go to #2 | **No**: Go to #3 |
| 2. Is the request for administration of esketamine once weekly or every 2 weeks? | **Yes:** Approve for up to 6 months (maximum of 12 per 28 days) | **No**: Pass to RPh. Deny; medical appropriateness. |
| 3. Has the patient been on therapy for at least 4 weeks? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Approve for completion of induction phase (total 28 days of treatment with a maximum of 24 nasal spray devices (each device contains 28 mg of esketamine) |

*P&T/DUR Review: 6/25(SS);6/24(KS);2/24; 12/23 (KS); 2/23, 10/21; 2/21; 7/19*
*Implementation:8/1/25; 7/1/24; 1/1/22; 3/1/21; 8/19/19*

# Estrogen Derivatives

**Goal(s):**

- Restrict use to medically appropriate conditions funded under the OHP

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Non-preferred estrogen derivatives

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products do not require prior authorization<br>• Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics (P&T) Committee. | **Yes:** Inform prescriber of covered alternatives in class | **No:** Go to #3 |
| 3. Is the request for a funded diagnosis? | **Yes**: Approve for up to 6 months | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #4 |
| 4. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical necessity. |
| 5. Is the request for:<br>a) an FDA approved indication AND<br>b) for a preferred product or has the patient failed to have benefit with, or have contraindications or intolerance to the preferred products? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T / DUR Review:* *8/23 (SS); 8/22 (KS); 1/17; 11/15*
*Implementation:* *9/1/23; 4/1/17; 1/1/16*

# Etranacogene dezaparvovec

**Goal(s):**
- Approve Etranacogene dezaparvovec (HEMGENIX) for conditions supported by evidence of benefit

**Length of Authorization:**
- Once in a lifetime dose.

**Requires PA:**
- Etranacogene dezaparvovec (billed as pharmacy or provider administered claim)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is it the FDA approved indication? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is there documentation that the patient has never received another gene therapy for any diagnosis? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Does the patient require continuous routine factor IX prophylaxis? | **Yes**: Go to #7 | **No:** Go to #5 |
| 5. Does the patient have a history of repeated, serious spontaneous bleeding OR current or historical life threatening hemorrhage? | **Yes**: Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Did these events occur during adherence to physician recommended and maximally adjusted factor IX therapy (including routine factor IX prophylaxis, if indicated) AND adherence to appropriate lifestyle precautions? | **Yes**: Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. Send to Medical Director for review. |

| Approval Criteria | | |
|---|---|---|
| 7. Does patient have congenital hemophilia B with:<br>• Severe Factor IX deficiency (<1% plasma factor IX activity) OR<br>• Moderately-Severe Factor IX deficiency (1 to 2% plasma factor IX activity) with a severe bleeding phenotype? | **Yes**: Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness. Send to Medical Director for review. |
| 8. Is the patient 18 years or older? | **Yes**: Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Is there documentation that the patient does not have factor IX inhibitors by a test within the past 3 months?<br><br>Note: If positive initial test, may retest, ideally within approximately 2 weeks of original test. | **Yes**: Go to #10<br>Test Date_____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 10. Has this patient had a liver health assessment including all of the following: AST, ALT, ALP, total bilirubin, hepatic ultrasound, elastography, and recent (previous 3 months) screening for hepatitis B and C? | **Yes**: Go to #11 | **No:** Pass to RPh. Deny; medical appropriateness |
| 11. Were all hepatic enzymes and hepatic radiological tests normal AND were hepatitis B and C screenings negative?<br><br>Note: Enzyme elevations which are transient and mild (less than twice the upper limit of normal) may answer “Yes” to this question. | **Yes**: Go to #13 | **No:** Go to #12 |
| 12. Has the patient been evaluated and cleared for gene therapy treatment by a gastroenterologist or hepatologist? | **Yes**: Go to #13 | **No:** Pass to RPh. Deny; medical appropriateness |
| 13. Is there documentation that the patient is either:<br>• HIV negative OR<br>• HIV positive and controlled (CD4 count ≤ 200/μL)? | **Yes**: Go to #14 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 14. Has the provider discussed enrollment in a study to measure pre-existing anti-AAV5 neutralizing antibodies with patient?<br><br>Note: study details and contact information in gene therapy package insert.[1] | **Yes:** Approve one lifetime dose. | **No:** Pass to RPh. Deny; medical appropriateness |

1. Hemgenix (etranacogene dezaparvovec-drlb) package insert.uniQure, Inc Lexington, MA: https://www.fda.gov/media/163467/download. November 2022.

*P&T/DUR Review: 10/23 (SF)*
*Implementation: 11/1/23*

# Evinacumab

**Goal(s):**
- Promote use of evinacumab that is consistent with medical evidence
- Promote use of high value products

**Length of Authorization:**
- 6-12 months

**Requires PA:**
- Evinacumab (Evkeeza™) pharmacy and provider administered claims

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code; go to #2 | |
| 2. Is the patient 12 years or older with a diagnosis of homozygous or familial hypercholesterolemia (HoFH) diagnosed by genetic testing or the following clinical criteria?<br>• Untreated LDL-C > 500 mg/dl or treated LDL-C > 300 mg/dl | **Yes:** Go to #3 | **No:** Pass to RPh; deny for medical appropriateness |
| 3. Does the patient still have an LDL-C of ≥ 100 mg/dl while taking a maximally tolerated dose (or have a contraindication) of all the following agents for at least 12 weeks:<br>• Statin, and<br>• Ezetimibe, and<br>• PCSK9 inhibitor (alirocumab or evolocumab) | **Yes:** Go to #4<br><br>LDL-C ____mg/dL<br>Date: _____ | **No:** Pass to RPh; deny for medical appropriateness. |
| 4. Is the patient of childbearing potential? | **Yes:** Go to #5 | **No:** Approve for up to 6 months |
| 5. Is the patient pregnant or actively trying to conceive? | **Yes:** Pass to RPh; deny for medical appropriateness. | **No:** Go to #6 |
| 6. Is there documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant? | **Yes:** Approve for up to 6 months | **No:** Pass to RPh; deny for medical appropriateness. |

| Renewal Criteria | | |
|---|---|---|
| 1. What is the most recent LDL-C (within last 12 weeks)? | Recent LDL-C _____ mg/dL<br>Date:_____ ; go to #2 | |
| 2. Did the patient achieve a LDL-C reduction to less than 70 mg/dl OR a 30% decrease from baseline prior to adding evinacumab? | **Yes:** Go to #3 | **No:** Pass to RPh; deny for medical appropriateness |
| 3. Is the patient adherent with other lipid-lowering therapies, including maximally tolerated statin, ezetimibe, and PCSK9 inhibitor therapy? | **Yes:** Go to #4<br><br>Note: pharmacy profile may be reviewed to verify >80% adherence | **No:** Pass to RPh; deny for medical appropriateness |
| 4. Is the patient of childbearing potential? | **Yes:** Go to #5 | **No:** Approve for up to 12 months |
| 5. Is the patient pregnant or actively trying to conceive? | **Yes:** Pass to RPh; deny for medical appropriateness. | **No:** Go to #6 |
| 6. Is there documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh; deny for medical appropriateness. |

*P&T / DUR Review:* *10/21 (MH); 08/21 (MH)*
*Implementation:* *1/1/22; 9/1/21*

## Exclusion List

- Deny payment for drugs that are only FDA-approved for indications that are not covered by the Oregon Health Plan (OHP).
- Allow case-by-case review for members covered under the EPSDT program.
- Other exclusionary criteria are in rules at: https://www.oregon.gov/oha/HSD/OHP/Pages/Policy-Pharmacy.aspx

| |
|---|
| A full list of exclusions and limitations is listed in OAR 410-121-0147 Exclusions and Limitations (DMAP Pharmaceutical Services Program): https://secure.sos.state.or.us/oard/displayChapterRules.action?selectedChapter=87 |
| Examples of drugs which are not covered include (but may not be limited to):<br>• Expired drug products;<br>• Drug products from non-rebatable manufacturers, with the exception of selected oral nutritionals, vitamins, and vaccines;<br>• Active Pharmaceutical Ingredients (APIs) and Excipients as described by Centers for Medicare and Medicaid (CMS);<br>• Drug products that are not assigned a National Drug Code (NDC) number;<br>• Drug products that are not approved by the Food and Drug Administration (FDA);<br>• Non-emergency drug products dispensed for Citizenship Waived Medical client benefit type;<br>• Drug Efficacy Study Implementation (DESI) drugs;<br>• Medicare Part D covered drugs or classes of drugs for fully dual eligible clients |

**NOTE: Returns as "70 – NDC NOT COVERED"**

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. For what reason is it being rejected? | | |
| 3. "70" NDC Not Covered (Transaction line states "Bill Medicare" | **Yes:** Go to the Medicare B initiative in these criteria. | **No:** Go to #4 |
| 4. "70" NDC Not Covered (Transaction line states "Bill Medicare or Bill Medicare D" | **Yes:** Informational PA to bill specific agency | **No:** Go to #5 |
| 5. "70" NDC Not Covered (due to expired or invalid NDC number) | **Yes:** Informational PA with message "The drug requested does not have a valid National Drug Code number and is not covered by Medicaid. Please bill with correct NDC number." | **No:** Go to #6 |
| 6. "70" NDC Not Covered (due to DME items, excluding diabetic supplies) (Error code M5 –requires manual claim) | **Yes:** Informational PA (Need to billed via DME billing rules) 1-800-336-6016 | **No:** Go to #7 |

| Approval Criteria | | |
|---|---|---|
| 7. "70" NDC Not Covered (Transaction line states "DESI Drug") | **Yes:** Pass to RPh. Deny (DESI Drug) with message, "The drug requested is listed as a "Less-Than-Effective Drug" by the FDA and not covered by Medicaid." | **No:** Go to #8 |
| 8. Is the patient eligible for EPSDT review? | **Yes**: Go to EPSDT assessment<br><br>Message: Requests for non-covered services can be considered with individual review under EPSDT. | **No**: Go to #9 |
| 9. "70" NDC Not Covered (Transaction line states "Non-Rebatable Drugs" ) | **Yes:** Go to #10 | **No:** Go to #12 |
| 10. Is the request for an over-the-counter (OTC) product?<br><br>See types of OTC products currently covered by OHP here: www.orpdl.org | **Yes**: Go to #11 | **No:** Pass to RPh. Deny (Non-Rebatable Drug) with message "The drug requested is made by company that does not participate in Medicaid Drug Rebate Program and is therefore not covered" |
| 11. Is there documentation that covered alternatives are not medically appropriate or are unavailable?<br><br>Note: many OTC products have rebatable or legend alternatives that are covered. | **Yes:** Pass to RPh; Deny and refer non-rebatable products to DMAP for consideration of a rebate-exception.<br><br>Document reason (e.g., drug shortage, lack of covered alternatives, intolerance/contraindication to alternatives, etc) | **No:** Pass to RPh. Deny (Non-Rebatable Drug) with message "The drug requested is made by company that does not participate in Medicaid Drug Rebate Program and is therefore not covered. Consider switching treatment to a covered alternative." |

| Approval Criteria | | |
|---|---|---|
| 12. RPh only: "70" NDC Not Covered (Drugs on the Exclusion List) All indications need to be evaluated to see if they are covered and whether they are above the line or below the line. | **Above:** Deny with yesterday's date (Medically Appropriateness) and use clinical judgment to APPROVE for 1 month starting today to allow time for appeal.<br><br>Message: "Although the request has been denied for long term use because it is considered medically inappropriate, it has also been APPROVED for one month to allow time for appeal." | **Below:** Pass to RPh; Deny. Not covered<br><br>Message: "The treatment for your condition is not a covered service on the Oregon Health Plan." |

| EPSDT Assessment | | |
|---|---|---|
| 1. Is the patient eligible for EPSDT review? | **Yes:** Go to #2 | **No:** Go to **Approval Criteria** |
| 2. Is the request for impotency, erectile dysfunction or infertility?<br><br>These conditions are not covered under the OHP.<br>See state plan full coverage list. | **Yes:** Pass to RPh. Deny; not covered<br><br>Message: "The treatment for your condition is not a covered service on OHP." | **No:** Go to #3 |
| 3. Is the request for an unfunded condition? | **Yes:** Go to #4 | **No:** Go to #5 |
| 4. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical necessity. |
| 5. Is the request for an FDA approved indication? | **Yes:** Go to #7 | **No:** Go to #6 |

| EPSDT Assessment | | |
|---|---|---|
| 6. Is there documentation that the requested treatment is supported by guidelines and compendia? | **Yes:** Go to #7<br><br>Document guideline, compendia, and/or literature referenced by the provider. | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Message: Off-label requests must include supporting literature. |
| 7. Is there documentation that alternative therapies (including covered pharmacologic and non-pharmacologic therapies) provide inadequate treatment, are not medically appropriate, are unavailable, or are inaccessible? | **Yes:** Pass to RPh; Deny; non-covered service and refer to DMAP for secondary evaluation.<br><br>Message: The requested treatment cannot be approved without secondary evaluation by DMAP. The request has been referred for evaluation under EPSDT. | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Message: Document therapies that have been previously tried. Consider switching to a covered alternative if appropriate. |

*If the DMAP call center notes a drug is often requested for a covered indication, notify Lead Pharmacist so that policy changes can be considered for valid covered diagnoses.*

**Table 1. Drug categories commonly used for non-covered conditions**

| Exclusion List | | |
|---|---|---|
| **Drug Code** | **Description** | **DMAP Policy** |
| DCC = 1 | Drugs To Treat Impotency/ Erectile Dysfunction | Impotency Not Covered on OHP List, BPH is covered |
| DCC = B | Fertility Agents | Fertility Treatment Not Covered on OHP List |
| HIC3= L1C | Hypertrichotic Agents, Systemic/Including Combinations | Cosmetic Indications Not Covered |
| HIC3= Q6F | Contact Lens Preparations | Cosmetic Indications Not Covered |
| HIC3=L5B | Sunscreens | Cosmetic Indications Not Covered |
| HIC3=L5C | Abrasives | Cosmetic Indications Not Covered |
| HIC3=L7A | Shampoos | Cosmetic Indications Not Covered |
| HIC3=L8A | Deodorants | Cosmetic Indications Not Covered |
| HIC3=L8B | Antiperspirants | Cosmetic Indications Not Covered |
| HIC3=L9A | Topical Agents, Misc | Cosmetic Indications Not Covered |
| HIC3=L9C | Antimelanin Agents | Cosmetic Indications Not Covered |
| HIC3=L9D | Topical Hyperpigmentation Agent | Cosmetic Indications Not Covered |
| HIC3=L9F | Topical Skin Coloring Dye Agent | Cosmetic Indications Not Covered |
| HIC3=L9I | Topical Cosmetic Agent; Vit A | Cosmetic Indications Not Covered |
| HIC3=L9J | Hair Growth Reduction Agents | Cosmetic Indications Not Covered |
| HIC3=Q5C | Topical Hypertrichotic Agents | Cosmetic Indications Not Covered |

Table 2. Items requiring alternative billing

| Exclusion List | | |
|---|---|---|
| **Drug Code** | **Description** | **DMAP Policy** |
| DCC = D | Diagnostics | DME Billing Required |
| DCC= Y | Ostomy Supplies | DME Billing Required |
| HIC3= B0P | Inert Gases | DME Billing Required |

Table 3. Drugs commonly used for unfunded conditions or OTC drugs that have not been reviewed for coverage under the Oregon Health Plan

| Exclusion List | | |
|---|---|---|
| **Drug Code** | **Description** | **DMAP Policy** |
| HIC3=L3P | Topical Antipruritic Agents | Not Covered OTC |
| HIC3=L4A | Astringents | Not Covered OTC |
| HIC3=L5A;<br>Except HSN=<br>002466 (Podophyllin Resin),<br>006081 (podofilox), 002470 (benzoyl peroxide) | Keratolytics | Not Covered OTC;<br>Warts, Corns/Calluses;<br>Seborrhea Are Not Funded on OHP List |
| HIC3=L5B | Sunscreens | Not Covered OTC |
| HIC3=L5C | Abrasives | Not Covered OTC;<br>Acne, Warts, Corns/Callouses;<br>Diaper Rash, Seborrhea Are Not Funded on OHP List |
| HIC3=L5E | Anti Seborrheic Agents | Seborrhea Not Funded on OHP List |
| HIC3=L5G | Rosacea Agents, Topical | Rosacea Not Funded on OHP list, some acne severities are Funded |
| HIC3=L6A;<br>Except HSN = 002577 (coal tar)<br>002576<br>002574<br>036916<br>002572 (Capsaicin) | Irritants | Not Covered OTC; Seborrhea, Sprains Not Funded on OHP List |
| HIC3=L7A | Shampoos | Not Covered OTC;<br>Seborrhea, Not Funded on OHP List |
| HIC3=L9A | Topical Agents, Misc | Not Covered OTC;<br>Warts, Corns/Callouses; Diaper Rash, Seborrhea, are Not Funded on OHP List |
| HIC3=Q6R, Q6U, Q6D | Antihistamine-Decongestant, Vasoconstrictor and Mast Cell Eye Drops | Allergic Conjunctivitis Not Funded on OHP List |
| HIC3= U5A, U5B, U5F & S2H plus HSN= 014173 | Herbal Supplements “ Natural Anti-Inflammatory | Not Covered OTC |

| | | |
|---|---|---|
| | Supplements" - Not Including Nutritional Supplements such as: Ensure, Boost, Etc. | |
| HSN=003344 | Sulfacetamide Sodium/Sulfur Topical | Seborrhea Not Funded on OHP list |
| HSN=025510 | Rosacea | Rosacea Not Funded on OHP List, some acne severities are funded |
| TC=93;<br>Except lotions, creams, and ointments | Emollients/Protectants | Not Covered OTC |
| AHFS Category = 94000000 | Devices (e.g. hyaluronic acid) | Devices are not a covered drug benefit; viscosupplementation for knee osteoarthritis is not funded on OHP List. |

*P&T Review:* *12/23; 3/18; 2/23/06*
*Implementation:* *1/1/24; 4/16/18; 5/1/16; 9/1/06; 1/1/12*

# Fabry Disease

**Goal(s):**
- Ensure medically appropriate use of drugs for Fabry Disease

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Agalsidase beta (pharmacy and provider administered claims) and migalastat

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this an FDA approved indication? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is this a request for continuation of therapy? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #4 |
| 4. Is the provider a specialist in managing Fabry disease? | **Yes**: Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the request for migalastat? | **Yes:** Go to #6 | **No:** Go to #9 |
| 6. Does the patient have a mutation that is amenable to migalastat therapy as confirmed by a genetic specialist? | **Yes**: Got to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is the patient currently receiving agalsidase beta? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #8 |
| 8. Is the patient 18 years of age or older? | **Yes**: Approve for 6 months | **No:** Pass to RPh. Deny; medical appropriateness. Migalastat is only FDA-approved for use in adults. |

| Approval Criteria | | |
|---|---|---|
| 9. Is the patient a male at least 2 years of age with diagnosis of Fabry disease confirmed by genetic testing or deficiency in alpha-galactosidase A enzyme activity in plasma or leukocytes? | **Yes:** Go to #10 | **No:** Go to #11 |
| 10. Does the patient have end stage renal disease requiring dialysis? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Approve for 12 months |
| 11. Is the patient a female at least 2 years of age and a documented Fabry disease carrier confirmed by genetic testing with significant clinical manifestations of Fabry disease such as:<br>• Uncontrolled pain that interferes with quality of life<br>• Gastrointestinal symptoms that are significantly reducing quality of life and not attributable to other pathology<br>• Mild to moderate renal impairment (GFR > 30 mL/min)<br>• Cardiac disease (left ventricular hypertrophy, conduction abnormalities, ejection fraction< 50%, arrhythmias)<br>• Previous stroke or TIA with retained neurologic function | **Yes:** Approve for 6 months | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Has the patient's condition improved as assessed by the prescribing provider and provider attests to patient's improvement in one of the following:<br>• Renal function<br>• Pain Scores<br>• Quality of Life measurement<br>• Cardiac function<br>• Neurologic status<br>• Growth and development in children | **Yes:** Approve for 12 months.<br>Document baseline assessment and provider attestation received. | **No**: Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 4/22 (DM); 9/19 (DM)*
*Implementation: 5/1/22; 11/1/19*

# Fenfluramine

**Goal(s):**
- To ensure appropriate drug use and restrict to indications supported by medical literature.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Fenfluramine

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for renewal of therapy previously approved by the FFS system? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Is this an FDA approved indication? | **Yes**: Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Does the patient have uncontrolled seizures on current baseline therapy with at least one other antiepileptic medication AND is fenfluramine intended to be prescribed as adjuvant antiepileptic therapy? | **Yes:** Go to #5<br><br>Document seizure frequency_____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the prescribed dose greater than 0.7 mg/kg/day or 26 mg/day OR 0.2 mg/kg/day or 17 mg/day in patients taking stiripentol plus clobazam? | **Yes**: Pass to RPh. Deny; medical appropriateness | **No**: Go to #6 |
| 6. Is baseline echocardiogram on file that was performed within past 6 months? | **Yes:** Approve for 12 months<br><br>Document results here:<br>Date of echocardiogram_____<br>Results_____ | **No**: Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Has an echocardiogram been obtained within the past 6 months? | **Yes:** Go to #2<br>Document results here:<br>Date of echocardiogram____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 2. Has seizure frequency decreased since beginning therapy? | **Yes:** Go to #3<br>Document baseline and current seizure frequency_____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the prescribed dose greater than 0.7mg/kg/day or 26 mg/day or greater than 0.2 mg/kg/day or 17 mg/day in patients taking stiripentol plus clobazam? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #4 |
| 4. Is fenfluramine prescribed as adjuvant therapy and is patient adherent to all prescribed seizure medications? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T Review:* *4/25 (DM); 10/22 (SF); 10/21; 10/20*
*Implementation:* *11/1/20*

# Fezolinetant (Veozah®)

**Goal(s):**
- To ensure appropriate and safe use of fezolinetant in specified patient populations.

**Length of Authorization:**
- 6 to 12 months

**Requires PA:**
- Fezolinetant 45 mg tablets.

**Step Therapy Required Prior to Coverage:**
- Prevention of vasomotor symptoms: conventional hormone therapy (see preferred drug list options at (www.orpdl.org)
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this a request for continuation of therapy previously approved by the FFS program? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Is the request to treat moderate to severe vasomotor symptoms due to menopause? | **Yes**: Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Does the patient, have inadequate effect, intolerance or contraindication to a 30-day trial of menopausal hormone therapy (e.g., estrogen/progestin)?<br><br>*Contraindications to estrogen include history of breast cancer, hepatic disease, cardiovascular disease, or a venous thromboembolism event. Intolerance to progestin include breast tenderness and vaginal bleeding. | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness<br><br>Refer provider to preferred drug list option for conventional hormone therapy at www.orpdl.org |
| 5. If patient has an intolerance or contraindication to hormonal therapy, do they have an inadequate effect, intolerance or contraindication to a 30-day trial of paroxetine, escitalopram, citalopram, venlafaxine, desvenlafaxine, or gabapentin? | **Yes**: Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 6. Is the patient currently taking a CYP1A2 inhibitor (i.e., cimetidine, amiodarone, mexiletine, ciprofloxacin, or fluvoxamine)? | **Yes:** Pass to RPh. Deny; medical appropriateness.<br><br>Note: CYP1A2 inhibitors are contraindicated with fezolinetant therapy. | **No:** Go to #7 |
| 7. Have baseline renal function tests been obtained? | **Yes:** Go to #8 and document baseline labs_____ | **No:** Pass to RPh. Deny; medical appropriateness. |
| 8. Is the estimated glomerular filtration rate (eGFR) < 30 mL/min? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #9 |
| 9. Have baseline liver function tests (AST, ALT, Alk Phos, and bilirubin) been obtained? | **Yes:** Go to #10 and document baseline labs_____ | **No:** Pass to RPh. Deny; medical appropriateness. |
| 10. Do liver function tests (LFTs) indicate presence of severe cirrhosis (i.e., serum transaminase concentrations or total bilirubin greater than 2 times the upper limit of normal)? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Approve for 3 months. |

| Renewal Criteria | | |
|---|---|---|
| 1. Have frequency and severity of vasomotor symptoms been reduced from baseline with fezolinetant treatment? | **Yes:** Go to #2 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 2. Have LFTs been requested at months 1-, 2-, and 3 after starting treatment with fezolinetant? | **Yes:** Go to #3 and document LFT results_____ | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Do LFTs indicate severe cirrhosis (i.e., serum transaminase concentrations or total bilirubin greater than 2 times the upper limit of normal)? | **Yes**: Pass to RPh. Deny; medical appropriateness. | **No:** Approve for 12 months**.** |

*P&T/DUR Review: 2/25 (DM) 6/24 (DM)*
*Implementation: 3/10/25; 7/1/24*

# Fidaxomicin (Dificid®)

**Goal(s):**
- To optimize appropriate treatment of *Clostridioides difficile*-associated infection.

**Length of Authorization:**
- 10 days

**Requires PA:**
- Fidaxomicin

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Does the patient have a diagnosis of *Clostridioides difficile*-associated infection (CDI)? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Does the patient have at least one documented trial of or contraindication to appropriate therapy with vancomycin? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Does the patient have severe, complicated CDI (life-threatening or fulminant infection or toxic megacolon)? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Approve for up to 10 days |

*P&T / DUR Review:* *6/23 (DM); 5/18 (DM); 5/15 (AG); 4/12*
*Implementation:* *7/1/23; 7/1/18; 10/15; 7/12*

# Finerenone

**Goal(s):**
- Promote use of finerenone that is consistent with medical evidence
- Promote use of high value products

**Length of Authorization:**
- 12 months

**Requires PA:**
- Finerenone (Kerendia™)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code; go to #2 | |
| 2. Is the patient 18 years or older with a diagnosis of type 2 diabetes? | **Yes:** Go to #3 | **No:** Pass to RPh; deny for medical appropriateness |
| 3. Does the patient have a diagnosis of chronic kidney disease? | **Yes:** Go to #4 | **No:** Pass to RPh; deny for medical appropriateness. |
| 4. Does the patient have a documented estimated glomerular filtration rate (eGFR) or creatinine clearance (CrCl) < 25 ml/min **OR** require hemodialysis? | **Yes:** Pass to RPh; deny for medical appropriateness.<br><br>Request eGFR if not provided | **No:** Document eGFR and go to #5<br><br>Recent eGFR: _____<br>Date: |
| 5. Is the patient currently on a maximally tolerated angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB), OR have a documented contraindication to both? | **Yes:** Go to #6 | **No:** Pass to RPh; deny for medical appropriateness. |
| 6. Is the patient's serum potassium ≤ 5.0 mEq/L? | **Yes:** Approve for up to 12 months<br><br>Recent potassium:____<br>Date: _____ | **No:** Pass to RPh; deny for medical appropriateness. |

*P&T / DUR Review:* *06/22 (MH)*
*Implementation:* *7/1/22*

# Ganaxolone Safety Edit

**Goal:**
- To ensure appropriate drug use and restrict to indications supported by medical literature

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Ganaxolone

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is the medication FDA-approved for the requested indication and patient age? | **Yes**: Go to #3 | **No:** Go to #5 |
| 3. What is the patient's current weight? | **Record weight:_____** (within past 6 months)<br><br>Go to #4 | |
| 4. Does the requested dosing align with the FDA-approved dosing? | **Yes:** Approve for up to 12 months | **No:** Go to #5 |
| 5. Has the patient already been taking this medication for longer than 4 weeks AND currently taking at time of this request? | **Yes:** Approve for 1 month and forward to medical director for review.<br><br>(Abrupt withdrawal may precipitate increased seizures) | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T / DUR Review:* *4/25 (DM); 10/22 (SF)*
*Implementation:* *1/1/23*

# Gaucher Disease

**Goal(s):**
- Ensure medically appropriate use of drugs for Gaucher disease

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Drugs for Gaucher disease (pharmacy and provider administered claims)

  Note: See Agents for Pompe Disease criteria if miglustat is being prescribed for Pompe Disease

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. FDA-Approved Minimum Ages**

| Drug | Age |
|---|---|
| Eliglustat | 18 |
| Imiglucerase | 2 |
| Miglustat | 18 |
| Taliglucerase alfa | 4 |
| Velaglucerase alfa | 4 |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for continuation of therapy previously approved by FFS? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Is the request from a provider experienced in the treatment of Gaucher disease? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness<br><br>See other criteria if miglustat is prescribed for Pompe Disease.<br><br>Approve if requested for Niemann-Pick disease type C in a patient with an active PA or treatment with arimoclomol. |

| Approval Criteria | | |
|---|---|---|
| 4. Is the request for treatment of Type 1 Gaucher Disease?<br><br>Note: Type 1 disease is characterized predominately by bone involvement without CNS symptoms. | **Yes**: Go to #6 | **No:** Go to #5 |
| 5. Is the request for treatment of Type 3 Gaucher Disease?<br><br>Note: Drugs are not FDA-approved for Type 2 or 3 Gaucher disease. Type 3 disease is characterized by both bone involvement and CNS symptoms. | **Yes:** Refer requests to the medical director for review. Provide relevant chart notes and literature documenting medical necessity. | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is the request for an FDA-approved age in Table 1? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Does the patient have current symptoms characteristic of bone involvement such as:<br>a. Low platelet count<br>b. Low hemoglobin and hematocrit levels<br>c. Radiologic bone disease, T-score less than -2.5 or bone pain<br>d. Delayed growth in children (<10$^{th}$ percentile for age) OR<br>e. Splenomegaly or hepatomegaly? | **Yes:** Go to #8<br><br>Document baseline labs and symptoms | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Is the request for combination treatment with more than one targeted therapy for Gaucher disease? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #9 |
| 9. Is the request for enzyme replacement therapy? | **Yes:** Go to #10 | **No:** Go to #11 |
| 10. Is the request for a non-preferred product and will the prescriber consider a change to a preferred product?<br><br>Message:<br>Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Inform prescriber of covered alternatives in class. Approve preferred therapy for up to 6 months. | **No:** Approve for up to 6 months |

| Approval Criteria | | |
|---|---|---|
| 11. Does the patient have a documented contraindication, intolerance, inadequate response, or inability to access or adhere to enzyme replacement therapy? | **Yes:** Go to #12 | **No:** Pass to RPh. Deny; medical appropriateness |
| 12. Is the request for eliglustat? | **Yes:** Go to #13 | **No:** Approve for up to 6 months |
| 13. Does the patient have cardiac disease, long-QT syndrome, or is currently taking a Class IA or Class III antiarrhythmic medication? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #14 |
| 14. Does the patient have moderate to severe hepatic impairment? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #15 |
| 15. Does testing for CYP2D6 metabolizer status indicate extensive, intermediate or poor CYP2D6 metabolism? | **Yes:** Go to #16 | **No:** Pass to RPh. Deny; medical appropriateness |
| 16. Is the dose consistent with FDA labeling based on CYP2D6 metabolism and use of concomitant CYP inhibitors (see FDA labeling for full details)? | **Yes:** Approve for up to 6 months | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is there documentation based on chart notes that the patient experienced a significant adverse reaction related to treatment for Gaucher disease? | **Yes**: Go to #2 | **No:** Go to #3 |
| 2. Has the adverse event been reported to the FDA Adverse Event Reporting System? | **Yes:** Go to #3<br><br>Document provider attestation | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Has the patient been adherent to current therapy? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 4. Is there objective documentation of benefit based on improved labs or patient symptoms? | **Yes:** Approve for up to 12 months<br><br>Document labs and patient symptoms | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 11/19 (SS)*
*Implementation: 1/1/2020*

# Glucagon-like Peptide-1 (GLP-1) Receptor Agonists and Glucose Dependent Insulinotropic Polypeptide (GIP) Receptor Agonist

**Goal(s):**
- Promote cost-effective and safe step-therapy for management of type 2 diabetes mellitus (T2DM).

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- All non-preferred GLP-1 receptor agonists and GLP-1 receptor + GIP receptor agonists. Preferred products do not require PA when prescribed as second-line therapy in conjunction with metformin.

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Does the patient have a diagnosis of Type 2 diabetes mellitus? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>For requests for non-alcoholic or metabolic dysfunction-associated steatohepatitis (NASH/MASH), cardiovascular risk reduction, or obstructive sleep apnea, see weight management PA criteria. |
| 3. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics (P&T) Committee. | **Yes:** Inform prescriber of covered alternatives in class | **No:** Go to #4 |

| Approval Criteria | | |
|---|---|---|
| 4. Has the patient tried and failed to meet hemoglobin A1C goals with metformin or have contraindications to metformin?<br><br>(document contraindication, if any) | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Recommend trial of metformin. See below for metformin titration schedule. |

**Initiating Metformin**

| | |
|---|---|
| 5. | Begin with low-dose metformin (500 mg) taken once or twice per day with meals (breakfast and/or dinner) or 850 mg once per day. |
| 6. | After 5-7 days, if gastrointestinal side effects have not occurred, advance dose to 850 mg, or two 500 mg tablets, twice per day (medication to be taken before breakfast and/or dinner). |
| 7. | If gastrointestinal side effects appear with increasing doses, decrease to previous lower dose and try to advance the dose at a later time. |
| 8. | The maximum effective dose can be up to 1,000 mg twice per day. Modestly greater effectiveness has been observed with doses up to about 2,500 mg/day. Gastrointestinal side effects may limit the dose that can be used. |

Nathan, et al. Medical management of hyperglycemia in Type 2 Diabetes: a consensus algorithm for the initiation and adjustment of therapy. *Diabetes Care*. 2008; 31;1-11.

*P&T Review:* *8/24, 10/22 (KS), 8/20, 6/20), 3/19, 7/18, 9/17; 1/17; 11/16; 9/16; 9/15; 1/15; 9/14; 9/13; 4/12; 3/11*
*Implementation:* *9/1//24; 1/1/23; 9/1/20; 5/1/19; 8/15/18; 4/1/17; 2/15; 1/14*

# Gonadotropin-Releasing Hormone Agonists

**Goals:**

- Restrict use of gonadotropin-releasing hormone (GnRH) agonists to medically appropriate conditions funded under the Oregon Health Plan.
- Promote use that is consistent with medical evidence and product labeling.

**Length of Authorization:**

- Up to 6 months

**Requires PA:**

- All GnRH agonists

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the diagnosis funded by OHP? | **Yes:** Go to #5 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #3. |
| 3. Will the prescriber consider switching to a preferred product, if appropriate?<br>Message:<br>• Preferred products do not require a PA.<br>• Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes**: Inform prescriber of covered alternatives in class. | **No**: Go to #4 |
| 4. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical necessity. |
| 5. Is the diagnosis central precocious puberty or other endocrine disorder? | **Yes:** Go to #6 | **No:** Go to #7 |

| Approval Criteria | | |
|---|---|---|
| 6. Is the prescriber a pediatric endocrinologist? | **Yes:** Approve for up to 6 months. | **No:** Pass to RPh; deny for medical appropriateness. |
| 7. Is the diagnosis gender dysphoria? | **Yes:** Approve for 1 year | **No:** Go to #8 |
| 8. Is the patient of childbearing potential and pregnant or actively trying to conceive? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #9 |
| 9. Is there documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant? | **Yes:** Go to # 10 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 10. Is this request for treatment of breast cancer or prostate cancer? | **Yes:** Approve up to 1 year | **No:** Go to #11 |
| 11. Is this request for leuprolide for the management of preoperative anemia due to uterine fibroids (leiomyoma)? | **Yes:** Approve for up to 3 months | **No:** Go to #12 |
| 12. Is this request for management of moderate to severe pain associated with endometriosis in a woman ≥18 years of age? | **Yes**: Go to #13 | **No:** Pass to RPh. Deny; medical appropriateness |
| 13. Has the patient tried and failed an adequate trial of at least 1 of the preferred first line endometriosis therapy options for at least 3 months including administration of combined hormonal contraceptives or progestins (oral, depot injection, or intrauterine) alone?<br>OR<br>Does the patient have a documented intolerance, FDA-labeled contraindication, or hypersensitivity the first-line therapy options? | **Yes:** Approve for 6 to 12 months, depending on selected medication.<br><br>*Note maximum recommended duration of therapy for nafarelin and goserelin is 6 months. Leuprolide therapy should not exceed 12 months. If requesting continuation of therapy beyond FDA-approved duration, pass to RPh. Deny; medical appropriateness. | **No:** Go to #14<br><br>*First-line therapy options such as hormonal contraceptives or progestins do not require PA |
| 14. RPh only:<br>All other indications need to be evaluated as to whether it is funded under the OHP. Refer unique situations to Medical Director of DMAP. | | |

*P&T / DUR Review:* *8/23 (DM); 12/21 (DM); 3/19 (DM); 5/15*
*Implementation:* *9/1/23; 1/1/22; 5/1/19*

# Gonadotropin-Releasing Hormone Antagonists

**Goal(s):**

- Promote safe use of elagolix and relugolix/estradiol/norethindrone in people with endometriosis-associated pain
- Promote safe use of elagolix/estradiol/norethindrone and relugolix/estradiol/norethindrone for heavy menstrual bleeding associated with uterine fibroids (leiomyoma).
- Promote use that is consistent with medical evidence and product labeling.
- Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**

- Initial: Up to 6 months
- Elagolix renewal: Up to 6 months for 150 mg daily dose with total cumulative lifetime treatment period not to exceed 24 months in patients with normal hepatic function. For patients with moderate hepatic impairment receiving 150 mg once daily, duration of therapy should not exceed 6 months. In patients receiving high dose elagolix therapy (200 mg twice daily), maximum treatment duration is 6 months.
- Elagolix/estradiol/norethindrone renewal: Up to 6 months for elagolix 300 mg dosed twice daily with a total cumulative treatment period not to exceed 24 months
- Relugolix/estradiol/norethindrone renewal: Up to 6 months for relugolix component 40 mg dosed once daily with a total cumulative treatment period not to exceed 24 months

**Requires PA:**

- Elagolix (ORLISSA)
- Elagolix/estradiol/norethindrone (ORIAHNN)
- Relugolix/estradiol/norethindrone (MYFEMBREE)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the diagnosis funded by OHP? | **Yes:** Go to #4 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #3 |
| 3. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical necessity. |

| Approval Criteria | | |
|---|---|---|
| 4. Is this a request for continuation of therapy previously approved by the FFS program? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #5 |
| 5. Is the patient pregnant or actively trying to conceive? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #6 |
| 6. Is there documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is this request for management of moderate to severe pain associated with endometriosis in a premenopausal patient? | **Yes**: Go to #8 | **No:** Go to #14 |
| 8. Has the patient tried and failed an adequate trial of preferred first line endometriosis therapy options including administration of combined hormonal contraceptives or progestins (oral, depot injection, or intrauterine) alone?<br>-or-<br>Does the patient have a documented intolerance, FDA- labeled contraindication, or hypersensitivity the first-line therapy options? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness<br><br>First-line therapy options such as combined hormonal contraceptives or progestins do not require PA |
| 9. Is the patient taking any concomitant medications that are strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine, gemfibrozil, etc.), combined P-glycoprotein inhibitor and moderate CYP3A inhibitor (e.g., erythromycin), combined P-glycoprotein inducer and strong CYP3A inducer (e.g., rifampin)?<br><br>Note: Elagolix levels are increased when co-administered with OATP1B1 inhibitors. Relugolix levels are increased when co-administered with inhibitors such as erythromycin and decreased when co-administered with inducers such as rifampin. Avoid combinations of these therapies due to drug interactions that can increase the risk of adverse reactions or decrease the efficacy of GnRH antagonists. | **Yes:** Deny; medical appropriateness | **No:** Go to #10 |

| Approval Criteria | | |
|---|---|---|
| 10. Does the patient have a diagnosis of osteoporosis or related bone-loss condition?<br><br>Note: In patients with major risk factors for decreased bone mineral density (BMD) such as chronic alcohol (> 3 units per day) or tobacco use, strong family history of osteoporosis, or chronic use of drugs that can decrease BMD, such as anticonvulsants or corticosteroids, use of GnRH antagonists may pose an additional risk, and the risks and benefits should be weighed carefully. | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #11 |
| 11. Does the patient have severe hepatic impairment as documented by Child-Pugh class C? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #12 |
| 12. Does the patient have moderate hepatic impairment as documented by Child-Pugh class B? | **Yes:** Go to #13 | **No:** Approve for 6 months<br><br>* FDA approved elagolix dosing for patients with normal liver function or mild liver impairment: 150 mg once daily for up to 24 months or 200 mg twice daily for up to 6 months |
| 13. Is the dose for elagolix 150 mg once daily or relugolix 40 mg /estradiol 1 mg/norethindrone 0.5 mg? | **Yes:** Approve for 6 months (cumulative lifetime treatment)<br><br>* FDA approved elagolix dosing for moderate hepatic impairment: 150 mg once daily for up to 6 months. | **No:** Pass to RPh. Deny; medical appropriateness |
| 14. Is the request for elagolix/estradiol/norethindrone or relugolix/estradiol/norethindrone for management of heavy menstrual bleeding associated with uterine fibroids (leiomyomas)? | **Yes:** Go to #15 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 15. Has the patient tried and failed a trial of first line therapy options including at least 1 of the following for at least 3 months:<br>a) hormone-releasing IUD OR<br>b) continuous administration of combined hormonal contraceptives OR<br>c) cyclic progestins OR<br>d) tranexamic acid?<br>OR<br>Does the patient have a documented intolerance, FDA-labeled contraindication, or hypersensitivity to the first-line therapy options? | **Yes**: Go to #16 | **No:** Pass to RPh. Deny; medical appropriateness<br><br>First-line therapy options such as hormonal contraceptives, progestins, or tranexamic acid do not require PA |
| 16. Does the patient have a diagnosis of osteoporosis or related bone-loss condition?<br><br>Note: In patients with major risk factors for decreased bone mineral density (BMD) such as chronic alcohol (> 3 units per day) or tobacco use, strong family history of osteoporosis, or chronic use of drugs that can decrease BMD, such as anticonvulsants or corticosteroids, use of GnRH antagonists may pose an additional risk, and the risks and benefits should be weighed carefully. | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Approve for 6 months (cumulative, lifetime treatment) |

| Renewal Criteria | | |
|---|---|---|
| 1. Has the patient been receiving elagolix/estradiol/norethindrone for management of uterine fibroids or relugolix/estradiol/norethindrone for management of uterine fibroids or pain associated with endometriosis? | **Yes:** Go to #4 | **No:** Go to #2 |
| 2. Has the patient been receiving therapy with elagolix 150 mg once daily for management of endometriosis? | **Yes:** Go to #3 | **No:** Pass to RPh; Deny; medical appropriateness.<br><br>(Elagolix 200 mg twice daily is limited to 6-month maximum treatment duration per FDA labeling) |

| Renewal Criteria | | |
|---|---|---|
| 3. Does the patient have moderate hepatic impairment as documented by Child-Pugh Class B? | **Yes:** Pass to RPh; Deny; medical appropriateness.<br><br>(Elagolix 150 mg once daily is limited to 6-month maximum treatment duration in patients with moderate hepatic impairment per FDA labeling) | **No:** Go to #4 |
| 4. Has the patient's condition* improved as assessed and documented by the prescriber?<br><br>*For endometriosis: has pain associated with endometriosis improved?<br>For uterine fibroids: has patient experienced at least a 50% reduction in menstrual blood loss from baseline? | **Yes:** Approve for up to 18 months<br><br>Document physician attestation received.<br><br>Total cumulative treatment period not to exceed 24 months. | **No:** Pass to RPh; Deny; medical appropriateness. |

*P&T/DUR Review: 2/23(DM); 12/21, 3/19 (DM),11/18 (DE)*
*Implementation: 4/1/23; 1/1/22; 5/1/19*

# Gout Agents

**Goal(s):**
- To provide evidenced-based step-therapy for the treatment of acute gout flares, prophylaxis of gout and chronic gout.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Non-preferred drugs
- Long-term colchicine use (>10 tablets every 180 days)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Will the provider switch to a preferred product?<br><br>Note: Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics Committee. Preferred products are available without a PA | **Yes:** Inform prescriber of covered alternatives in the class | **No:** Go to #3 |
| 3. Is the request for colchicine? | **Yes:** Go to #4 | **No:** Go to #7 |
| 4. Does the patient have a diagnosis of Behcet's Syndrome with mucocutaneous and/or joint involvement (concomitant NSAID is appropriate)? | **Yes:** Approve for up to 12 months | **No:** Go to #5 |
| 5. Does the patient have a cardiovascular diagnosis for which colchicine has demonstrated benefit (e.g., pericarditis, recent myocardial infarction or high cardiovascular disease risk [concomitant NSAID is appropriate])? | **Yes:** Approve for up to 12 months | **No:** Go to #6 |

| Approval Criteria | | |
|---|---|---|
| 6. Does the patient have gout and failed NSAID therapy or have contraindications to NSAIDs or is a candidate for combination therapy, due to failure of monotherapy or initial presentation justifies combination therapy (i.e., multiple joint involvement and severe pain)? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; recommend trial of NSAID |
| 7. Is the request for febuxostat? | **Yes:** Go to #8 | **No:** Go to #9 |
| 8. Has the patient tried and failed allopurinol or has contraindications to allopurinol? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny; recommend trial of allopurinol |
| 9. Is the request for probenecid? | **Yes:** Go to # 10 | **No:** Pass to RPh. Deny; medical appropriateness |
| 10. Has the patient tried allopurinol and febuxostat or have contraindications to one or both of these treatments? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny; recommend a trial of allopurinol or febuxostat |

*P&T/DUR Review:* *12/20 (KS), 1/17 (KS)*
*Implementation:* *1/1/2021; 4/1/2017*

# Growth Hormones

**Goal(s):**
- Restrict use of growth hormone (GH) in adults for where there is medical evidence of effectiveness and safety and supported by expert guidelines.

NOTE: Treatment with GH in children and adolescents (for any indication) are evaluated for medical appropriateness and medical necessity on a case-by-case basis.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- All GH products require prior authorization for OHP coverage. Treatment is not included for use in antiaging therapy or to enhance athletic ability or for body building.

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What is the diagnosis being treated? | Record ICD10 code | |
| 2. Is the diagnosis promotion of growth delay in a child with 3rd degree burns? | **Yes:** Document and send to DHS Medical Director for review and pending approval | **No:** Go to #3 |
| 3. Is the request for one of the conditions listed below?<br>For children and adolescents age 17 and younger<br>• Growth hormone deficiency (GHD)<br>• Prader-Willi syndrome<br>• Noonan syndrome<br>• Turner syndrome<br>• Idiopathic Short Stature<br>• Growth Failure secondary to chronic kidney disease (CKD)<br>• Small for gestational age<br>• Short stature homeobox-containing (SHOX) gene deficiency<br>• HIV Associated Cachexia<br>For adults age 18 years and older<br>• Growth hormone deficiency (GHD)<br>• HIV Associated Cachexia<br>• Short Bowel Syndrome (SBS) | **Yes:** Go to #4 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; medical appropriateness<br><br>If eligible for EPSDT review: Go to #5. |

| Approval Criteria | | |
|---|---|---|
| 4. Has the provider documented goals of therapy and objective baseline assessment (e.g., quality of life, exercise capacity, height, body composition improvements, etc)?<br>Note: these same assessments should be evaluated for continuation of treatment. | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #11 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is this a request for initiation of growth hormone therapy? | **Yes:** Go to #7 | **No:** Go to **Renewal Criteria** |
| 7. Is the agent being prescribed by, or in consultation with, an appropriate specialist (e.g., an endocrinologist for adults or a pediatric endocrinologist or pediatric nephrologist for children/adolescents)? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Is the request for a pediatric patient with Prader-Willi syndrome who also has:<br>• Severe obesity?<br>Or<br>• A history of upper airway obstruction or sleep apnea?<br>Or<br>• Severe respiratory impairment?<br><br>Note: Recombinant somatropin is contraindicated in these patients due to the risk of sudden death. | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #9 |
| 9. Is the request for treatment of hypopituitarism (E23.0)? | **Yes:** Go to #10 | **No:** Go to #11 |
| 10. Is the growth hormone deficiency confirmed by a negative response to a growth hormone stimulation test (eg, serum GH levels of <5 ng/ml on stimulation testing with either glucagon or insulin)?<br>OR<br>Is there evidence that the patient had the pituitary removed/destroyed or has had panhypopituitarism since birth? | **Yes:** Go to #11 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 11. Is the request for a preferred product OR has the patient failed to have benefit with, or have contraindications or intolerance to, at least 2 preferred products?<br>Message: Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Approve for up to 12 months | **No:** Go to #12 |
| 12. Will the prescriber change to a preferred product?<br>Message:<br>• Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics (P&T) Committee. | **Yes:** Inform prescriber of covered alternatives in class and approve for up to 12 months. | **No:** Go to #13 |
| 13. Is the request for lonapegsomatropin? | **Yes:** Go to #14 | **No:** Approve for up to 6 months |
| 14. Is the request for a pediatric patient 1 year or older with a body weight ≥11.5 kg? | **Yes:** Approve for up to 6 months | **No:** Pass to RPh. Deny; medical appropriateness. |

| Renewal Criteria | | |
|---|---|---|
| 1. Document approximate date of initiation of therapy and diagnosis (if not already done). | | |
| 2. Was treatment with this agent initiated in a patient prior to reaching adulthood (<18 years of age) to improve growth velocity or height? | **Yes:** Go to #3 | **No:** Go to #5 |
| 3. Is growth velocity 2 cm or more per year? | **Yes:** Go to #6 | **No:** Go to #4 |
| 4. Is there documentation that benefits of therapy continue to outweigh risks?<br><br>When main goal of therapy is growth promotion in children to normalize final adult height, current guidelines recommend discontinuation of treatment once growth velocity is less than 2-2.5 cm per year. Risks, benefits, and goals of therapy should be reassessed in patients whose epiphyses are closed. | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 5. Is there documentation of improvement from baseline as assessed by the prescribing provider? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical |

| | | |
|---|---|---|
| | | appropriateness. |
| 6. Is the product requested preferred? | **Yes:** Approve for up to 12 months | **No:** Go to #7 |
| 7. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics (P&T) Committee. | **Yes:** Inform prescriber of covered alternatives in class and approve for up to 12 months | **No:** Approve for up to 6 months |

*P&T Review: 4/23 (DE); 12/22;12/21; 6/21;11/18; 9/17; 9/16; 9/15; 9/14; 9/10; 5/10; 9/08; 2/06; 11/03; 9/03*
*Implementation: 1/1/19; 10/13/16; 1/1/11, 7/1/10, 4/15/09, 10/1/03, 9/1/06; 10/1/03*

# Hepatitis C Direct-Acting Antivirals

**Goals:**

- Approve use of cost-effective treatments supported by the medical evidence.
- Provide consistent patient evaluations across hepatitis C treatments.
- Ensure appropriate patient regimen based on prior treatment experience and genotype.

**Length of Authorization:**

- 8-24 weeks

**Requires PA:**

- Non-preferred direct acting antivirals (DAAs)
- Preferred regimens for patients with treatment experience with a DAA

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for treatment of Hepatitis C infection? | **Yes:** Go to #3<br>Document baseline quantitative HCV RNA level<br>_____ | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Has all the following pre-treatment testing been documented:<br>a. Genotype testing in past 3 years is required if the patient has decompensated cirrhosis, prior treatment experience with a DAA regimen, and if prescribed a regimen which is not pan-genotypic<br>b. History of previous HCV treatment, viral load after treatment, and outcome are required only if there is documentation of treatment experience | **Yes:** Record results of each test and go to #4 | **No**: Pass to RPh. Request updated testing. |
| 4. Which regimen is requested? | Document and go to #5 | |
| 5. Has the patient been treated with a direct acting antiviral regimen previously? | **Yes:** Go to #6 | **No:** Go to #8 |

| Approval Criteria | | |
|---|---|---|
| 6. Did the patient achieve a sustained virological response (SVR) at week 12 or longer following the completion of their last DAA regimen? | **Yes:** Go to #7 | **No:** Document as treatment failure and treat as indicated for treatment experienced.<br>Go to #8 |
| 7. Is this likely a reinfection, indicated by at least one of the following:<br>a. Does the patient have ongoing risk factors for hepatitis C reinfection (e.g. sexually active men who have sex with men, persons who inject drugs), OR<br>b. Is the hepatitis C infection a different genotype than previous | **Yes:** Document as reinfection. Use regimens recommended for treatment naïve patients.<br>Go to #8 | **No:** Document as treatment failure and treat as indicated for treatment experienced.<br>Go to #8 |
| 8. Is the prescribed drug:<br>a) Elbasvir/grazoprevir for GT 1a infection; or<br>b) Ledipasvir/sofosbuvir for GT 1a treatment-experienced infection; or<br>c) Sofosbuvir/velpatasvir for GT 3 in cirrhosis or treatment-experienced infection | **Yes:** Go to #9 | **No:** Go to #10 |
| 9. Has the patient had a baseline NS5a resistance test that documents a resistant variant to one of the agents in #10?<br><br>Note: Baseline NS5A resistance testing is required. | **Yes:** Pass to RPh; deny for appropriateness | **No:** Go to #10<br><br>Document test and result. |
| **10.** Is the prescribed drug regimen a recommended regimen based on the patient's genotype, age, treatment status (retreatment or treatment naïve) and cirrhosis status (see **Table 1 and Table 2**)?<br><br>Note: Safety and efficacy of DAAs for children < 3 years of age have not been established Pediatric dosing available in **Table 3** & **Table 4** | **Yes:** Approve for 8-24 weeks based on duration of treatment indicated for approved regimen<br><br>Referral will be made for optional case management (patient may choose to opt-in). | **No:** Pass to RPh. Deny; medical appropriateness. |

**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 PEGylated interferon/ribavirin | Non-cirrhotic or compensated cirrhosis | SOF/VEL x 12 weeks<br>G/P x 8 weeks |
| | Compensated cirrhosis | G/P x 8 weeks<br>SOF/VEL x 12 weeks (baseline resistance testing recommended for GT3) |
| | Decompensated Cirrhosis | SOF/VEL + RBV x 12 weeks<br>SOF/VEL x 24 weeks (if ribavirin ineligible*) |
| **Treatment Experienced (Genotype 1-6)** | | |
| Sofosbuvir based regimen treatment failures, including:<br>Sofosbuvir + ribavirin<br>Ledipasvir/sofosbuvir<br>Velpatasvir/sofosbuvir | Non-cirrhotic or compensated cirrhosis | SOF/VEL/VOX x12 weeks<br>G/P x 16 weeks (except GT3) |
| 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<br>SOF/VEL/VOX x 12 weeks (plus RBV if compensated cirrhosis) |
| Multiple DAA Treatment Failures, including:<br>sofosbuvir/velpatasvir/voxilaprevir<br>glecaprevir/pibrentasvir + sofosbuvir | Non-cirrhotic or compensated cirrhosis | G/P + SOF + RBV x 16-24 weeks<br>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<br><br>* Ribavirin ineligible/intolerance may include: 1) neutrophils < 750 $mm^3$, 2) hemoglobin < 10 g/dl, 3) platelets <50,000 cells/$mm^3$, 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 pegylated interferon/ribavirin | Non-cirrhotic or compensated cirrhosis | SOF/VEL x 12 weeks<br>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<br>• 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).<br>• 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 glecaprevir/pibrentasvir |
|---|---|
| **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**<br>**OR**<br>**12 years of age and older** | Three 100mg/40 mg tablets once daily |

*P&T Review:* *10/24 (MH); 4/22); 10/21; 6/20; 9/19; 1/19; 11/18; 9/18; 1/18; 9/17; 9/16; 1/16; 5/15; 3/15; 1/15; 9/14; 1/14*
*Implementation:* *1/1/23; 7/1/20; 1/1/20; 3/1/2019; 1/1/2019; 3/1/2018; 1/1/2018; 2/12/16; 4/15; 1/15*

# Hepatitis B Antivirals

**Goal(s):**

- Approve treatment supported by medical evidence and consensus guidelines
- Cover preferred products when feasible for covered diagnosis

**Length of Authorization:**

- Up to 12 months; quantity limited to a 30-day supply per dispensing.

**Requires PA:**

- All nonpreferred Hepatitis B antivirals

**Covered Alternatives:**

- Preferred alternatives listed at http://www.orpdl.org/drugs/

**Pediatric Age Restrictions:**

- lamivudine (Epivir HBV) – ≥ 2 years
- adefovir dipivoxil (Hepsera) – ≥ 12 years
- entecavir (Baraclude) – ≥ 2 years
- tenofovir disoproxil fumarate (Viread) – ≥ 2 years and weight ≥ 10 kg
- tenofovir alafenamide (Vemlidy) – ≥ 6 years and ≥ 25 kg

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is the request for an antiviral for the treatment of HIV/AIDS? | **Yes:** Approve for up to 12 months | **No:** Go to #3 |
| 3. Is the request for treatment of chronic Hepatitis B Virus infection? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the request for a pediatric patient? | **Yes**: Go to #5 | **No:** Go to #6 |
| 5. Does the pediatric patient meet the age and weight requirements for the requested drug (see Pediatric Age Restrictions above). | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is this a continuation of current therapy previously approved by the FFS program (i.e. filled prescription within prior 90 days)? Verify via pharmacy claims. | **Yes:** Go to Renewal Criteria | **No:** Go to #7 |

| Approval Criteria | | |
|---|---|---|
| 7. Has the client tried and is intolerant to, resistant to, or has a contraindication to the preferred products? | **Yes:** Document intolerance, resistance, or contraindication. Approve requested treatment for 6 months with monthly quantity limit of 30-day supply. | **No:** Go to #8 |
| 8. Will the prescriber consider a change to a preferred product? | **Yes:** Inform prescriber of covered alternatives in class | **No:** Approve requested treatment for 6 months with monthly quantity limit of 30-day supply |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the patient adherent with the requested treatment (see refill history)? | **Yes:** Go to #2 | No: Deny; Pass to RPh for provider consult |
| 2. Is HBV DNA undetectable (below 10 IU/mL by real time PCR) or the patient has evidence of cirrhosis?<br><br>Note: Antiviral treatment is indicated irrespective of HBV DNA level in patients with cirrhosis to prevent reactivation. | **Yes:** Approve for up to 1 year with monthly quantity limit of 30-day supply | No: Deny; pass to RPh for provider consult |

*P&T Review:* *8/25 (DM); 3/17(MH); 3/12*
*Implementation:* *9/15/25; 4/1/17; 5/29/14; 1/13*

# Hereditary Angioedema

**Goal(s):**
- To promote safe and effective use of hereditary angioedema treatments.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- All pharmacotherapy for hereditary angioedema (pharmacy and provider administered claims).

  NOTE: This policy does not apply to hereditary angioedema treatments administered during emergency department visits or hospitalization.

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1.** FDA Approved indications and dosing for hereditary angioedema treatments

| Drug Name | Place in Therapy | FDA Indication(s) | Dose and Frequency |
|---|---|---|---|
| **C1 esterase inhibitor (Berinert®)** | Acute | Abdominal, facial, or laryngeal attacks | 20 units/kg intravenously as a single dose |
| **C1 esterase inhibitor, recombinant (Ruconest®)** | Acute | Attacks in adults and adolescents. Efficacy has not been established in laryngeal attacks. | 50 units/kg intravenously as a single dose; maximum dose: 4,200 units; may repeat once within 24 hours if attack continues |
| **Ecallantide (Kalbitor®)** | Acute | Attacks in patients ≥12 years of age | 30 mg as a one-time dose (3 subcutaneous injections); may repeat once within 24 hours if attack continues |
| **Icatibant (Firazyr®)** | Acute | Attacks in adults ≥18 years of age | 30 mg injection once; may repeat every 6 hours if response is inadequate; maximum dose per day: 90 mg |
| **C1 esterase inhibitor (Cinryze®)** | Prophylaxis | HAE prophylaxis in patients ≥6 years of age | 1,000 units intravenously every 3 to 4 days (twice weekly); doses up to 2,500 units (≤100 units/kg) every 3 or 4 days may be considered based on individual patient response. |
| **C1 esterase inhibitor (Haegarda®)** | Prophylaxis | HAE prophylaxis in patients ≥6 years of age | 60 units/kg subcutaneous every 3 to 4 days (twice weekly) |
| **Berotralstat (Orladayo™)** | Prophylaxis | HAE prophylaxis in patients ≥12 years of age | 110 mg or 150 mg orally daily |
| **Lanadelumab-flyo (Takhzyro™)** | Prophylaxis | HAE prophylaxis in patients ≥2 years of age | 300 mg subcutaneous injection every 2 weeks (for ≥12 years) or 150 mg every 2 weeks (for 6-12 years); may consider dosing every 4 weeks for patients who are well-controlled for > 6 months; 150 mg every 4 weeks for 2-6 years of age |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this a request for continuation of prophylactic therapy OR for treatment of a second acute attack previously approved through fee-for-service? | **Yes**: Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Is the request for an FDA approved indication and place in therapy according to **Table 1** and is there confirmed laboratory diagnosis of hereditary angioedema (e.g., low C4 levels and either low C1 inhibitor antigenic levels or low C1 inhibitor functional levels)? | **Yes**: Go to #4<br><br>Document labs | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Has the provider documented discussion with the patient of risks (including thrombotic events and/or anaphylaxis) versus benefits of therapy? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Notify provider of potential serious adverse effects of therapy. See notes below. |
| 5. Is the request for a C1 esterase inhibitor or ecallantide? | **Yes:** Go to #6 | **No:** Go to #7 |
| 6. Is the patient prescribed concurrent epinephrine or do they have epinephrine on hand? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 7. Is the medication intended to be administered by a non-healthcare professional (e.g., self-administered)? | **Yes:** Go to #8 | **No:** Go to #9 |
| 8. Has the member received training on identification of an acute attack? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 9. Is the request for treatment of an acute hereditary angioedema attack? | **Yes:** Go to #12<br><br>Document attack severity if available | **No:** Go to #10 |

| Approval Criteria | | |
|---|---|---|
| 10. Is the request for prophylactic use in a patient with a history of hereditary angioedema attacks? | **Yes:** Go to #11<br><br>Document baseline number of attacks in the last 6 months | **No:** Pass to RPh. Deny; medical appropriateness. |
| 11. Have potential triggering factors for angioedema including medications such as estrogens, progestins, or angiotensin converting enzyme inhibitors been assessed and discontinued when appropriate? | **Yes:** Go to #12 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 12. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Approve for the following recommended durations:<br><br>Acute treatment: Approve based on standard FDA dosing for treatment of a single acute attack (see **Table 1**)<br><br>Prophylactic treatment: Approve for up to 6 months or length of therapy, whichever is less. |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the request for additional treatment for acute attacks? | **Yes:** Go to #2 | **No:** Go to #5 |
| 2. Is there documented utilization and benefit of the initial approved dose? | **Yes:** Approve based on standard FDA dosing for treatment of a single acute attack (see **Table 1**).<br><br>Document attack severity if available | **No:** Go to #3 |
| 3. Does the patient currently already have at least one on-demand dose for an acute attack? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #4 |

| Renewal Criteria | | |
|---|---|---|
| 4. Is there documentation from the prescriber that an on-demand dose is necessary and risks of therapy continue to outweigh the benefits? | **Yes:** Approve based on standard FDA dosing for treatment of a single acute attack (see **Table 1**).<br><br>Document attack severity if available | **No:** Pass to RPh. Deny; medical appropriateness. |
| 5. Since initiation of therapy, has the number or severity of hereditary angioedema attacks decreased? | **Yes:** Go to #6<br><br>Document change in attack frequency or severity | **No:** Pass to RPh. Deny; medical appropriateness. |
| 6. Has the patient been attack free for at least 6 months? | **Yes:** Go to #7 | **No:** Approve for up to 12 months. |
| 7. Is there documentation from the prescriber that they have evaluated continued necessity of long-term prophylactic treatment at the current dose? | **Yes:** Approve for up to 6 months. | **No:** Pass to RPh. Deny; medical appropriateness. |

<u>Notes on adverse effects of treatment:</u>

Berotralstat

- Doses above 150 mg daily have been associated with QT prolongation. Dose adjustment is recommended for patients with moderate to severe hepatic impairment or with concomitant p-glycoprotein or BCRP inhibitors. Avoid use with p-glycoprotein inducers.

C1 esterase inhibitors

- In clinical trials of patients with moderate to severe hereditary angioedema attacks, use of C1 esterase inhibitors improved the duration of symptoms by an average 1-2 hours compared to placebo. Prophylactic use has only been evaluated in patients with more than 2 attacks per month.
- Hypersensitivity reactions have been observed with C1 esterase inhibitors. Due to the risk of anaphylaxis, it is recommended that all patients prescribed human derived C1 esterase inhibitors have epinephrine immediately available.
- Serious arterial and venous thrombotic events have been reported with use of C1 esterase inhibitors, particularly in patients with pre-existing risk factors for thromboembolism. The exact incidence of thrombosis with C1 esterase inhibitors is unclear. In patients using prophylactic therapy with Cinryze®, over an average of 2.6 years, 3% of patients experienced thrombosis.

Ecallantide

- The average improvement in symptoms compared to placebo at 4 hours after treatment of an acute attack was 0.4 points on a 0-3 point scale.
- Ecallantide has a box warning for anaphylaxis. In clinical trials, 3-4% of patients treated with ecallantide experienced anaphylaxis. Risks of treatment should be weighed against the benefits.

Icatibant

- In clinical trials of icatibant for acute attacks, time to 50% overall symptom improvement was 17.8 hours better than placebo (19 vs. 2 hours). A second study demonstrated no difference from placebo in time to symptom

improvement. There are no data available on quality of life, daily activities, physical or mental functioning with use of icatibant.

Lanadelumab-flyo

- Prophylactic use has only been evaluated in patients with more than 1 moderate-severe attack per month. Hypersensitivity reactions were observed in 1% of patients treated with C1 esterase inhibitors. Elevated liver enzymes were also observed more frequently with lanadelumab compared to placebo (2% vs. 0%), and the long-term safety is unknown.

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*P&T/DUR Review: 6/21 (SS); 3/19 (SS)*
*Implementation: 7/1/2021; 5/1/19*

# Immunoglobulins

**Goal(s):**
- Ensure that medications for immunoglobulins are used appropriately for OHP-funded conditions.
- Provide coverage for off-label indications that have evidence for use.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Non-preferred immunoglobulin

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. FDA Approved Indications and Off-label Immune Globulin Indications**

| FDA Approved Indications | Adults | Pediatrics |
|---|---|---|
| B-cell chronic lymphocytic leukemia variant (CLL) | Yes | No |
| Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) | Yes | No |
| Dermatomyositis | Yes | No |
| Hepatitis A Prophylaxis | Yes | No |
| Idiopathic thrombocytopenic purpura (ITP) | Yes | Yes -2 years and up |
| Kawasaki Disease | No | Yes |
| Measles Prophylaxis and post-exposure prophylaxis | Yes | Yes |
| Multifocal motor neuropathy (MMN) | Yes | No |
| Primary humoral immunodeficiencies (PI)* | Yes | Yes - 2 years and up |
| Rubella in pregnancy | Yes | No |
| Varicella prophylaxis | Yes | No |
| **Off-Label Indications with Evidence for Efficacy** | **Adults** | **Pediatrics** |
| Autoimmune hemolytic anemia | Yes | No |
| Autoimmune necrotizing myopathy | Yes | No |
| Autoimmune neutropenia | Yes | No |
| Cytomegalovirus infection | Yes | No |
| Guillain-Barre syndrome | Yes | Yes |
| Human Immunodeficiency Virus (HIV) | No | Yes |
| IgA nephropathy | Yes | No |
| Multisystem inflammatory syndrome in children; associated with SARS-CoV-2 | No | Yes |
| Myasthenia Gravis | Yes | No |
| Neonatal jaundice | No | Yes |
| Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) | No | Yes |
| Pemphigus | Yes | No |
| Respiratory syncytial virus | No | Yes |
| Toxic shock syndrome | Yes | No |
| Transplant rejection or desensitization | Yes | No |

| | | |
|---|---|---|
| Uveitis | Yes | No |
| Von Willebrand disorder | Yes | No |

* Primary humoral immunodeficiency includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies

| **Approval Criteria** | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Will the prescriber consider a change to a preferred product?<br><br>Message: Preferred products do not generally require a PA. Preferred products are evidence-based and reviewed for comparative effectiveness and safety by the P&T Committee. | **Yes:** Inform prescriber of covered alternatives in class. | **No**: Go to #3 |
| 3. Is the request for continuation of therapy previously approved by fee-for-service? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #4 |
| 4. Is the request for an FDA-approved indication or for an off-label indication, with evidence of efficacy, listed in Table 1? | **Yes**: Approve for 6 months | **No:** Go to #5 |
| 5. Is the request for continuation after a hospital discharge? | **Yes:** Approve for 6 months | **No:** Go to #6 |
| 6. Is the medication prescribed by, or in consultation with a neurologist, transplant provider, infectious disease, or other relevant specialist for the requested condition? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is the request for acute treatment anticipated to last less than 3 months? | **Yes:** Approve for requested duration | **No:** Go to #8 |
| 8. Is there objective documentation of disease severity using a validated measure?<br><br>Examples could include number of hospitalizations, quality of life assessed using the Short-Form 36, clinical test results, or other symptom assessment scale relevant to the requested condition. | **Yes:** Go to #9<br><br>Document disease severity | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria |
|---|
| 9. All other diagnoses must be evaluated as to the OHP-funding level and evidence for clinical benefit.<br>• Evidence supporting treatment for conditions which are not outlined above is currently insufficient and should be denied for “medical appropriateness”<br><br>If new evidence or guideline-recommendations are provided by the prescriber, please forward request to Oregon DMAP for consideration and potential modification of current PA criteria. |

| Renewal Criteria | | |
|---|---|---|
| 1. Is there documentation to demonstrate clinically meaningful improvement in symptoms, function, disease severity, or quality of life since initiation of treatment?<br><br>The same clinical measure used to document disease severity is recommended to document clinical benefit. | **Yes:** Approve for 12 months | **No**: Pass to RPh. Deny; medical appropriateness. |

*P&T/DUR Review: 10/24 (KS)*
*Implementation: 12/1/2024*

# Inhaled Corticosteroids (ICS)

**Goals:**
- To optimize the safe and effective use of ICS therapy in patients with asthma and COPD.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Non-preferred ICS products

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 Code | |
| 2. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics (P&T) Committee. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Go to #3 |
| 3. Is the request for treatment of asthma or reactive airway disease? | **Yes:** Go to #6 | **No:** Go to #4 |
| 4. Is the request for treatment of COPD, mucopurulent chronic bronchitis and/or emphysema? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Need a supporting diagnosis. If prescriber believes diagnosis is appropriate, inform prescriber of the appeals process for Medical Director Review. |
| 5. Does the patient have an active prescription for an inhaled long-acting bronchodilator (anticholinergic or beta-agonist)? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 6. Does the patient have an active prescription for an on-demand short-acting beta-agonist (SABA) or an alternative rescue medication for acute asthma exacerbations? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review:* *2/24 (DM); 10/23 (SF); 10/22 (KS), 10/20 (KS), 5/19 (KS), 1/18; 9/16; 9/15*
*Implementation:* *3/1/18; 10/13/16; 10/9/15*

# Insulins

**Goal:**
- Provide evidence-based and cost-effective insulin options to patients with diabetes mellitus.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Non-preferred insulins
- Select preferred insulin pens (Novolin® 70/30 and Humulin® 70/30)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee | **Yes:** Inform prescriber of covered alternatives | **No:** Go to #3 |
| 3. Is the request for an insulin pen or cartridge? | **Yes:** Go to #4 | **No:** Approve for up to 12 months |
| 4. Has the patient tried and failed or have contraindications to any of the preferred pens or cartridges?<br><br>Note: Documentation of trial and failure or contraindication to a long-acting or basal preferred product is required for non-preferred long-acting or basal insulin requests. | **Yes:** Go to #5 | **No:** Pass to RPh; deny and recommend a trial of one of the preferred insulin products |

| Approval Criteria | | |
|---|---|---|
| 5. Will the insulin be administered by the patient or a non-professional caregiver **AND** do any of the following criteria apply:<br>• The patient has physical dexterity problems/vision impairment<br>• The patient is unable to comprehend basic administration instructions<br>• The patient has a history of dosing errors with use of vials<br>• The patient is a child less than 18 years of age? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh; deny for medical appropriateness |

*P&T / DUR Review:* *6/24 (SF); 2/20(KS); 9/19; 11/18; 9/17; 3/16; 11/15; 9/10*
*Implementation:* *11/1/2019; 11/1/17; 10/13/16; 1/1/11*

# Drugs for Interstitial Lung Disease

**Goal:**

- Restrict use to populations with chronic interstitial lung disease in which the drugs have demonstrated efficacy with FDA approval.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Non-preferred drugs

**Preferred Alternatives:**

- No preferred alternatives at this time

Table 1. FDA-approved Indications.

| Indication | Nintedanib | Pirfenidone |
|---|---|---|
| Idiopathic pulmonary fibrosis | X | X |
| Chronic fibrosing interstitial lung disease with a progressive phenotype | X | |
| Systemic sclerosis-associated interstitial lung disease | X | |

| Approval Criteria | | |
|---|---|---|
| 1. Is the claim for a drug with an FDA-approved interstitial lung disease indication as outlined in Table 1? | **Yes:** Go to #2 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 2. Is the treatment prescribed by a pulmonologist? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is the patient a current smoker? | **Yes:** Pass to RPh. Deny; medical appropriateness.<br><br>Efficacy of approved drugs for IPF may be altered in smokers due to decreased exposure (see prescribing information). | **No:** Approve for up to 12 months. |

*P&T/DUR Review:* *6/20 (AG); 7/15*
*Implementation:* *7/1/20, 8/16, 8/25/15*

# Intranasal Allergy Drugs

**Goals:**

- Restrict use of intranasal allergy inhalers for conditions funded by the OHP and where there is evidence of benefit.
- Treatment for allergic or non-allergic rhinitis is funded by the OHP only if it complicates asthma, sinusitis or obstructive sleep apnea. Only intranasal corticosteroids have evidence of benefit for these conditions.
- Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**

- 30 days to 12 months

**Requires PA:**

- Preferred intranasal corticosteroids without prior claims evidence of asthma for people 21 years of age and older.
- Preferred intranasal antihistamines for people 21 years of age and older.
- Non-preferred intranasal corticosteroids and antihistamines
- Intranasal ipratropium and cromolyn sodium

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/
- Preferred intranasal corticosteroids, preferred antihistamines DO NOT require prior authorization for children and adolescents up to their 21st birthday.

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is the prescribed drug intranasal ipratropium or cromolyn? | **Yes:** Pass to RPh. Deny; not funded by the OHP | **No:** Go to #3 |
| 3. Does patient have co-morbid conditions funded by the OHP?<br>• Chronic Sinusitis ( J320-J329)<br>• Acute Sinusitis (J0100; J0110; J0120; J0130; J0140; J0190)<br>• Sleep Apnea (G4730; G4731; G4733; G4739) | **Yes:** Document ICD10 code(s) and approve for up to 12 months for chronic sinusitis or sleep apnea and approve for no more than 30 days for acute sinusitis | **No:** Go to #4 |
| 4. Is there a diagnosis of asthma or reactive airway disease in the past 1 year (J4520-J4522; J45901-45998)? | **Yes:** Go to #5 | **No:** Go to #6 |

| Approval Criteria | | |
|---|---|---|
| 5. Is there a claim for an *orally* inhaled corticosteroid in the past 90 days?<br><br>Note: Asthma-related outcomes are not improved by the addition of an intranasal corticosteroid to an orally inhaled corticosteroid. | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Approve for up to 6 months |
| 6. Is the prescribed drug a preferred product? | **Yes:** Go to #8 | **No:** Go to #7 |
| 7. Will the prescriber consider switching to a preferred product?<br><br>Note: Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee | **Yes:** Inform prescriber of preferred alternatives. Go to #8 | **No:** Go to #8 |
| 8. Is the patient eligible for EPSDT review AND is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Approve for 6 months | **No:** Go to #9 |
| 9. RPh only: Is the diagnosis funded by the OHP? | **Funded:** Deny; medical appropriateness.<br><br>(eg, COPD; Obstructive Chronic Bronchitis; or other Chronic Bronchitis [J449; J40; J410-418; J42; J440-449]<br><br>Use clinical judgment to APPROVE for 1 month to allow time for appeal.<br><br>Message: "The request has been denied because it is considered medically inappropriate; however, it has been APPROVED for 1 month to allow time for appeal." | **Not Funded:** Deny; not funded by the OHP.<br><br>(eg, allergic rhinitis (J300-J309); chronic rhinitis (J310-312); allergic conjunctivitis (H1045); upper respiratory infection (J069); acute nasopharyngitis (common cold) (J00); urticaria (L500-L509); etc.) |

*P&T / DUR Review:* *8/22 (DM);11/15 (AG); 7/15; 9/08; 2/06; 9/04; 5/04; 5/02*
*Implementation:* *10/1/22; 10/13/16; 1/1/16; 8/25/15; 8/09; 9/06; 3/06; 5/05; 10/04; 8/02*

# Ivabradine (Corlanor®)

**Goals:**

- Restrict use of ivabradine to populations in which the drug has demonstrated efficacy.
- Encourage use of ACE-inhibitors or angiotensin II receptor blockers (ARBs) with demonstrated evidence of mortality reduction in heart failure with reduced ejection fraction.
- Encourage use of with demonstrated evidence of mortality reduction in heart failure with reduced ejection fraction.

**Length of Authorization:**

- 6 to 12 months

**Requires PA:**

- Ivabradine (Corlanor®)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. Is this a request for continuation of therapy previously approved by the FFS program (patient already on ivabradine)? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #2 |
| 2. What diagnosis is being treated? | Record ICD10 code. | |
| 3. Does the patient have current documentation of New York Heart Association Class II or III heart failure with reduced ejection fraction less than or equal to 35% (LVEF ≤ 35%)? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the patient in normal sinus rhythm with a resting heart rate of 70 beats per minute or greater (≥70 BPM)? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Has the patient had a previous hospitalization for heart failure in the past 12 months? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 6. Is the patient currently on a maximally tolerated dose of carvedilol, sustained-release metoprolol succinate, or bisoprolol; and if not, is there a documented intolerance or contraindication to each of these beta-blockers?<br><br>*Note: the above listed beta-blockers have evidence for mortality reduction in chronic heart failure at these target doses and are recommended by national and international heart failure guidelines.[1,2] Carvedilol and metoprolol succinate are preferred agents on the PDL.* | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is the patient currently on a maximally tolerated dose of an ACE-inhibitor or an ARB; and if not, is there a documented intolerance or contraindication to both ACE-inhibitors and ARBs? | **Yes:** Go to # 8 | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Is the patient currently on an aldosterone antagonist; and if not, is there a documented intolerance or contraindication to therapy (CrCl < 30 ml/min or potassium ≥ 5.0 mEq/L)?<br><br>*Note: Aldosterone receptor antagonists (spironolactone or eplerenone) are recommended in patients with NYHA class II–IV HF and who have LVEF of 35% or less, unless contraindicated, to reduce morbidity and mortality. Patients with NYHA class II HF should have a history of prior hospitalization or elevated plasma natriuretic peptide levels to be considered for aldosterone receptor antagonists.* | **Yes:** Approve for up to 6 months | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the patient in normal sinus rhythm with no documented history of atrial fibrillation since ivabradine was initiated? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

References:
1. Yancy CW, Jessup M, Bozkurt B, et al. 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;62(16):e147-239. doi: 10.1016/j.jacc.2013.05.019.
2. McMurray J, Adamopoulos S, Anker S, et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012. *Eur J Heart Fail*. 2012;14:803-869. doi:10.1093/eurjhf/hfs105.

*P&T / DUR Review:* *11/15 (AG)*
*Implementation:* *8/16, 1/1/16*

# Long-acting Beta-agonists (LABA)

**Goals:**
- To optimize the safe and effective use of LABA therapy in patients with asthma and COPD.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Non-preferred LABA products

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 Code | |
| 2. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics (P&T) Committee. | **Yes:** Inform prescriber of covered alternatives in class | **No:** Go to #3 |
| 3. Does the patient have a diagnosis of asthma or reactive airway disease? | **Yes:** Go to #5 | **No:** Go to #4 |
| 4. Does the patient have a diagnosis of COPD, mucopurulent chronic bronchitis and/or emphysema? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Need a supporting diagnosis. If prescriber believes diagnosis is appropriate, inform prescriber of the appeals process for Medical Director Review. |
| 5. Does the patient have an active prescription for an inhaled corticosteroid (ICS) or an alternative asthma controller medication? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

# Long-acting Muscarinic Antagonist/Long-acting Beta-agonist (LAMA/LABA) and LAMA/LABA/Inhaled Corticosteroid (LAMA/LABA/ICS) Combinations

**Goals:**
- To optimize the safe and effective use of LAMA/LABA/ICS therapy in patients with asthma and COPD.
- Step-therapy required prior to coverage:
  - Asthma and COPD: short-acting bronchodilator and previous trial of two drug combination therapy (ICS/LABA, LABA/LAMA or ICS/LAMA). Preferred monotherapy inhaler LAMA and LABA products do NOT require prior authorization.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- All non-preferred LAMA/LABA and LAMA/LABA/ICS products

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 Code | |
| 2. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics (P&T) Committee. | **Yes:** Inform prescriber of preferred LAMA and LABA products in each class | **No:** Go to #3 |
| 3. Does the patient have a diagnosis of asthma or reactive airway disease without COPD? | **Yes:** Go to #8 | **No:** Go to #4 |
| 4. Does the patient have a diagnosis of COPD, mucopurulent chronic bronchitis and/or emphysema? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Need a supporting diagnosis. If prescriber believes diagnosis is appropriate, inform prescriber of the appeals process for Medical Director Review. |

| Approval Criteria | | |
|---|---|---|
| 5. Is the request for a LAMA/LABA combination product? | **Yes:** Approve for up to 12 months. Stop coverage of all other LAMA and LABA inhalers or scheduled SAMA/SABA inhalers (PRN SABA or SAMA permitted). | **No:** Go to #6 |
| 6. Is the request for a 3 drug ICS/LABA/LAMA combination product and is there a documented trial of a LAMA and LABA, or ICS and LABA or ICS and LAMA? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 7. Is there documentation that the prescriber is willing to stop coverage of all other LAMA, LABA, and ICS inhaler combination products? | **Yes:** Approve for up to 12 months. Stop coverage of all other LAMA, LABA and ICS inhalers. | **No:** Pass to RPh. Deny; medical appropriateness. |
| 8. Does the patient have an active prescription for an on-demand short-acting acting beta-agonist (SABA) and/or for ICS-formoterol? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 9. Is the request for Trelegy Ellipta (ICS/LAMA/LABA) combination product and is there a documented trial of an ICS/LABA? | **Yes:** Approve for up to 12 months. Stop coverage of all other LAMA, LABA and ICS inhalers (with the exception of ICS-formoterol which may be continued) | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T Review:* *2/24 (DM); 10/23; 10/22, 10/21; 12/20, 10/20, 5/19; 1/18; 9/16; 11/15; 9/15; 11/14; 11/13; 5/12; 9/09; 2/06*
*Implementation:* *4/1/24; 1/1/21; 3/1/18; 10/13/16; 1/1/16; 1/15; 1/14; 9/12; 1/10*

# Lidocaine Patch

**Goal(s):**

- Provide coverage only for diagnoses that are supported by the medical literature.
- Restrict use to OHP-funded diagnoses in adults. Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**

- 90 days to 12 months (criteria specific)

**Requires PA:**

- Lidocaine Patch

**Covered Alternatives**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is the diagnosis supported by evidence for its use in that condition (refer to Table 1 for examples)? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is the diagnosis an OHP-funded diagnosis (refer to Table 1 for examples)? | **Yes:** Go to # 5 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #4. |
| 4. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Approve for 90 days | **No:** Pass to RPh. Deny; medical necessity. |
| 5. Is this a request for renewal of a previously approved prior authorization for lidocaine patch? | **Yes**: Go to **Renewal Criteria** | **No**: Go to # 6 |
| 6. Is the prescription for Lidoderm patch greater than 3 patches/day? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Approve for 90 days |

| Renewal Criteria | | |
|---|---|---|
| 1. Does the patient have documented improvement from lidocaine patch? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny for medical appropriateness. |

**Table 1. OHP Funded Diagnosis and Evidence Supports Drug Use in Specific Indication**

| Condition | Lidocaine Patch |
|---|---|
| Funded | Evidence Supports Use |
| Diabetic Neuropathy | X |
| Postherpetic Neuropathy | X |
| Painful Polyneuropathy | X |
| Spinal Cord Injury Pain | |
| Chemotherapy Induced Neuropathy | |
| Non-funded | |
| Fibromyalgia | |

*P&T Review:* *8/20 (DM); 7/18; 3/17*
*Implementation:* *4/1/17*

# Milnacipran

**Goal(s):**

- Provide coverage only for diagnoses that are supported by the medical literature.
- Restrict use to OHP-funded diagnoses in adults. Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**

- 90 days

**Requires PA:**

- Milnacipran

**Covered Alternatives**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is the diagnosis an OHP-funded diagnosis with evidence supporting its use in that condition (see Table 1 below for examples)? | **Yes:** Approve for 90 days | **No:** Go to #3. Pass to RPh. |
| 3. Pass to RPh.<br>• The prescriber must provide documentation of therapeutic failure, adverse event, or contraindication alternative drugs approved by FDA for the funded condition. The prescriber must provide medical literature supporting use for the funded condition. RPh may use clinical judgement to approve drug for up to 6 months or deny request based on documentation provided by prescriber.<br>• If not funded and the patient is eligible for EPSDT review, documentation is required that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc) | | |

**Table 1. OHP Funded or Non-Funded Diagnosis and Evidence Supports Drug Use in Specific Indication**

| Condition | Milnacipran |
|---|---|
| Funded | |
| Diabetic Neuropathy | |
| Postherpetic Neuropathy | |
| Painful Polyneuropathy | |
| Spinal Cord Injury Pain | |
| Chemotherapy Induced Neuropathy | |
| Non-funded | |
| Fibromyalgia | X |

*P&T Review: 7/18 (DM); 3/17*
*Implementation: 4/1/17*

# Moisturizers, topical

**Goal(s):**

- Limit use to funded conditions. Allow case-by-case review for members covered under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) program.

**Length of Authorization:**

- 12 months

**Requires PA:**

- Non-preferred topical emollients, protectants, or moisturizers
- Formulations other than lotions, creams and ointments are not covered

**Covered Alternatives:**

- Covered products include: topical lotions, ointments, and creams
- Preferred alternatives listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD 10 code. | |
| 2. Is the request for treatment of severe skin disease?<br><br>Severe disease is defined by the prioritized list as: Having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's DLQI ≥ 13 (or severe score on other validated tool) AND one or more of the following:<br>1. At least 10% body surface area involved OR<br>2. Hand, foot, face, or mucous membrane involvement | **Yes:** Go to #4 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #3 |
| 3. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical necessity |
| 4. Is the request for a preferred product? | **Yes:** Approve for 12 months | **No:** Go to #5 |
| 5. Has the patient failed to have benefit with (or have contraindications to) at least 2 preferred products? | **Yes**: Approve for 12 months | **No**: Pass to RPh. Deny; medical appropriateness. |

# Molluscum Contagiosum

**Goal(s):**

- Ensure that medications for molluscum contagiosum (MC) are used appropriately for OHP-funded conditions.
- Define medically appropriate and necessary therapy supported by the medical literature for members covered under the EPSDT program.

**Length of Authorization:**

- Up to 12 weeks

**Requires PA:**

- Cantharidin (pharmacy and provider administered claims) and berdazimer for pharmacy claims.

**Table 1. FDA-Approved Dosing**

| Product Name (BRAND NAME) | Indication | Dosing and Duration | Maximum Duration |
|---|---|---|---|
| Cantharidin (YCANTH) | Topical treatment of molluscum contagiosum in adults and pediatric patients 2 years of age and older. | Apply a single application directly to each lesion every 3 weeks as needed; do not use more than 2 applicators during a single treatment session. | 4 treatments |
| Berdazimer (ZELSUVMI) | Topical treatment of molluscum contagiosum (MC) in adults and pediatric patients 1 year of age and older. | Apply a thin even layer once daily to each lesion | 12 weeks |

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this an FDA approved indication for the age and diagnosis submitted? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the diagnosis funded by OHP? | **Yes:** Go to #4 | **No:** If not eligible for EPSDT review, Pass to RPh. Deny; not funded by the OHP.<br><br>If eligible for EPSDT Review, Go to #4 |

| Approval Criteria | | |
|---|---|---|
| 4. Have the patient's lesions been present and unresolved for 6 months or longer? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Have the patient's lesions been previously treated with the requested agent? | **Yes:** Go to #6 | **No:** Go to #7 |
| 6. Has the patient already received the maximum duration of therapy recommended in **Table 1**?<br>• 4 or more treatment doses of cantharidin<br>OR<br>• 12 or more weeks of berdazimer | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #7 |
| 7. Is the requested agent being prescribed by or in consultation with a dermatologist? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Has the provider performed an objective baseline assessment and determined one of the following:<br>• The molluscum contagiosum lesions are extremely troublesome (e.g. pain, itching, etc.)<br>OR<br>• Patient is immunocompromised. | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Is the requested agent being used to treat lesions in or near the mouth, eyes, or mucosal tissues? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #10 |
| 10. Is the agent requested being used in combination with another treatment modality for MC (e.g. cryotherapy, curettage, or another agent listed in **Table 1**)? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Approve for up to 12 weeks<br><br>Cumulative treatment not to exceed 12 weeks of therapy. |

*P&T/DUR Review: 6/25 (DE)*
*Implementation: 8/1/25*

# Multiple Sclerosis, Injectable Drugs

**Goal(s):**
- Promote safe and effective use of injectable or infused disease-modifying drugs for multiple sclerosis.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Non-preferred injectable or infused multiple sclerosis drugs (both pharmacy or provider administered claims).
- Note: Tysabri® (natalizumab) should be reviewed under separate Tysabri® PA criteria.
- Note: Requests for Arzerra™ (ofatumumab) should be reviewed under the Oncology PA.

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for an FDA-approved form of multiple sclerosis (see Table 1)? | **Yes:** Go to #3. | **No:** Pass to RPH; Deny for medical appropriateness. |
| 3. Is this a request for continuation of therapy? | **Yes**: Go to **Renewal Criteria** | **No:** Go to #4 |
| 4. Is the drug prescribed by or in consultation with a neurologist? | **Yes**: Go to # 5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the patient on concurrent treatment with a disease modifying drug (i.e., glatiramer, interferon, mitoxantrone, natalizumab, ofatumumab, ocrelizumab, or peginterferon) to treat MS? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #6 |
| 6. Is there documentation of recommended baseline testing to mitigate safety concerns (Table 2)? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 7. Is the request for a drug with potential risks during pregnancy (e.g., ofatumumab, mitoxantrone, or ublituximab)? | **Yes**: Go to #8 | **No**: Approve for up to 1 year |
| 8. Is the patient of childbearing potential? | **Yes:** Go to #9 | **No:** Approve for up to 1 year |

| Approval Criteria | | |
|---|---|---|
| 9. Is the patient pregnant or actively trying to conceive? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #10 |
| 10. Is there documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant? | **Yes:** Approve for up to 1 year | **No:** Pass to RPh. Deny; medical appropriateness. |

| Renewal Criteria | | |
|---|---|---|
| 1. Has the patient's condition stabilized (i.e., reduced activity seen on magnetic resonance imaging (MRI), fewer relapses, and/or minimal or no disease progression) as assessed by the prescribing physician and physician attests to patient's improvement? | **Yes:** Approve for 12 months.<br><br>Document baseline assessment and physician attestation received. | **No:** Pass to RPh; Deny; medical appropriateness. |

**Table 1. FDA-Approved Indications for Injectable MS Drugs**

| Generic Name | Brand Name | FDA Indication | | | |
|---|---|---|---|---|---|
| | | CIS | RRMS | SPMS | PPMS |
| Alemtuzumab | LEMTRADA | | X | X | |
| Glatiramer acetate | GLATOPA, COPAXONE | X | X | X | |
| Interferon beta-1a | AVONEX, REBIF | X | X | X | |
| Interferon beta-1b | BETASERON, EXTAVIA | X | X | X | |
| Mitoxantrone | NOVANTRONE | | X | X | |
| Ocrelizumab | OCREVUS | X | X | X | X |
| Ofatumumab | KESIMPTA | X | X | X | |
| Ublituximab | BRIUMVI | X | X | X | |

Abbreviations: CIS = clinically isolated syndrome; PPMS = primary progressive multiple sclerosis; RRMS = relapsing-remitting multiple sclerosis; SPMS = secondary progressive multiple sclerosis

**Table 2. FDA-Recommended Baseline Safety Assessments**

| | LFTs | CBC | Thyroid Function Tests | Hepatitis B Virus Screening | Other Screening |
|---|---|---|---|---|---|
| Alemtuzumab | X | X | X | | VZV and TB Screening, SCr, UA, up to date with all vaccinations, completed screening for John Cunningham (JC) virus |
| Glatiramer acetate | | | | | |
| Interferon beta-1a | X | X | X | | |
| Interferon beta-1b | X | X | X | | |

| | | | | | |
|---|---|---|---|---|---|
| Mitoxantrone | X | X | | | ECG and LVEF, negative pregnancy test |
| Ocrelizumab | | | | X | Serum immunoglobulins, up to date with all vaccinations, completed screening for John Cunningham (JC) virus |
| Ofatumumab | | | | X | Serum immunoglobulins, up to date with all vaccinations, negative pregnancy test, completed screening for John Cunningham (JC) virus |
| Ublituximab | | | | X | Serum immunoglobulins, up to date with all vaccinations, negative pregnancy test prior to each infusion, completed screening for John Cunningham (JC) virus |
| Abbreviations: CBC = complete blood count; ECG = electrocardiogram; FDA = U.S. Food and Drug Administration; JCV = John Cunningham Virus; LFTs = liver function tests; LVEF= left ventricular ejection fraction; PML = progressive multifocal leukoencephalopathy; SCr = serum creatinine; TB = tuberculosis; UA = urinalysis; VZV = varicella zoster virus | | | | | |

*P&T / DUR Action:* *10/24 (DM); 10/22 (DM)*
*Implementation:* *12/1/2024; 1/1/23*

# Multiple Sclerosis, Oral Drugs

**Goal(s):**
- Promote safe and effective use of oral disease-modifying drugs for multiple sclerosis or ulcerative colitis.
- Promote use of preferred multiple sclerosis drugs.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- All oral MS therapy including:
  - Sphingosine 1-phosphate receptor modulators (e.g. fingolimod, ozanimod, ponesimod, siponimod, etc.)
  - Teriflunomide
  - Fumarate salts (e.g., dimethyl fumarate, monomethyl fumarate, diroximel fumarate, etc.)
  - Cladribine

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for ozanimod to treat moderate-to-severe ulcerative colitis? | **Yes:** Go to #3 | **No:** Go to #4 |
| 3. Has the patient failed to respond or had an inadequate response to at least one of the following conventional immunosuppressive therapies for ≥6 months:<br>• Mercaptopurine, azathioprine, or budesonide; or<br>• Have a documented intolerance or contraindication these conventional therapies?<br>AND<br>• Has the patient tried and failed a 3-month trial of a Humira® product? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 4. Is the request for an FDA-approved form of multiple sclerosis in the appropriate age range? (see Table 1) | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 5. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products are reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics Committee and do not require PA. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Go to #6 |
| 6. Is the medication being prescribed by or in consultation with a neurologist or gastroenterologist (if the diagnosis is ulcerative colitis)? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 7. Is the patient on concurrent treatment with a disease modifying drug (i.e. interferon beta-1b, glatiramer acetate, interferon beta-1a, natalizumab, ofatumumab, ocrelizumab, or mitoxantrone)? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #8 |
| 8. Is this a request for continuation of therapy? | **Yes**: Go to **Renewal Criteria** | **No:** Go to #9 |
| 9. Is there documentation of recommended baseline testing to mitigate safety concerns (Table 2)? | **Yes:** Go to #10 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 10. Is the prescription for teriflunomide? | **Yes:** Go to #15 | **No:** Go to #11 |
| 11. Is the prescription for a sphingosine 1-phosphate receptor modulator (Table 1)? | **Yes:** Go to #12 | **No:** Go to #14 |
| 12. Does the patient have preexisting cardiac disease, risk factors for bradycardia, or is on an anti-arrhythmic, beta-blocker, or calcium channel blocker? | **Yes:** Go to #13 | **No:** Go to #15 |
| 13. Has the patient had a cardiology consultation before initiation (see clinical notes)? | **Yes:** Go to #15 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 14. Is the prescription for cladribine? | **Yes:** Go to # 15 | **No:** Go to #17 |
| 15. Is the patient of childbearing potential? | **Yes:** Go to #16 | **No:** Approve for up to 12 months |
| 16. Is the patient pregnant or actively trying to conceive? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #17 |

| Approval Criteria | | |
|---|---|---|
| 17. Is there documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant? | **Yes:** Approve for 6 months | **No:** Pass to RPh. Deny; medical appropriateness. |

| Renewal Criteria | | |
|---|---|---|
| 1. Has the patient's condition stabilized (i.e reduced activity seen on magnetic resonance imaging (MRI), fewer relapses, and/or minimal or no disease progression) as assessed by the prescribing physician and physician attests to patient's improvement? | **Yes:** Approve for 12 months.<br><br>Document baseline assessment and physician attestation received. | **No:** Pass to RPh; Deny; medical appropriateness. |

**Table 1. Dosing And FDA-Approved Indications for Oral MS Drugs**

| Generic Name | FDA Indication (Adults unless otherwise indicated) | | | |
|---|---|---|---|---|
| | **CIS** | **RRMS** | **SPMS** | **Ulcerative Colitis** |
| Cladribine | | X | X | |
| Fingolimod | X *(≥10 years)* | X *(≥10 years)* | X *(≥10 years)* | |
| Siponimod | X | X | X | |
| Ozanimod | X | X | X | X |
| Ponesimod | X | X | X | |
| Teriflunomide | X | X | X | |
| Dimethyl Fumarate | X | X | X | |
| Monomethyl Fumarate | X | X | X | |
| Diroximel Fumarate | X | X | X | |
| Abbreviations: CIS = clinically isolated syndrome; RRMS = relapsing-remitting multiple sclerosis; SPMS = secondary progressive multiple sclerosis | | | | |

**Table 2. FDA-recommended Baseline Safety Assessments (see clinical notes for details)**

| | Negative Pregnancy Test | LFTs | CBC with lymphocyte count | Ophthalmic Exam | Varicella Zoster Antibodies | CYP2C9 genotype | Other Screening |
|---|---|---|---|---|---|---|---|
| Fumarate salts | | X | X (>500) | | | | |
| Fingolimod* | X | X | X | X | X | | JCV |
| Ozanimod* | X | X | X | X | X | | JCV |
| Ponesimod* | X | X | X | X | X | | JCV |
| Siponimod* | X | X | X | X | X | X | JCV |
| Teriflunomide | X (box warning) | X (box warning) | X | | | | |
| Cladribine | X (box warning) | X | X (WNL) | | X | | TB; HBV; HIV; HCV; JCV |
| Abbreviations: HBV = hepatitis B; HCV = hepatitis C; HIV = human immunodeficiency virus; JCV = John Cunningham virus; MRI = magnetic resonance imaging; PML = progressive multifocal leukoencephalopathy; TB = tuberculosis; WNL = within normal limits | | | | | | | |

* Sphingosine 1-phosphate receptor modulators

**Sphingosine 1-Phosphate Receptor Modulators (fingolimod, ozanimod, ponesimod, siponimod) Clinical Notes:**

- Because of bradycardia and atrioventricular conduction, patients must be observed for 4 to 6 hours after initial dose in a clinically appropriate area (fingolimod, ponesimod, siponimod).
- Patients on antiarrhythmics, beta-blockers or calcium channel blockers or with risk factors for bradycardia (h/o MI, age >70 yrs., electrolyte disorder, hypothyroidism) may be more prone to development of symptomatic bradycardia and should be initiated on fingolimod, ozanimod, ponesimod, or siponimod with caution. A cardiology evaluation should be performed before considering treatment.
- An ophthalmology evaluation should be repeated 3-4 months after fingolimod, ozanimod, ponesimod, or siponimod initiation with subsequent evaluations based on clinical symptoms.
- Patients starting on siponimod therapy must be tested for CYP2C9 variants to determine CYP2C9 genotype before starting siponimod. Siponimod is contraindicated in patients with a CYP2C9*3/*3 genotype. The recommended maintenance dosage in patients with a CYP2C9*1/*3 or *2/*3 genotype is 1 mg. The recommended maintenance dosage in all other patients is 2 mg.

**Teriflunomide Clinical Notes:**

Before starting teriflunomide, screen patients for latent tuberculosis infection with a TB skin test, exclude pregnancy, confirm use of reliable contraception in individuals of childbearing potential, check blood pressure, and obtain a complete blood cell count within the 6 months prior to starting therapy. Instruct patients to report symptoms of infection and obtain serum transaminase and bilirubin levels within the 6 months prior to starting therapy.

- After starting teriflunomide, monitor ALT levels at least monthly for 6 months. Consider additional ALT monitoring when teriflunomide is given with other potentially hepatotoxic drugs. Consider stopping teriflunomide if serum transaminase levels increase (>3-times the upper limit of normal). Monitor serum transaminase and bilirubin particularly in patients who develop symptoms suggestive of hepatic dysfunction. Discontinue teriflunomide and start accelerated elimination in those with suspected teriflunomide-induced liver injury and monitor liver tests weekly until normalized. Check blood pressure periodically and manage hypertension. Check serum potassium level in teriflunomide-treated patients with hyperkalemia symptoms or acute renal failure. Monitor for signs and symptoms of infection.
- Monitor for hematologic toxicity when switching from teriflunomide to another agent with a known potential for hematologic suppression because systemic exposure to both agents will overlap.

**Fumarate Salts (Dimethyl Fumarate, Monomethyl Fumarate, Diroximel Fumarate) Clinical Notes:**

- Fumarate salts may decrease a patient's white blood cell count. In the clinical trials the mean lymphocyte counts decreased by approximately 30% during the first year of treatment with dimethyl fumarate and then remained stable. The incidence of infections (60% vs. 58%) and serious infections (2% vs. 2%) was similar in patients treated with dimethyl fumarate or placebo, respectively. There was no increased incidence of serious infections observed in patients with lymphocyte counts <0.8 $x10^3$ cells/$mm^3$ (equivalent to <0.8 cells/µL). A transient increase in mean eosinophil counts was seen during the first 2 months of therapy.
- Fumarate salts should be held if the WBC falls below 2 $x10^3$ cells/$mm^3$ or the lymphocyte count is below 0.5 $x10^3$ cells/$mm^3$ (cells/µL) and permanently discontinued if the WBC did not increase to over 2 $x10^3$ cells/$mm^3$ or lymphocyte count increased to over 0.5 $x10^3$ cells/$mm^3$ after 4 weeks of withholding therapy.
- Patients should have a CBC with differential monitored every 6 to 12 months.

**Cladribine Clinical Notes:**

- Cladribine is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.
- Prior to initiating cladribine follow standard cancer screening guidelines because of the risk of malignancies.
- Obtain a CBC with differential including lymphocyte count. Lymphocytes must be: within normal limits before initiating the first treatment course and at least 800 cells per microliter before initiating the second treatment course. If necessary, delay the second treatment course for up to 6 months to allow for recovery of lymphocytes to at least 800 cells per microliter. If this recovery takes more than 6 months, the patient should not receive further treatment with cladribine.
- Infection screening: exclude HIV infection, perform TB and hepatitis screening. Evaluate for active infection; consider a delay in cladribine treatment until any acute infection is fully controlled.
- Administer all immunizations according to immunization guidelines prior to starting cladribine. Administer live-attenuated or live vaccines at least 4 to 6 weeks prior to starting cladribine.
- Obtain a baseline (within 3 months) magnetic resonance imaging prior to the first treatment course because of the risk of progressive multifocal leukoencephalopathy (PML).

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*P&T/DUR Review:* *10/24 (DM); 10/22; 10/21; 8/21; 6/21; 8/20; 6/20; 11/17; 11/16; 9/15; 9/13; 5/13; 3/12*
*Implementation:* *12/1/2024; 1/1/2023, 1/1/2022, 9/1/20; 1/1/18; 1/1/17; 1/1/14*

# Multivitamins

**Goals:**

- Restrict use for documented nutritional deficiency or diagnosis associated with nutritional deficiency (e.g., Cystic Fibrosis)
- Prenatal and pediatric multivitamins are not subject to this policy.
- Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- All multivitamins in HIC3 = C6B, C6G, C6H, C6I, C6Z

**Covered Alternatives:**

- Upon PA approval, only vitamins generically equivalent to those listed below will be covered:

| GSN | Generic Name | Example Brand |
|---|---|---|
| 002532 | MULTIVITAMIN | DAILY VITE OR TAB-A-VITE |
| 039744 | MULTIVITS, TH W-FE, OTHER MIN | THEREMS-M |
| 002523 | MULTIVITAMINS, THERAPEUTIC | THEREMS |
| 064732 | MULTIVITAMIN/ IRON/ FOLIC ACID | CEROVITE ADVANCED FORMULA |
| 048094 | MULTIVITAMIN W-MINERALS/ LUTEIN | CEROVITE SENIOR |
| 002064 | VITAMIN B COMPLEX | VITAMIN B COMPLEX |
| 058801 | MULTIVITS-MIN/ FA/ LYCOPENE/ LUT | CERTAVITE SENIOR-ANTIOXIDANT |
| 047608 | FOLIC ACID/ VITAMIN B COMP W-C | NEPHRO-VITE |
| 022707 | BETA-CAROTENE (A) W-C & E/MIN | PROSIGHT |
| 061112 | VIT A, C & E/ LUTEIN/ MINERALS | OCUVITE WITH LUTEIN |
| 066980 | MULTIVAMIN/ FA/ ZINC ASCORBATE | SOURCECF |
| 067025 | PEDIATRIC MULTIVIT #22/ FA/ ZINC | SOURCECF |
| 058068 | MULTIVITAMIN/ ZINC GLUCONATE | SOURCECF |
| 068128 | PEDIATRIC MULTIVIT #32/ FA/ ZINC | AKEDAMINS |
| 061991 | PEDI MULTIVIT #40/ PHYTONADIONE | AQUADEKS |
| 066852 | MULTIVITS & MINS/ FA/ COENZYME Q10 | AQUADEKS |
| 068035 | MULTIVITS & MINS/ FA/ COENZYME Q10 | AQUADEKS |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this an OHP-funded diagnosis? | **Yes:** Go to #4 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #3 |

| Approval Criteria | | |
|---|---|---|
| 3. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical necessity. |
| 4. Does the patient have a documented nutrient deficiency<br>**OR**<br>Does the patient have an increased nutritional need resulting from severe trauma (e.g., severe burn, major bone fracture, etc.)<br>**OR**<br>Does the patient have a diagnosis resulting in malabsorption (e.g., Crohn's disease, Cystic Fibrosis, bowel resection or removal, short gut syndrome, gastric bypass, renal dialysis, dysphagia, achalasia, etc.)<br>**OR**<br>Does the patient have a diagnosis that requires increased vitamin or mineral intake? | **Yes:** Approve up to 1 year | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T Review:* *3/16 (MH/KK); 3/14*
*Implementation:* *5/1/16, 4/1/2014*

# Natalizumab

**Goal(s):**

- Approve therapy for covered diagnosis which are supported by the medical literature.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Natalizumab (Tysabri®) and biosimilars (pharmacy or provider administered claims)

**Covered Alternatives:**

- Preferred alternatives listed at www.orpdl.org

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Has the patient been screened for John Cunningham (JC) Virus? | **Yes:** Go to #3 | **No:** Pass to RPh; Deny; medical appropriateness |
| 3. Does the patient have a diagnosis of relapsing multiple sclerosis (CIS, RRMS, or SPMS)? | **Yes:** Go to #4 | **No:** Go to #5 |
| 4. Is the medication being prescribed by or in consultation with a neurologist? | **Yes:** Approve for 12 months | **No:** Pass to RPh; Deny; medical appropriateness. |
| 5. Does the patient have Crohn's Disease? | **Yes:** Go to #6 | No: Pass to RPh; Deny; medical appropriateness. |
| 6. Has the patient been screened for latent or active tuberculosis and if positive, started tuberculosis treatment? | **Yes:** Go to #7 | **No:** Pass to RPh; Deny; medical appropriateness. |
| 7. Has the patient failed to respond to at least one of the following conventional immunosuppressive therapies for ≥6 months:<br>• Mercaptopurine, azathioprine, or budesonide; or<br>• Have a documented intolerance or contraindication to conventional therapy?<br>AND<br>• Has the patient tried and failed a 3-month trial of Humira? | **Yes:** Approve for up to 12 months.<br><br>Document each therapy with dates.<br><br>If applicable, document intolerance or contraindication(s). | **No:** Pass to RPh. Deny; medical appropriateness. |

# New Drug Policy

**Goal:**

- Restrict coverage of selected new drugs until the Oregon Pharmacy & Therapeutics Committee can review the drug for appropriate coverage. New drug criteria will apply until drug specific criteria are developed or for a maximum of 1 year (whichever is less). This policy does not apply to new oncology drugs.
- Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**

- Up to 6 months

**Requires PA:**

- A new drug, identified by the reviewing pharmacist during the weekly claim processing drug file load, which is not subject to existing prior authorization criteria, costing more than $5,000 per claim or $5,000 per month based on wholesale acquisition cost.

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is the medication FDA-approved for the requested indication and does the requested dosing align with the FDA-approved dosing? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is the drug being used to treat an OHP-funded condition? | **Yes:** Go to #5 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #4 |
| 4. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical necessity. |
| 5. Is baseline monitoring recommended for efficacy or safety and has the provider submitted documentation of recommended monitoring parameters? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 6. Does the requested therapy have an orphan drug designation and is this the only FDA-approved therapy for the funded condition? | **Yes:** Approve for up to 6 months or length of treatment (whichever is less). | **No:** Go to #7 |

## Approval Criteria

7. Pass to RPh.
   If funded: The prescriber must provide documentation that alternative drugs approved by the FDA for the funded condition are not appropriate due to history of therapeutic failure, an adverse event, or a contraindication. Otherwise, the prescriber must provide medical literature supporting use for the funded condition. RPh may use clinical judgement to approve drug for up to 6 months or deny request based on documentation provided by prescriber.

   If not funded:
   a. If member is eligible for EPSDT review; Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)?
      i. Is yes, The prescriber must provide documentation that alternative drugs approved by the FDA for the funded condition are not appropriate due to history of therapeutic failure, an adverse event, or a contraindication. Otherwise, the prescriber must provide medical literature supporting use for the funded condition. RPh may use clinical judgement to approve drug for up to 6 months or deny request based on documentation provided by prescriber.
      ii. If No, Deny (medical appropriateness)
   b. If member is not eligible for EPSDT review: Deny; not funded by the OHP.

*P&T / DUR Review:* *8/25; 7/18 (SS); 11/17; 11/15; 12/09*
*Implementation:* *8/15/18; 1/1/18; 1/1/16; 1/1/10*

# Nutritional Supplements (Oral Administration Only)

The policy for nutritional supplements is determined by Home Enteral/Parenteral Nutrition and IV Services (EPIV) and detailed in OAR 410-148-0260

**Goals:**

- Restrict use to patients unable to meet their recommended caloric/protein or micronutrient needs through regular, liquified, blenderized, or pureed foods in any modified texture or form.
- Requires ANNUAL nutritional assessment for continued use.
- Use restriction consistent with Division EPIV rules at: OAR 410-148-0260

These products are NOT federally rebate-able; Oregon waives the rebate requirement for this class.

Note:

- Nutritional formulas, when administered enterally (e.g., G-tube) are no longer available through the point-of-sale system.
- Service providers should use the CMS 1500 form and mail to DMAP, P.O. Box 14955, Salem, Oregon, 97309 or the 837P electronic claim form and not bill through POS.
- When billed correctly with HCPCS codes for enterally given supplements, enterally administered nutritional formulas do not require prior authorization (PA). Oral thickeners should be requested using HCPCS codes.
- For complete information on how to file a claim, go to: www.oregon.gov/OHA/HSD/OHP/Pages/Policy-Home-EPIV.aspx

**Length of Authorization:**

- Up to 12 months

**Not Covered:**

- Supplements such as *L. acidophilus*, Chlorophyll, Coenzyme Q10 are not covered and should not be approved.
- Oral solid dosage forms (e.g., tablets, capsules)

**Requires PA:**

- All supplemental nutrition products as defined in OAR 410-148-0260. Not all nutritional supplements are covered.
- Supplements that can be billed by a pharmacy include qualifying supplemental nutrition in HIC3 = C5C, C5F, C5G, C5U, C5B, C5X
  (nutritional bars, liquids, packets, powders, wafers such as Ensure, Ensure Plus, Nepro, Pediasure, Promod).
- Products administered orally must meet approval criteria below. Enteral administration (e.g., gastrostomy [G]-tube, jejunostomy [J]-tube, orogastric [OG]-tube, percutaneous endoscopic gastrostomy [PEG]-tube, etc.) are exempt from prior authorization when billed as a medical claim.

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. Covered conditions for which nutrition supplements are an integral part of treatment (OAR 410-148-0260)**

| |
|---|
| Diagnosed acute or chronic malnutrition |
| Documentation of weight, either currently or historically, supported by oral nutritional supplements (i.e., documentation that nutritional supplements are necessary to maintain weight) |
| Increased metabolic need resulting from severe trauma |
| Malabsorption difficulties (e.g., short-gut syndrome, fistula, cystic fibrosis, renal dialysis) |
| Inborn errors of metabolism (e.g., fructose intolerance, galactosemia, maple syrup urine disease [MSUD], or phenylketonuria [PKU]) |
| Ongoing cancer treatment, advanced Acquired Immune Deficiency Syndrome (AIDS) or pulmonary insufficiency |
| Oral aversion or other psychological condition making it difficult for a client to consume their recommended caloric/protein or micronutrient needs through regular, liquified, blenderized, or pureed foods in any modified texture or form |

| **Approval Criteria** | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this request for continuation of therapy previously approved by the Fee-for-service program for a patient who has not changed eligibility status for EPSDT review since last approval? | **Yes:** Go to #8 | **No:** Go to #3 |
| 3. Has an assessment been performed by a registered dietitian or treating practitioner, within the last 12 months, attesting or documenting the patient is unable to meet their recommended caloric/protein or micronutrient needs through regular, liquified, blenderized, or pureed foods in any modified texture or form? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical necessity. |
| 4. Is there provider attestation or documentation showing the prescribed oral nutritional formula and/or nutritional supplements are an integral part of *treatment* for a nutritional deficiency as identified in **Table 1**? | **Yes:** Go to # 7 | **No:** Go to #5 |
| 5. Is the patient eligible for EPSDT review? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical necessity. |

| Approval Criteria | | |
|---|---|---|
| 6. Is the request for the *prevention* of nutritional deficiency or malnutrition as identified by one of the following:<br><br>-Patient is unable to meet their recommended caloric/protein or micronutrient needs through regular, liquified, blenderized, or pureed foods in any modified texture or form<br>OR<br>-Presence of malabsorption or other diagnosed medical condition which involves dietary restriction as part of the treatment, including but not limited to food allergy, Eosinophilic disorders (EoE), Food Protein Induced Enterocolitis (FPIES)<br>OR<br>-Documented delayed growth or failure to thrive | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical necessity. |
| 7. Is the requested product an oral solid dosage form (e.g., tablet or capsule)? | **Yes:**<br>If not eligible for EPSDT review: Pass to RPh. Deny. Not covered by OHP<br><br>If eligible for EPSDT review: prescriber provides documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc) AND evidence supported off-label use: Approve for up to 12 months. | **No:** Approve for up to 12 months. |

| Approval Criteria | | |
|---|---|---|
| 8. Has there been an annual assessment by a registered dietitian or treating practitioner for continued use of nutritional supplementation? | **Yes:** Approve up to 12 months<br><br>Document assessment date<br>_____ | **No:** Request documentation of assessment. Without documentation, pass to RPh. Deny; medical appropriateness. |

*P&T Review:* *11/14*
*Implementation:* *1/1/2025; 10/13/16; 1/1/15; 6/22/07; 9/1/06; 4/1/03*

# Obeticholic Acid (Ocaliva®)

**Goal(s):**
- Encourage use of ursodiol or ursodeoxycholic acid which has demonstrated decrease disease progression and increase time to transplantation.
- Restrict use to populations for which obeticholic acid has demonstrated efficacy.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Obeticholic acid

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is this request for continuation of therapy previously approved by the FFS program (patient has already been on obeticholic acid)? | **Yes:** Go to Renewal Criteria | **No:** Go to #3 |
| 3. Is the treatment for an adult with primary biliary cholangitis either:<br>• without cirrhosis OR<br>• with compensated cirrhosis who do not have evidence of portal hypertension (e.g. ascites, gastroesophageal varices, persistent thrombocytopenia)? | **Yes**: Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Does patient have a documented intolerance or contraindication to ursodiol? | **Yes:** Document symptoms of intolerance or contraindication and go to #6. | **No:** Go to #5 |
| 5. Has patient had a 12-month trial of ursodiol with inadequate response to therapy (Alkaline phosphatase [ALP] ≥1.67-times the ULN or total bilirubin greater than the ULN)? | **Yes**: Document baseline ALP and total bilirubin level and go to # 6<br><br>ALP:____ units/L<br>Total Bilirubin __ mg/dL | **No**: Pass to RPh. Deny; medical appropriateness |
| 6. Is obeticholic acid dosed according to the guidelines outlined in Table 1? | **Yes:** Approve for 12 months | **No**: Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is there evidence of improvement of primary biliary cholangitis, defined as:<br>a. ALP <1.67-times the ULN; AND<br>b. Decrease of ALP >15% from baseline: AND<br>c. Normal total bilirubin level? | **Yes**: Document ALP and total bilirubin level go to # 2<br><br>ALP:_____ units/L<br>Total Bilirubin __ mg/dL | **No**: Pass to RPh. Deny; medical appropriateness |
| 2. Does dosing meet parameters outlined in Table 1? | **Yes**: Approve for up to 12 months | **No**: Pass to RPh. Deny; medical appropriateness |

**Table 1. Obeticholic Acid Dosing Regimen by Patient Population[1]**

| Staging/Classification | Non-Cirrhotic or Compensated Child-Pugh Class A | Patients with Intolerable Pruritus* | Decompensated cirrhosis (Child-Pugh Class B or C OR Patients with a Prior Decompensation Event (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia). |
|---|---|---|---|
| Initial dose for first 3 months | 5 mg once daily | 5 mg every other day for patients intolerant to 5 mg once daily<br><br>5 mg once daily for patients intolerant to 10 mg once daily<br><br>Temporarily interrupt administration for 2 weeks. Restart at reduced dosage. | **Obeticholic acid therapy is contraindicated in these patients.** |
| Dose titration after first 3 months for patients who have not achieved adequate reduction in ALP and/or total bilirubin and who are tolerating obeticholic acid | 10 mg once daily | | |
| Maximum dose | 10 mg once daily | 5 mg once daily | |

*Add an antihistamine or bile acid binding resin

1. OCALIVA (obeticholic acid) oral tablet Prescribing Information. New York, NY; Intercept Pharmaceuticals, Inc. May 2021.

*P&T / DUR Review:* *12/21 (DM); 01/17 (SS)*
*Implementation:* *1/1/22; 4/1/17*

# Ocular Vascular Endothelial Growth Factors

**Goal(s):**
- Promote use of preferred drugs and ensure that non-preferred drugs are used appropriately for OHP-funded conditions
- Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Non-preferred drugs

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is this an OHP-funded diagnosis? | **Yes**: Go to #3 | **No**: Go to #4 |
| 3. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>Preferred products do not require a PA. Preferred products are evidence-based and reviewed for comparative effectiveness and safety by the P&T Committee. | **Yes**: Inform prescriber of covered alternatives in class. | **No**: Approve for 12 months, or for length of the prescription, whichever is less |
| 4. RPh only: All other indications need to be evaluated as to whether they are funded or contribute to a funded diagnosis on the OHP prioritized list.<br><br>• If funded and clinic provides supporting literature: Approve for 12 months, or for length of the prescription, whichever is less.<br>• If not funded:<br>  ○ Members not eligible for EPSDT review: Deny; not funded by the OHP<br>  ○ Members eligible for EPSDT review: If clinic provides supporting literature, and documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc) then approve for 12 months, or for length of the prescription, whichever is less. | | |

*P&T / DUR Review:* *4/24 (SS); 8/20; 3/17*
*Implementation:* *TBD*

# Omaveloxolone (SKYCLARYS™)

**Goal(s):**
- Promote use that is consistent with medical evidence and product labeling in patients with Friedreich's ataxia.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Omaveloxolone oral capsules (pharmacy claims)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. Recommended Dosage of Omaveloxolone with Concomitant use of CYP3A4 Inhibitors or Inducers**

| Concomitant Drug Class | Dosage |
|---|---|
| Strong CYP3A4 Inhibitor (such as, but not limited to: ketoconazole, nefazodone, voriconazole) | Recommended to avoid concomitant use.<br><br>If co-administration cannot be avoided:<br>• Reduce omaveloxolone dose to 50 mg once daily with close monitoring to detect adverse effects<br>• If adverse effects emerge, coadministration with strong CYP3A4 inhibitor should be discontinued |
| Moderate CYP3A4 Inhibitor (such as, but not limited to: erythromycin, verapamil, diltiazem, cyclosporine) | Recommended to avoid concomitant use.<br><br>If co-administration cannot be avoided:<br>• Reduce omaveloxolone dose to 100 mg once daily with close monitoring to detect adverse effects<br>• If adverse effects emerge, further reduce omaveloxolone dose to 50 mg once daily |
| Strong or Moderate CYP3A4 Inducer (such as, but not limited to: phenytoin, carbamazepine, rifampin) | Recommended to avoid concomitant use. |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for continuation of therapy previously approved by the FFS program? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Is the medication prescribed by or in consultation with a neurologist? | **Yes**: Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 4. Is the request for a patient who has had a trinucleotide repeat expansion assay genetic test confirming the diagnosis of Friedreich's ataxia in a patient 16 years of age and older? | **Yes**: Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the patient able to swallow whole capsules or capsule contents mixed into an appropriate amount of applesauce?<br><br>Note: Capsules should be swallowed whole or mixed into 30 mL of applesauce. Capsule contents should not be mixed with milk, orange juice, or given via enteral feeding tube. Capsules may not be crushed or chewed. | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 6. Have baseline labs (alanine transaminase [ALT], aspartate aminotransferase [AST], bilirubin, b-type natriuretic peptide [BNP] and lipid parameters) been obtained prior to initiating therapy? | **Yes:** Document date and results:<br><br>Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is baseline BNP > 200 pg/mL? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #8 |
| 8. Has the provider documented the patient does not have severe hepatic impairment (Child-Pugh Class C)? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. If patient has moderate liver impairment (Child-Pugh Class B) has the dose been modified to 100 mg once daily? | **Yes:** Go to #10 | **No:** Pass to RPh. Deny; medical appropriateness |
| 10. If patient is taking other medications, are they CYP3A4 inhibitors or inducers that require omaveloxolone dosing adjustments as outlined in Table 1 and has the omaveloxolone dose been adjusted? | **Yes:** Approve for up to 6 months. | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 2. Has the patient's condition progressed slower than expected, stabilized, or improved as assessed by the prescribing provider and provider attests to patient's current status. | **Yes:** Approve for 12 months. Document baseline assessment and provider attestation received. | **No:** Pass to RPh; Deny; medical appropriateness. |

*P&T/DUR Review: 2/25 (DM); 6/23 (DM)*
*Implementation: 3/10/25; 7/1/23*

# Omega-3 Fatty Acids

**Goal(s):**

- Restrict use of non-preferred omega-3 fatty acids to patients at increased risk for pancreatitis.
- Promote use of agents that have demonstrated a substantial benefit on cardiovascular outcomes that is consistent with medical evidence

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Icosapent Ethyl (Vascepa®)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is the diagnosis an OHP funded diagnosis? | **Yes:** Go to #4 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #3. |
| 3. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #4 | **No**: Pass to RPh. Deny; medical appropriateness. |
| 4. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products do not require PA.<br>• Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics Committee. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Go to #5 |
| 5. Does the patient have clinically diagnosed hypertriglyceridemia with triglyceride levels ≥ 500 mg/dL? | **Yes:** Go to #6 | **No:** Go to #7 |

| Approval Criteria | | |
|---|---|---|
| 6. Has the patient failed or have a contraindication to an adequate trial (at least 8 weeks) of a fibric acid derivative (fenofibrate or gemfibrozil) at a maximum tolerable dose (as seen in dosing table below); **OR**<br>Is the patient taking a statin and unable to take a fibric acid derivative due to an increased risk of myopathy? | **Yes:** Approve up to 1 year. | **No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of other agent(s). |
| 7. Is the prescription for icosapent ethyl? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 8. Does the patient have established clinical atherosclerotic cardiovascular disease (ASCVD), (defined as documented history of acute coronary syndrome, ischemic stroke, peripheral artery disease, coronary artery disease) or type 2 diabetes mellitus and ≥ 2 CV risk factors? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 9. Does the patient have triglycerides greater than or equal to 150 mg/dl while on maximally tolerated statin treatment? | **Yes:** Approve up to 1 year. | **No:** Pass to RPh. Deny; medical appropriateness. |

**Table 1: Dosing of Fenofibrate and Derivatives for Hypertriglyceridemia.**

| Trade Name (generic) | Recommended dose | Maximum dose |
|---|---|---|
| Antara (fenofibrate capsules) | 43-130 mg once daily | 130 mg once daily |
| Fenoglide (fenofibrate tablet) | 40-120 once daily | 120 mg once daily |
| Fibricor (fenofibrate tablet) | 25-105 mg once daily | 105 mg once daily |
| Lipofen (fenofibrate capsule) | 50-150 mg once daily | 150 mg once daily |
| Lofibra (fenofibrate capsule) | 67-200 mg once daily | 200 mg once daily |
| Lofibra (fenofibrate tablet) | 54-160 mg once daily | 160 mg once daily |
| Lopid (gemfibrozil tablet) | 600 mg twice daily | 600 mg twice daily |
| Tricor (fenofibrate tablet) | 48-145 mg once daily | 145 mg once daily |
| Triglide (fenofibrate tablet) | 50-160 mg once daily | 160 mg once daily |
| Trilipix (fenofibrate DR capsule) | 45-135 mg once daily | 135 mg once daily |

*P&T/DUR Review:* *8/21 (MH); 8/20; 5/19; 11/16; 3/14*
*Implementation:* *1/1/17; 5/1/14*

# Oncology Agents

**Goal(s):**

- To ensure appropriate use for oncology medications based on FDA-approved and compendia-recommended (i.e., National Comprehensive Cancer Network® [NCCN]) indications.

**Length of Authorization:**

- Up to 1 year

**Requires PA:**

- Initiation of therapy for drugs listed in **Table 1** (applies to both pharmacy and provider administered claims). This does not apply to oncologic emergencies administered in an emergency department or during inpatient admission to a hospital.

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1: National Comprehensive Cancer Network (NCCN) Categories for Recommendations**

| | |
|---|---|
| Category 1 | Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate |
| Category 2A | Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate |
| Category 2B | Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate |
| Category 3 | Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate |
| For the 'Uniformed NCCN consensus' defined in Category 1 and 2A, a majority Panel vote of at least 85% is required. For the 'NCCN consensus' defined in Category 2B, a Panel vote of at least 50% (but less than 85%) is required. Strong Panel disagreement regardless of the quality of evidence is a vote of at least 25%. | |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for treatment of an oncologic emergency (e.g., superior vena cava syndrome [ICD-10 I87.1] or spinal cord compression [ICD-10 G95.20]) administered in the emergency department? | **Yes:** Approve for length of therapy (if specified) or 12 months, (if duration is unspecified). | **No:** Go to #3 |
| 3. Is the request for any continuation of therapy? | **Yes:** Approve for length of therapy (if specified) or 12 months (if duration is unspecified). | **No**: Go to #4 |
| 4. Is the diagnosis funded by OHP? | **Yes:** Go to #6 | **No: If not eligible for EPSDT review:** Pass to RPh. Deny; not funded by the OHP |

| | | |
|---|---|---|
| | | **If eligible for EPSDT review:** Go to #5. |
| 5. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical necessity. |
| 6. Is the indication FDA-approved for the requested drug?<br><br>Note: This includes all information required in the FDA-approved indication, including but not limited to the following as applicable: diagnosis, stage of cancer, biomarkers, place in therapy, and use as monotherapy or combination therapy. | **Yes**: Go to #8 | **No:** Go to #7 |
| 7. Is the indication recommended by National Comprehensive Cancer Network (NCCN) Guidelines® for the requested drug?<br><br>Note: This includes all information required in the NCCN recommendation, including but not limited to the following as applicable: diagnosis, stage of cancer, biomarkers, place in therapy, and use as monotherapy or combination therapy. | **Yes:** Go to #8 | **No:** Go to #9 |
| 8. Are there equally or higher recommended alternative agents based on NCCN categories of evidence (Table 1) for the requested indication and place in therapy? | **Yes:** Pass to RPh. Approve for length of therapy (if specified) or 12 months (if duration is unspecified)<br><br>Note: When efficacy is similar, the choice of agent should be determined by safety, and then cost. In the absence of a safety concern, the prescriber is expected to use the least costly alternative. | **No:** Pass to RPh. Approve for length of therapy (if specified) or 12 months (if duration is unspecified). |
| 9. Is there documentation based on chart notes that the patient is enrolled in a | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #10 |

| | | |
|---|---|---|
| clinical trial to evaluate efficacy or safety of the requested drug? | Note: The Oregon Health Authority is statutorily unable to cover experimental or investigational therapies. | |
| 10. Is the request for a rare cancer which is not addressed by National Comprehensive Cancer Network (NCCN) Guidelines® and which has no FDA approved treatment options? | **Yes:** Go to #11 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 11. All other diagnoses must be evaluated for evidence of clinical benefit.<br><br>The prescriber must provide the following documentation:<br>• medical literature or guidelines supporting use for the condition,<br>• clinical chart notes documenting medical necessity, and<br>• documented discussion with the patient about treatment goals, treatment prognosis and the side effects, and knowledge of the realistic expectations of treatment efficacy.<br><br>RPh may use clinical judgement to approve drug for length of treatment or deny request based on documentation provided by prescriber. If new evidence is provided by the prescriber, please forward request to Oregon DMAP for consideration and potential modification of current PA criteria. | | |

**Table 1. Oncology agents which apply to this policy (Updated 7/8/2025)**
New Antineoplastics are immediately subject to the policy and will be added to this table at the next P&T Meeting

| Generic Name | Brand Name |
|---|---|
| abemaciclib | VERZENIO |
| abiraterone acet,submicronized | YONSA |
| abiraterone acetate | ZYTIGA |
| abiraterone acetate/niraparib tosylate | AKEEGA |
| acalabrutinib | CALQUENCE |
| adagrasib | KRAZATI |
| ado-trastuzumab emtansine | KADCYLA |
| afatinib dimaleate | GILOTRIF |
| afamitresgene autoleucel | TECELRA |
| alectinib HCl | ALECENSA |
| amivantamab-vmjw | RYBREVANT |
| alpelisib | PIQRAY |
| asciminib | SCEMBLIX |
| apalutamide | ERLEADA |
| asparaginase (Erwinia chrysanthemi) | ERWINAZE |
| asparaginase Erwinia crysanthemi (recombinant)-rywn | RYLAZE |
| atezolizumab | TECENTRIQ |
| avapritinib | AYVAKIT |
| avelumab | BAVENCIO |
| avutometinib and defactinib | AVMAPKI FAKZYNJA CO-PACK |
| axicabtagene ciloleucel | YESCARTA |
| axitinib | INLYTA |
| azacitidine | ONUREG |
| belantamab mafodotin-blmf | BLENREP |
| belinostat | BELEODAQ |
| belzutifan | WELIREG |
| bendamustine HCl | BENDAMUSTINE HCL |
| bendamustine HCl | TREANDA |
| bendamustine HCl | BENDEKA |
| binimetinib | MEKTOVI |
| blinatumomab | BLINCYTO |
| bosutinib | BOSULIF |
| brentuximab vedotin | ADCETRIS |
| brexucabtagene autoleucel | TECARTUS |
| brigatinib | ALUNBRIG |
| cabazitaxel | JEVTANA |
| cabozantinib s-malate | CABOMETYX |
| cabozantinib s-malate | COMETRIQ |
| calaspargase pegol-mknl | ASPARLAS |
| capivasertib | TRUQAP |
| capmatinib | TABRECTA |
| carfilzomib | KYPROLIS |

| Generic Name | Brand Name |
|---|---|
| cemiplimab-rwlc | LIBTAYO |
| ceritinib | ZYKADIA |
| ciltacabtagene autoleucel | CARVYKTI |
| cobimetinib fumarate | COTELLIC |
| copanlisib di-HCl | ALIQOPA |
| cosibelimab-ipdl | UNLOXCYT |
| crizotinib | XALKORI |
| dabrafenib mesylate | TAFINLAR |
| dacomitinib | VIZIMPRO |
| daratumumab | DARZALEX |
| daratumumab/hyaluronidase-fihj | DARZALEX FASPRO |
| darolutamide | NUBEQA |
| datopotamab deruxtecan-dlnk | DATROWAY |
| decitabine and cedazuridine | INQOVI |
| degarelix acetate | FIRMAGON |
| denileukin diftitox-cxdl | LYMPHIR |
| dostarlimab-gxly | JEMPERLI |
| dinutuximab | UNITUXIN |
| durvalumab | IMFINZI |
| duvelisib | COPIKTRA |
| eflornithine | IWILFIN |
| elacestrant | ORSERDU |
| elotuzumab | EMPLICITI |
| elranatamab-bcmm | ELREXFIO |
| enasidenib mesylate | IDHIFA |
| encorafenib | BRAFTOVI |
| enfortumab vedotin-ejfv | PADCEV |
| ensartinib | ENSACOVE |
| entrectinib | ROZLYTREK |
| enzalutamide | XTANDI |
| epcoritamab-bysp | EPKINLY |
| erdafitinib | BALVERSA |
| eribulin mesylate | HALAVEN |
| everolimus | AFINITOR |
| everolimus | AFINITOR DISPERZ |
| fam-trastuzumab deruxtecan-nxki | ENHERTU |
| fedratinib | INREBIC |
| fruquintinib | FRUZAQLA |
| futibatinib | LYTGOBI |
| gilteritinib | XOSPATA |
| glasdegib | DAURISMO |
| glofitamab-gxbm | COLUMVI |
| ibrutinib | IMBRUVICA |

| Generic Name | Brand Name |
|---|---|
| idecabtagene vicleucel | ABECMA |
| idelalisib | ZYDELIG |
| imetelstat | RYTELO |
| infigratinib | TRUSELTIQ |
| ingenol mebutate | PICATO |
| inotuzumab ozogamicin | BESPONSA |
| ipilimumab | YERVOY |
| isatuximab | SARCLISA |
| ivosidenib | TIBSOVO |
| ixazomib citrate | NINLARO |
| larotrectinib | VITRAKVI |
| lazertinib | LAZCLUZE |
| lenvatinib mesylate | LENVIMA |
| lifileucel | AMTAGVI |
| linvoseltamab-gcpt | LYNOZYFIC |
| lisocabtagene maraleucel | BREYANZI |
| loncastuximab tesirine-lpyl | ZYNLONTA |
| lorlatinib | LORBRENA |
| lurbinectedin | ZEPZELCA |
| lutetium Lu 177 dotate | LUTATHERA |
| lutetium Lu 177 vipivotide tetraxetan | PLUVICTO |
| margetuximab-cmkb | MARGENZA |
| melphalan flufenamide | PEPAXTO |
| melphalan hcl/hepatic delivery kit (HDS) | HEPZATO KIT |
| midostaurin | RYDAPT |
| mirvetuximab soravtansine-gynx | ELAHERE |
| mobecertinib | EXKIVITY |
| momelotinib | OJJAARA |
| mosunetuzumab-axgb | LUNSUMIO |
| motixafortide | APHEXDA |
| moxetumomab pasudotox-tdfk | LUMOXITI |
| nadofaragene firadenovec-vncg | ADSTILADRIN |
| naxitamab-gqgk | DANYELZA |
| necitumumab | PORTRAZZA |
| neratinib maleate | NERLYNX |
| niraparib and abiraterone acetate | AKEEGA |
| niraparib tosylate | ZEJULA |
| nirogacestat hydrobromide | OGSIVEO |
| nivolumab | OPDIVO |
| nivolumab and hyaluronidase-nvhy | OPDIVO QVANTIG |
| nivolumab; relatlimab-rmbw | OPDUALAG |
| nogapendekin alfa inbakicept-pmln | ANKTIVA |
| obecabtagene autoleucel | AUCATZYL |

| Generic Name | Brand Name |
|---|---|
| obinutuzumab | GAZYVA |
| ofatumumab | ARZERRA |
| olaparib | LYNPARZA |
| olaratumab | LARTRUVO |
| olatuzumab vedotin-piiq | POLIVY |
| omacetaxine mepesuccinate | SYNRIBO |
| omidubicel-onlv | OMISIRGE |
| osimertinib mesylate | TAGRISSO |
| olutasidenib | REZLIDHIA |
| pacritinib | VONJO |
| palbociclib | IBRANCE |
| panobinostat lactate | FARYDAK |
| pazopanib HCl | VOTRIENT |
| pembrolizumab | KEYTRUDA |
| pemigatinib | PEMAZYRE |
| penpulimab-kcqx | none |
| pertuzumab | PERJETA |
| pertuzumab/trastuzumab/haluronidase-zzxf | PHESGO |
| pexidartinib | TURALIO |
| pirtobrutinib | JAYPIRCA |
| polatuzumab vedotin-piiq | POLIVY |
| pomalidomide | POMALYST |
| ponatinib | ICLUSIG |
| pralatrexate | FOLOTYN |
| pralsetinib | GAVRETO |
| quizartinib | VANFLYTA |
| ramucirumab | CYRAMZA |
| regorafenib | STIVARGA |
| relugolix | ORGOVYX |
| repotrectinib | AUGTYRO |
| retifanlimab-dlwr | ZYNYZ |
| revumenib | REVUFORJ |
| ribociclib succinate | KISQALI |
| ribociclib succinate/letrozole | KISQALI FEMARA CO-PACK |
| ripretinib | QINLOCK |
| romidepsin | ISTODAX |
| romidepsin | ROMIDEPSIN |
| ropeginterferon alfa-2b-njft | BESREMI |
| rucaparib camsylate | RUBRACA |
| ruxolitinib phosphate | JAKAFI |
| sacitizumab govitecan-hziy | TRODELVY |
| selinexor | XPOVIO |
| selpercatinib | RETEVMO |

| Generic Name | Brand Name |
|---|---|
| siltuximab | SYLVANT |
| sipuleucel-T/lactated ringers | PROVENGE |
| sirolimus albumin-bound nanoparticles | FYARRO |
| sonidegib phosphate | ODOMZO |
| sotorasib | LUMAKRAS |
| sunvozertinib | ZEGFROVY |
| tafasitamab-cxix | MONJUVI |
| tagraxofusp-erzs | ELZONRIS |
| talazoparib | TALZENNA |
| taletrectinib | IBTROZI |
| talimogene laherparepvec | IMLYGIC |
| talquetamab-tgvs | TALVEY |
| tarlatamab-dlle | IMDELLTRA |
| tazemetostat | TAZVERIK |
| tebentafusp-tebn | KIMMTRAK |
| teclistamab-cqyv | TECVAYLI |
| telisotuzumab vedotin-tllv | EMRELIS |
| tepotinib | TEPMETKO |
| tisagenlecleucel | KYMRIAH |
| tislelizumab-jsgr | TEVIMBRA |
| tisotumab vedotin-tftv | TIVDAK |
| tivozanib | FOTIVDA |
| toripalimab-tpzi | LOQTORZI |
| tovorafenib | OJEMDA |
| trabectedin | YONDELIS |
| trametinib dimethyl sulfoxide | MEKINIST |
| trastuzumab-anns | KANJINTI |
| trastuzumab-dkst | OGIVRI |
| trastuzumab-dttb | ONTRUZANT |
| trastuzumab-hyaluronidase-oysk | HERCEPTIN HYLECTA |
| trastuzumab-pkrb | HERZUMA |
| trastuzumab-qyyp | TRAZIMERA |
| trastuzumab-strf | HERCESSI |
| tremlimumab | IMJUDO |
| treosulfan | GRAFAPEX |
| trifluridine/tipiracil HCl | LONSURF |
| trilaciclib | COSELA |
| tucatinib | TUKYSA |
| umbralisib | UKONIQ |
| vandetanib | VANDETANIB |
| vandetanib | CAPRELSA |
| vemurafenib | ZELBORAF |
| venetoclax | VENCLEXTA |
| venetoclax | VENCLEXTA STARTING PACK |
| vimseltinib | ROMVIMZA |
| vismodegib | ERIVEDGE |
| vorasidenib | VORANIGO |
| zanidatamab-hrii | ZIIHERA |
| zanubrutinib | BRUKINSA |
| zenocutuzumab-Zbco | BIZENGRI |
| ziv-aflibercept | ZALTRAP |

*P&T/DUR Review: 6/2020 (JP)*
*Implementation: 10/1/20*

# Ophthalmic Complement Inhibitors

**Goal(s):**

- To ensure appropriate use of complement inhibitors in patients with geographic atrophy (GA) due to age-related macular degeneration (AMD).

**Length of Authorization:**

- Initial 12 months
- Maximum total cumulative lifetime treatment per affected eye:
    - pegcetacoplan: 24 months
    - avacincaptad pegol: 12 months

**Requires PA:**

- Pegcetacoplan (SYFOVRE); Avacincaptad Pegol (IZERVAY); (applies to both provider administered and pharmacy claims)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Dosage and Administration per FDA Labeling.**

| | **Pegcetacoplan (SYFOVRE)** | **Avacincaptad pegol (IZERVAY)** |
|---|---|---|
| **Dose (per single affected eye)** | 15 mg (0.1 mL of 150 mg/mL solution) | 2 mg (0.1 mL of 20 mg/mL solution) |
| **Route of Administration** | Intravitreal Injection | Intravitreal Injection |
| **Frequency** | Once every 25 to 60 days | Once monthly (approximately 28 ± 7 days) |
| **Maximum Lifetime Limit** | Unknown | 12 months |

| **Approval Criteria** | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the patient an adult with a diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) supported by clinical documentation of appropriate testing (e.g. fundus autofluorescence (FAF), optical coherence tomography (OCT))? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Does the patient have any of the following:<br>• active intraocular inflammation?<br>• active ocular or periocular infections?<br>• history of intraocular surgery or laser therapy in the macular region? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #4 |

| Approval Criteria | | |
|---|---|---|
| 4. Is the request for continuation of therapy for a patient who has received ≥ 6 months of initial therapy with the requested agent? | **Yes:** Go to **Renewal Criteria**. | **No:** Go to #5 |
| 5. Is the agent being prescribed and administered by or under the supervision of an ophthalmologist? | **Yes**: Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Does the patient have a best corrected visual acuity (BCVA) in the affected eye of 24 letters or better using Early Treatment Diabetic Retinopathy Study (ETDRS) charts (approximately 20/320 Snellen equivalent)? | **Yes**: Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is there evidence that the patient is currently receiving therapy with a different ophthalmic complement inhibitor or medication for GA treatment? | **Yes:** Go to #8 | **No:** Go to #9 |
| 8. Is this a switch in GA therapy due to intolerance, allergy or ineffectiveness and has therapy with the previous agent been discontinued? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Does the patient have active choroidal neovascularization or wet age-related macular degeneration? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #10 |
| 10. Is the dose, route, and frequency consistent with the FDA-labeling for the requested agent? | **Yes**: Approve for 12 months. | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is this a request for avacincaptad pegol? | **Yes**: Go to #2 | **No:** Go to #3 |
| 2. Has the patient already received 12 months of cumulative therapy in the affected eye(s)? | **Yes**: Pass to RPh. Deny; medical appropriateness | **No:** Go to #3 |

| Renewal Criteria | | |
|---|---|---|
| 3. Does the patient exhibit any evidence of the following:<br>• Unacceptable toxicity or adverse events (e.g. endophthalmitis, retinal detachment, or conversion to wet AMD)?<br>• Significant decline in visual acuity (loss of 10 or more letters on EDTRS chart)? | **Yes**: Pass to RPh. Deny; medical appropriateness | **No:** Go to #4 |
| 4. Has the prescriber documented a positive patient response to therapy such as disease stabilization or slowing in the growth rate of geographic atrophy lesions compared to pre-treatment baseline? | **Yes**: Approve for up to 6 months. | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 4/24 (DE)*
*Implementation: 5/1/24*

# Opioid Analgesics, Long-acting

**Goals:**

- Promote the well-being of OHP members and reduce risk for opioid misuse.
- Provide appropriate opioid coverage for OHP-funded conditions when there is documented sustained improvement in pain and function and routine monitoring for opioid misuse. Restrict use of long-acting opioid analgesics for conditions of the back and/or spine due to evidence of increased risk of misuse or increasing dose vs. benefit.
- Support appropriate risk mitigation strategies for patients on long-term opioid therapy.
- Promote the safe use of long-acting opioid analgesics by restricting use of high doses that have not demonstrated improved benefit and are associated with greater risk for accidental opioid overdose and death.

**Length of Authorization:**

- Initial: 90 days (except 12 months for end-of-life, sickle-cell disease, severe burn, or cancer-related pain)
- Renewal: Up to 12 months

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Requires a PA:**

- All long-acting opioids and opioid combination products.

Note:

- Patients on palliative care with a terminal diagnosis or with cancer-related pain, or pain associated with sickle cell disease or severe burn injury are exempt from this PA.

**Table 1**. Daily Dose Threshold (90 Morphine Milligram Equivalents per Day) of Opioid Products.

| Opioid | 90 MME/day | Notes |
|---|---|---|
| Fentanyl (transdermal patch) | 37.5 mcg/hr | Use only in opioid-tolerant patients who have been taking ≥60 MME daily for a ≥1 week. Deaths due to a fatal overdose of fentanyl have occurred when pets, children and adults were accidentally exposed to fentanyl transdermal patch. Strict adherence to the recommended handling and disposal instructions is of the utmost importance to prevent accidental exposure.) |
| Hydrocodone | 90 mg | |
| Hydromorphone | 22.5 mg | |
| Morphine | 90 mg | |
| Oxycodone | 60 mg | |
| Oxymorphone | 30 mg | |
| Tapentadol | 225 mg | |
| Tramadol | 300 mg | 300 mg/day is max dose and is not equivalent to 90 MME/day. Tramadol is not recommended for pediatric use as it is subject to different rates of metabolism placing certain populations at risk for overdose. |
| Methadone* | 20 mg<br><br>***DO NOT USE unless very familiar with the complex pharmacokinetic and pharmacodynamics properties of methadone**. Methadone exhibits a non-linear relationship due to its long half-life and accumulates with chronic dosing. Methadone also has complex | |

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| | interactions with several other drugs. The dose should not be increased more frequently than once every 7 days. Methadone is associated with an increased incidence of prolonged QTc interval, torsades de pointe and sudden cardiac death. |

**Table 2**. Specific Long-acting Opioid Products Subject to Frequency Limits per FDA-approved Labeling.

| Drug Product | Quantity Limit |
|---|---|
| BELBUCA | 2 doses/day |
| BUTRANS | 1 patch/7 days |
| EMBEDA | 2 doses/day |
| EXALGO | 1 dose/day |
| Fentanyl patch | 1 dose/72 hr |

| Drug Product | Quantity Limit |
|---|---|
| HYSINGLA ER | 1 doses/day |
| KADIAN | 2 doses/day |
| MORPHABOND | 2 doses/day |
| MS CONTIN | 3 doses/day |
| NUCYNTA ER | 2 doses/day |
| OPANA ER | 2 doses/day |

| Drug Product | Quantity Limit |
|---|---|
| OXYCONTIN | 2 doses/day |
| TROXYCA ER | 2 doses/day |
| XARTEMIS XR | 4 doses/day |
| XTAMPZA ER | 2 doses/day |
| ZOHYDRO ER | 2 doses/day |

| **Approval Criteria** | | |
|---|---|---|
| 1. What is the patient's diagnosis? | Record ICD10 code | |
| 2. Is the patient already established on any opioid treatment for >6 weeks (long-term, chronic treatment)? | **Yes**: Go to **Renewal Criteria** | **No**: Go to #3 |
| 3. Has the patient failed to have adequate benefit with daily use of short-acting opioids?<br><br>Note: long-acting opioids are not recommended as initial opioid therapy due to increased risk of death, overdose, and abuse. If trial of an opioid is necessary, short-acting opioids are recommended for initial treatment. | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 4. Is the diagnosis funded by the OHP?<br><br>Note: Management of pain associated with *back or spine conditions with long-acting opioids* is not funded by the OHP*. Other conditions, such as fibromyalgia, TMJ, neuropathy, tension headache and pelvic pain syndrome are also not funded by the OHP. | **Yes:** Go to #5 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #5<br><br>Note: Management of opioid dependence is funded by the OHP. |

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| 5. Is there documentation that the patient has inadequate response or contraindication to all applicable pharmacologic and non-pharmacologic treatments for the requested condition?<br><br>Relevant treatments may include: Pharmacologic: topical pain medications, NSAIDs, acetaminophen, or muscle relaxants. Non-pharmacologic: cognitive behavioral therapy, physical or occupational therapy, acupuncture, supervised exercise therapy, interdisciplinary rehabilitation, yoga/pilates, and chiropractic/osteopathic manipulation. | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 6. Is the requested medication a preferred agent? | **Yes:** Go to #8 | **No:** Go to #7 |
| 7. Will the prescriber change to a preferred product?<br><br>Note: Preferred opioids are reviewed and designated as preferred agents by the Oregon Pharmacy & Therapeutics Committee based on published medical evidence for safety and efficacy. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Go to #8 |
| 8. Is the patient being treated for pain associated with sickle cell disease, severe burn injury, cancer-related pain or under palliative care services with a life-threatening illness or severe advanced illness expected to progress toward dying? | **Yes:** Approve for up to 12 months | **No:** Go to #9 |
| 9. Is the prescription for pain associated with migraine or other type of headache?<br><br>Note: there is limited or insufficient evidence for opioid use for many pain conditions, including migraine or other types of headache. | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #10 |
| 10. Does the total daily opioid dose exceed 90 MME (see Table 1)? | **Yes:** Pass to RPh. Deny; medical appropriateness.<br><br>Note: Management of opioid dependence is funded by the OHP. | **No:** Go to #11 |

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|---|---|---|
| 11. Is the prescriber enrolled in the Oregon Prescription Drug Monitoring Program (www.orpdmp.com) and has the prescriber verified at least once in the past month that opioid prescribing is appropriate? | **Yes:** Go to #12 | **No:** Pass to RPh. Deny; medical appropriateness |
| 12. Is the patient concurrently on other short- or long-acting opioids (patients may receive a maximum of one opioid product regardless of formulation)?<br><br>Note: There is insufficient evidence for use of concurrent opioid products (e.g., long-acting opioid with short-acting opioid). | **Yes:** Pass to RPh. Deny; medical appropriateness<br><br>Note: Management of opioid dependence is funded by the OHP. | **No:** Go to #13 |
| 13. Is the patient currently taking a benzodiazepine or other central nervous system (CNS) depressant?<br><br>Note: All opioids have a black box warning about the risks of profound sedation, respiratory depression, coma or death associated with concomitant use of opioids with benzodiazepines or other CNS depressants. | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #14 |
| 14. Does the prescription exceed quantity limits applied in Table 2 (if applicable)? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #15 |
| 15. Can the prescriber provide documentation of sustained improvement of at least 30% in pain, function, or quality of life in the past 3 months compared to baseline (e.g., prior to opioid prescribing)?<br><br>Note: Pain control, quality of life, and function can be quickly assessed using the 3-item PEG scale. ** | **Yes:** Go to #16<br><br>Document tool used and score vs. baseline: _____ | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Note: Management of opioid dependence is funded by the OHP. |
| 16. Has the patient had a urinary drug screen (UDS) within the past 3 months to verify absence of illicit drugs and non-prescribed opioids? | **Yes:** Approve for up to 90 days. | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Note: Management of opioid dependence is funded by the OHP. |

| Renewal Criteria | | |
|---|---|---|
| 1. What is the patient's diagnosis? | Record ICD10 code | |
| 2. Is the request for a patient already established on opioid treatment for >6 weeks (long-term treatment)? | **Yes**: Go to #3 | **No**: Go to **Approval Criteria** |
| 3. Does the request document a taper plan for the patient? | **Yes:** Document taper plan and approve for duration of taper or 3 months whichever is less. | **No:** Go to #4 |
| 4. Is the diagnosis funded by the OHP?<br><br>Note: Management of pain associated with *back or spine conditions with long-acting opioids* is not funded by the OHP*. Other conditions, such as fibromyalgia, TMJ, neuropathy, tension headache and pelvic pain syndrome are also not funded by the OHP. | **Yes:** Go to #5 | **No:** Go to #6 |
| 5. Does the patient have risk factors for overdose?<br><br>Risk factors may include, but are not limited to:<br>a. Concomitant CNS depressants (i.e., benzodiazepines, muscle relaxants, sedating antipsychotics, etc.)<br>b. Total daily opioid dose > 90 MME or exceeding quantity limits in Table 2<br>c. Recent urine drug screen indicating illicit or non-prescribed opioids<br>d. Concurrent short- and long-acting opioid use<br>e. Diagnosis of opioid use disorder<br>f. History of opioid overdose<br>g. Household members, including children, or other close contacts at risk for accidental ingestion or opioid overdose without documentation of secure storage mechanisms (e.g., lockbox, etc) | **Yes:** Go to #6 | **No:** Go to #7 |

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| 6. Is there documentation indicating it is **unsafe** to initiate a taper at this time? | **Yes:** Go to #7<br><br>Document provider attestation and rationale | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>May approve one time for a maximum of 1 month to allow time to document a taper plan or rationale for why a taper is unsafe at this time. |
| 7. Is the prescriber enrolled in the Oregon Prescription Drug Monitoring Program (www.orpdmp.com) and has the prescriber verified at least once in the past 1 month that opioid prescribing is appropriate? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny. Medical appropriateness |
| 8. Has the patient had a urinary drug screen (UDS) in the past 1 year and verified absence of illicit drugs and non-prescribed opioids? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny. Medical appropriateness |
| 9. Can the prescriber provide documentation of sustained improvement of at least 30% in pain, function, or quality of life in the past 3 months compared to baseline (e.g., prior to opioid use)?<br><br>Note: Pain control, quality of life, and function can be quickly assessed using the 3-item PEG scale. ** | **Yes:** Go to #11<br><br>Document tool used and score vs. baseline: _____ | **No:** Go to #10 |
| 10. Has the patient been referred for alternative non-pharmacologic modalities of pain treatment (e.g., physical therapy, supervised exercise, spinal manipulation, yoga, or acupuncture)? | **Yes:** Go to #11 | **No:** Pass to RPh. Deny. Medical appropriateness. |
| 11. Is the request for an increased cumulative dose compared to previously approved therapy or average dose in the past 6 weeks? | **Yes:** Go to #12 | **No:** Go to #15 |
| 12. Does the prescription exceed quantity limits applied in Table 2 (if applicable)? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #13 |
| 13. Does the total cumulative daily opioid dose exceed 90 MME (see Table 1)? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #14 |

| | | |
|---|---|---|
| 14. Is there documented rationale (e.g., new acute injury) to support the increase in dose? | **Yes:** Go to #15 | **No:** Pass to RPh; deny; medical appropriateness |
| 15. Has the member been prescribed or have access to naloxone? | **Yes:** Go to #16 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 16. Does the patient have a pain agreement on file with the prescriber? | **Yes:** Go to #17 | **No:** Pass to RPh. Deny; medical appropriateness |
| 17. Has the provider evaluated goals of treatment within the past 3 months?<br><br>Risk factors may include, but are not limited to:<br>h. Concomitant CNS depressants (i.e., benzodiazepines, muscle relaxants, sedating antipsychotics, etc.)<br>i. Total daily opioid dose > 90 MME or exceeding quantity limits in Table 2<br>j. Recent urine drug screen indicating illicit or non-prescribed opioids<br>k. Concurrent short- and long-acting opioid use<br>l. Diagnosis of opioid use disorder<br>m. History of opioid overdose<br>n. Household members, including children, or other close contacts at risk for accidental ingestion or opioid overdose without documentation of secure storage mechanisms (e.g., lockbox, etc) | **Yes:** Approval duration is based on the number of identified risk factors for overdose or length of treatment (whichever is less):<br><br>Risk factors:<br>>=1: 3 months<br>0: 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

*See Guideline Note 60 within the Prioritized List of Health Services for conditions of coverage for pain associated with back or spine conditions: http://www.oregon.gov/OHA/HPA/CSI-HERC/Pages/Prioritized-List.aspx
**The PEG is freely available to the public http://www.agencymeddirectors.wa.gov/Files/AssessmentTools/1-PEG%203%20item%20pain%20scale.pdf.
Citation of the original publication:
Krebs EE, Lorenz KA, Bair MJ, Damush TA, Wu J, Sutherland JM, Asch SM, Kroenke K. Development and initial validation of the PEG, a 3-item scale assessing pain intensity and interference. *Journal of General Internal Medicine*. 2009 Jun; 24:733-738.

## Clinical Notes:

How to Discontinue Opioids.

Adapted from the following guidelines on opioid prescribing:

- The Washington State Interagency Guideline on Prescribing Opioids for Pain; Agency Medical Directors' Group, June 2015. Available at http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf.

Selecting the optimal timing and approach to tapering depends on multiple factors. The decision to taper should be based on shared decision making between the patient and provider based on risks and benefits of therapy. Involving the patient in the decision to taper helps establish trust with the patient, ensures patient-focused tapering, incorporates the patient's values into the taper plan, provides education on the risks of opioid use, and establishes realistic goals and expectations. Avoid insisting on opioid tapering or discontinuation when opioid use may be warranted. The rate of opioid taper should be based primarily on safety considerations, and special attention is needed for patients on high dose opioids or with significant long-term use, as too rapid a taper may precipitate withdrawal symptoms or drug-seeking behavior. In addition, behavioral issues or physical withdrawal symptoms can be a major obstacle during an opioid taper. Patients who feel overwhelmed or desperate may try to convince the provider to abandon the taper. Although there are no methods for preventing behavioral issues during taper, strategies implemented at the beginning of chronic opioid therapy such as setting clear expectations, allowing for pauses during the taper, and development of an exit strategy are most likely to prevent later behavioral problems if a taper becomes necessary.

1. Consider sequential tapers for patients who are on chronic benzodiazepines and opioids. Coordinate care with other prescribers (e.g. psychiatrist) as necessary. In general, taper off opioids first, then the benzodiazepines.
2. Do not use ultra-rapid detoxification or antagonist-induced withdrawal under heavy sedation or anesthesia (e.g. naloxone or naltrexone with propofol, methohexital, ketamine or midazolam).
3. Establish an individualized rate of taper based on safety considerations and patient history. Common tapers have a dose reduction of 5% to 20% per month:
    a. Assess for substance use disorder and transition to appropriate medication assisted treatment if there is diversion or non-medical use,
    b. Rapid taper (over a 2 to 3 week period) if the patient has had a severe adverse outcome such as overdose or substance use disorder, or
    c. Slow taper for patients with no acute safety concerns. May consider starting with a taper of ≤10% of the original dose per month and assess the patient's functional and pain status at each visit.
4. Adjust the rate, intensity, and duration of the taper according to the patient's response (e.g. emergence of opioid withdrawal symptoms (see Table below)).
5. Watch for signs of unmasked mental health disorders (e.g. depression, PTSD, panic disorder) during taper, especially in patients on prolonged or high dose opioids. Consult with specialists to facilitate a safe and effective taper. Use validated tools to assess conditions.
6. Consider the following factors when making a decision to continue, pause or discontinue the taper plan:
    a. Assess the patient behaviors that may be suggestive of a substance use disorder
    b. Address increased pain with use of non-opioid pharmacological and non-pharmacological options.
    c. Evaluate patient for mental health disorders.
    d. If the dose was tapered due to safety risk, once the dose has been lowered to an acceptable level of risk with no addiction behavior(s) present, consider maintaining at the established lower dose if there is a clinically meaningful improvement in function, reduced pain and no serious adverse outcomes.
7. Do not reverse the taper; it must be unidirectional. The rate may be slowed or paused while monitoring for and managing withdrawal symptoms.
8. Increase the taper rate when opioid doses reach a low level (e.g. <15 mg/day MED), since formulations of opioids may not be available to allow smaller decreases.
9. Use non-benzodiazepine adjunctive agents to treat opioid abstinence syndrome (withdrawal) if needed. Unlike benzodiazepine withdrawal, opioid withdrawal symptoms are rarely medically serious, although they may be extremely unpleasant. Symptoms of mild opioid withdrawal may persist for 6 months after opioids have been discontinued (see Table below).
10. Refer to a crisis intervention system if a patient expresses serious suicidal ideation with plan or intent, or transfer to an emergency room where the patient can be closely monitored.
11. Do not start or resume opioids or benzodiazepines once they have been discontinued, as they may trigger drug cravings and a return to use. Counsel the patient on the increased risk of overdose with abrupt return to a previously prescribed higher dose. Provide opioid overdose education and consider offering naloxone.
12. Consider inpatient withdrawal management if the taper is poorly tolerated.

| Symptoms and Treatment of Opioid Withdrawal.<br>Adapted from the Washington State Interagency Guideline on Prescribing Opioids for Pain; Agency Medical Directors' Group, June 2015. Available at http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf) | |
|---|---|
| Restlessness, sweating or tremors | Clonidine 0.1-0.2 mg orally every 6 hours or transdermal patch 0.1-0.2 mg weekly (If using the patch, oral medication may be needed for the first 72 hours) during taper. Monitor for significant hypotension and anticholinergic side effects. |
| Nausea | Anti-emetics such as ondansetron or prochlorperazine |
| Vomiting | Loperamide or anti-spasmodics such as dicyclomine |
| Muscle pain, neuropathic pain or myoclonus | NSAIDs, gabapentin or muscle relaxants such as cyclobenzaprine, tizanidine or methocarbamol |
| Insomnia | Sedating antidepressants (e.g. nortriptyline 25 mg at bedtime or mirtazapine 15 mg at bedtime or trazodone 50 mg at bedtime). Do not use benzodiazepines or sedative-hypnotics. |

*P&T Review:* *2/23 (SS); 4/21(AG); 2/20 (SS), 9/19 (DM), 3/17; 11/16; 05/16*
*Implementation:* *4/1/23; 5/1/21; 3/1/20; 10/1/19*

# Opioid Analgesics, Short-acting

**Goals:**

- Restrict use of short-acting opioid analgesics for acute conditions funded by the OHP.
- Promote use of preferred short-acting opioid analgesics.
- Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**

- Initial: 7 to 30 days (except 12 months for end-of-life, sickle cell disease, severe burn injury, or cancer-related pain)
- Renewal: Up to 6 months

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Requires a PA:**

- Non-preferred short-acting opioids and opioid combination products.
- All short-acting products prescribed for more than 14 days. Each prescription is limited to 7 days in treatment-naïve patients. Patients may fill up to 2 prescriptions every 90 days without prior authorization.
- All codeine and tramadol products for patients under 19 years of age

Note:

- Patients on palliative care with a terminal diagnosis or with cancer-related pain or with pain associated with sickle cell disease or severe burn injury are exempt from this PA.

**Table 1**. Daily Dose Threshold (90 morphine milligram equivalents per day (MME/day) of Oral Opioid Products.

| Opioid | 90 MME/day Dose | Notes |
|---|---|---|
| Benzhydrocodone | 73.5 mg | |
| Codeine | 600 mg | Codeine is not recommended for pediatric use; codeine is a prodrug of morphine and is subject to different rates of metabolism, placing certain populations at risk for overdose. |
| Dihydrocodeine | 360 mg | |
| Hydrocodone bitartrate | 90 mg | |
| Hydromorphone | 22.5 mg | |
| Levorphanol tartrate | 8 mg | |
| Meperidine | 900 mg | Meperidine is not recommended for management of chronic pain due to potential accumulation of toxic metabolites. |
| Morphine | 90 mg | |
| Oxycodone | 60 mg | |
| Oxymorphone | 30 mg | |
| Tapentadol | 225 mg | |
| Tramadol | 400 mg | 400 mg/day is max dose and is not equivalent to 90 MME/day. Tramadol is not recommended for pediatric use as it is subject to different rates of metabolism placing certain populations at risk for overdose. |

| Approval Criteria | | |
|---|---|---|
| 1. What is the patient's diagnosis? | Record ICD10 | |
| 2. Has the patient been prescribed any opioid analgesics (short or long-acting) for more than 6 weeks? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Is the diagnosis funded by the OHP?<br><br>Note: Currently, conditions such as fibromyalgia, TMJ, pelvic pain syndrome, neuropathy, and tension headache are not funded by the OHP. | **Yes:** Go to #5 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #4<br><br>Note: Management of opioid dependence is funded by the OHP. |
| 4. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical necessity. |
| 5. Is the requested medication a preferred agent? | **Yes:** Go to #7 | **No:** Go to #6 |
| 6. Will the prescriber change to a preferred product?<br><br>Note: Preferred opioids are reviewed and designated as preferred agents by the Oregon Pharmacy & Therapeutics Committee based on published medical evidence for safety and efficacy. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Go to #7 |
| 7. Is the patient being treated for pain associated with sickle cell disease, severe burn injury or cancer-related pain or under palliative care services with a life-threatening illness or severe advanced illness expected to progress toward dying? | **Yes:** Approve for up to 12 months. | **No:** Go to #8 |
| 8. Is the prescription for a product containing codeine or tramadol in a patient less than 19 years of age?<br><br>Note: Cold symptoms are not funded on the prioritized list | **Yes:** Deny for medical appropriateness | **No:** Go to #9 |

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|---|---|---|
| 9. Is the prescription for a short-acting fentanyl product?<br><br>Note: Short-acting transmucosal fentanyl products are designed for breakthrough cancer pain only. This PA does not apply to transdermal fentanyl patches. | **Yes:** Pass to RPh. Deny; medical appropriateness<br><br>Note: Management of opioid dependence is funded by the OHP. | **No:** Go to #10 |
| 10. Is the opioid prescribed for pain related to migraine or other type of headache?<br><br>Note: there is limited or insufficient evidence for opioid use for many pain conditions, including migraine or other types of headache. | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #11 |
| 11. Is the prescriber enrolled in the Oregon Prescription Drug Monitoring Program (www.orpdmp.com) and has the prescriber reviewed at least once in the past month and verified that opioid prescribing is appropriate? | **Yes:** Go to #12 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 12. Is the patient currently taking a benzodiazepine or other central nervous system (CNS) depressant?<br><br>Note: All opioids have a black box warning about the risks of profound sedation, respiratory depression, coma or death associated with concomitant use of opioids with benzodiazepines or other CNS depressants. | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #13 |
| 13. Within the past 6 weeks, has a 5-day trial of at least one non-opioid analgesic (e.g., NSAID, acetaminophen, and/or muscle relaxant) been tried for this indication at its maximum effective dose and found to be ineffective or are contraindicated? | **Yes:** Go to #14 | **No:** Pass to RPh. Deny; medical appropriateness |
| 14. Is the opioid prescription for pain associated with a back or spine condition? | **Yes:** Go to #15 | **No:** Approve for up to 30 days not to exceed 90 MME |
| 15. Has the prescriber also developed a plan with the patient to stay active (home or prescribed exercise regimen) and with consideration of additional therapies such as spinal manipulation, physical therapy, yoga, weight loss, massage therapy, or acupuncture? | **Yes:** Go to #16 | **No:** Pass to RPh. Deny; medical appropriateness |

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| 16. Is this the first opioid prescription the patient has received for this pain condition? | **Yes:** Approve for up to 7 days not to exceed 90 MME | **No:** Go to #17 |
| 17. Can the prescriber provide documentation of sustained improvement in function of at least 30% compared to baseline with prior use of opioid analgesics (e.g., validated tools to assess function include: Oswestry, Neck Disability Index, SF-MPQ, 3-item PEG scale, and MSPQ)? | **Yes:** Approve for up to 7 days not to exceed 90 MME | **No:** Pass to RPh. Deny; medical appropriateness. |

| **Renewal Criteria** | | |
|---|---|---|
| 1. What is the patient's diagnosis? | Record ICD10 code | |
| 2. Is the request for a patient already established on opioid treatment for >6 weeks (long-term treatment)? | **Yes**: Go to #3 | **No**: Go to **Approval Criteria** |
| 3. Does the request document a taper plan for the patient? | **Yes:** Document taper plan and approve for duration of taper or 3 months whichever is less. | **No:** Go to #4 |
| 4. Is there documentation indicating it is **unsafe** to initiate a taper at this time? | **Yes:** Go to #5<br><br>Document provider attestation and rationale | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the prescriber enrolled in the Oregon Prescription Drug Monitoring Program (www.orpdmp.com) and has the prescriber verified at least once in the past 1 month that opioid prescribing is appropriate? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny. Medical appropriateness |
| 6. Has the patient had a urinary drug screen (UDS) within the past year to verify absence of illicit drugs and non-prescribed opioids? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny. Medical appropriateness |
| 7. Can the prescriber provide documentation of sustained improvement of at least 30% in pain, function, or quality of life in the past 3 months compared to baseline?<br><br>Note: Pain control, quality of life, and function can be quickly assessed using the 3-item PEG scale. * | **Yes:** Go to #9<br><br>Document tool used and score vs. baseline: _____ | **No:** Go to #8 |

| | | |
|---|---|---|
| 8. Has the patient been referred for alternative non-pharmacologic modalities of pain treatment (e.g., physical therapy, supervised exercise, spinal manipulation, yoga, or acupuncture)? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny. Medical appropriateness |
| 9. Is the request for an increased cumulative daily dose compared to previously approved therapy or average dose in the past 6 weeks? | **Yes:** Go to #10 | **No:** Go to #12 |
| 10. Does the total cumulative daily opioid dose exceed 90 MME (see Table 1)? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #11 |
| 11. Is there documented rationale (e.g., new acute injury) to support the increase in dose? | **Yes:** Go to #12 | **No:** Pass to RPh; deny; medical appropriateness |
| 12. Does the patient have any of the following risk factors for overdose?<br>a. Concomitant CNS depressants (benzodiazepines, muscle relaxants, sedating antipsychotics, etc)<br>b. Total daily opioid dose > 90 MME<br>c. Recent urine drug screen indicating illicit or non-prescribed opioids<br>d. Concurrent short- and long-acting opioid use<br>e. Diagnosis of opioid use disorder | **Yes:** Go to #13<br><br>Document number of risk factors | **No:** Go to #14 |
| 13. Has the member been prescribed or have access to naloxone? | **Yes:** Go to #14 | **No:** Pass to RPh. Deny. Medical appropriateness |
| 14. Does the patient have a pain contract on file with the prescriber? | **Yes:** Approved duration is based on the number of identified risk factors for overdose or length of treatment (whichever is less):<br><br>Risk factors:<br>>=3: 2 month<br>1-2: 4 months<br>0: 6 months | **No:** Pass to RPh. Deny; medical appropriateness |

*The PEG is freely available to the public http://www.agencymeddirectors.wa.gov/Files/AssessmentTools/1-PEG%203%20item%20pain%20scale.pdf.
Citation of the original publication:
Krebs EE, Lorenz KA, Bair MJ, Damush TA, Wu J, Sutherland JM, Asch SM, Kroenke K. Development and initial validation of the PEG, a 3-item scale assessing pain intensity and interference. *Journal of General Internal Medicine*. 2009 Jun; 24:733-738

**Clinical Notes:**

How to Discontinue Opioids.

Adapted from the following guidelines on opioid prescribing:

- The Washington State Interagency Guideline on Prescribing Opioids for Pain; Agency Medical Directors' Group, June 2015. Available at http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf.

Selecting the optimal timing and approach to tapering depends on multiple factors. The decision to taper should be based on shared decision making between the patient and provider based on risks and benefits of therapy. Involving the patient in the decision to taper helps establish trust with the patient, ensures patient-focused tapering, incorporates the patient's values into the taper plan, provides education on the risks of opioid use, and establishes realistic goals and expectations. Avoid insisting on opioid tapering or discontinuation when opioid use may be warranted. The rate of opioid taper should be based primarily on safety considerations, and special attention is needed for patients on high dose opioids or with significant long-term use, as too rapid a taper may precipitate withdrawal symptoms or drug-seeking behavior. In addition, behavioral issues or physical withdrawal symptoms can be a major obstacle during an opioid taper. Patients who feel overwhelmed or desperate may try to convince the provider to abandon the taper. Although there are no methods for preventing behavioral issues during taper, strategies implemented at the beginning of chronic opioid therapy such as setting clear expectations, allowing for pauses during the taper, and development of an exit strategy are most likely to prevent later behavioral problems if a taper becomes necessary.

1. Consider sequential tapers for patients who are on chronic benzodiazepines and opioids. Coordinate care with other prescribers (e.g. psychiatrist) as necessary. In general, taper off opioids first, then the benzodiazepines.
2. Do not use ultra-rapid detoxification or antagonist-induced withdrawal under heavy sedation or anesthesia (e.g. naloxone or naltrexone with propofol, methohexital, ketamine or midazolam).
3. Establish an individualized rate of taper based on safety considerations and patient history. Common tapers have a dose reduction of 5% to 20% per month:
    a. Assess for substance use disorder and transition to appropriate medication assisted treatment if there is diversion or non-medical use,
    b. Rapid taper (over a 2 to 3 week period) if the patient has had a severe adverse outcome such as overdose or substance use disorder, or
    c. Slow taper for patients with no acute safety concerns. May consider starting with a taper of ≤10% of the original dose per month and assess the patient's functional and pain status at each visit.
4. Adjust the rate, intensity, and duration of the taper according to the patient's response (e.g. emergence of opioid withdrawal symptoms (see Table below)).
5. Watch for signs of unmasked mental health disorders (e.g. depression, PTSD, panic disorder) during taper, especially in patients on prolonged or high dose opioids. Consult with specialists to facilitate a safe and effective taper. Use validated tools to assess conditions.
6. Consider the following factors when making a decision to continue, pause or discontinue the taper plan:
    a. Assess the patient behaviors that may be suggestive of a substance use disorder
    b. Address increased pain with use of non-opioid pharmacological and non-pharmacological options.
    c. Evaluate patient for mental health disorders.
    d. If the dose was tapered due to safety risk, once the dose has been lowered to an acceptable level of risk with no addiction behavior(s) present, consider maintaining at the established lower dose if there is a clinically meaningful improvement in function, reduced pain and no serious adverse outcomes.
7. Do not reverse the taper; it must be unidirectional. The rate may be slowed or paused while monitoring for and managing withdrawal symptoms.
8. Increase the taper rate when opioid doses reach a low level (e.g. <15 mg/day MED), since formulations of opioids may not be available to allow smaller decreases.
9. Use non-benzodiazepine adjunctive agents to treat opioid abstinence syndrome (withdrawal) if needed. Unlike benzodiazepine withdrawal, opioid withdrawal symptoms are rarely medically serious, although they may be extremely unpleasant. Symptoms of mild opioid withdrawal may persist for 6 months after opioids have been discontinued (see Table below).
10. Refer to a crisis intervention system if a patient expresses serious suicidal ideation with plan or intent, or transfer to an emergency room where the patient can be closely monitored.
11. Do not start or resume opioids or benzodiazepines once they have been discontinued, as they may trigger drug cravings and a return to use. Counsel the patient on the increased risk of overdose with abrupt return to a previously prescribed higher dose. Provide opioid overdose education and consider offering naloxone.
12. Consider inpatient withdrawal management if the taper is poorly tolerated.

| Symptoms and Treatment of Opioid Withdrawal.<br>Adapted from the Washington State Interagency Guideline on Prescribing Opioids for Pain; Agency Medical Directors' Group, June 2015. Available at http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf) | |
|---|---|
| Restlessness, sweating or tremors | Clonidine 0.1-0.2 mg orally every 6 hours or transdermal patch 0.1-0.2 mg weekly (If using the patch, oral medication may be needed for the first 72 hours) during taper. Monitor for significant hypotension and anticholinergic side effects. |
| Nausea | Anti-emetics such as ondansetron or prochlorperazine |
| Vomiting | Loperamide or anti-spasmodics such as dicyclomine |
| Muscle pain, neuropathic pain or myoclonus | NSAIDs, gabapentin or muscle relaxants such as cyclobenzaprine, tizanidine or methocarbamol |
| Insomnia | Sedating antidepressants (e.g. nortriptyline 25 mg at bedtime or mirtazapine 15 mg at bedtime or trazodone 50 mg at bedtime). Do not use benzodiazepines or sedative-hypnotics. |

*P&T Review:* *4/21 (AG); 2/20 (SS), 9/19 (DM), 11/16 (AG)*
*Implementation:* *5/1/21; 3/1/20; 10/1/19; 8/21/17*

# Orphan Drugs

**Goal(s):**

- To support medically appropriate use of orphan drugs (as designated by the FDA) which are indicated for rare conditions
- To limit off-label use of orphan drugs

**Length of Authorization:**

- Up to 6 months

**Requires PA:**

- See Table 1 (pharmacy and provider administered claims)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1. Included orphan drugs

| |
|---|
| ADAMTS13, recombinant-krhn (ADZYNMA) |
| Allogeneic processed thymus tissue-agdc (RETHYMIC) |
| Alpelisib (VIJOICE) |
| arimoclomol citrate (MIPLYFFA) |
| Atidarsagene autotemcel (LENMELDY) |
| Avacopan (TAVNEOS) |
| Axatilimab-csfr (NIKTIMVO) |
| Belumosudil (REZUROCK) |
| Beremagene geperpavec-svdt (VYJUVEK) |
| Birch triterpenes (FILSUVEZ) |
| Burosumab-twza (CRYSVITA) |
| Cerliponase alfa (BRINEURA) |
| Chenodiol (CTEXLI) |
| Crinecefont (CRENESSITY) |
| Crovalimab-akkz (PIASKY) |
| Danicopan (VOYDEYA) |
| Eculizumab (SOLIRIS) |
| Eculizumab-aagh (EPYSQLI) |
| Eculizumab-aeeb (BKEMV) |
| Eladocagene exuparvovec-tneq (KEBILDI) |
| Elafibranor (IQIRVO) |
| Elapegademase-lvlr (REVCOVI) |
| Elivaldogene autotemcel (SKYSONA) |
| Fosdenopterin (NULIBRY) |
| Givosiran (GIVLAARI) |
| Inebilizumab-cdon (UPLIZNA) |
| Iptacopan (FABHALTA) |
| Leniolisib (JOENJA) |
| Levacetylleucine (AQNEURSA) |
| Levoketoconazole (RECORLEV) |
| Lonafarnib (ZOKINVY) |
| Lumasiran (OXLUMO) |
| Luspatercept (REBLOZYL) |
| Maralixibat (LIVMARLI) |
| Mavacamten (CAMZYOS) |
| Mavorixafor (XOLREMDI) |
| Mirdametinib (GOMEKLI) |

| |
|---|
| Mitapivat (PYRUKYND) |
| Nedosiran (RIVFLOZA) |
| Nipocalimab-aahu (IMAAVY) |
| Odevixibat (BYLVAY) |
| Olipudase alfa-rpcp (XENPOZYME) |
| Palovarotene (SOHONOS) |
| Palopegteriparatide (YORVIPATH) |
| Pegcetacoplan (EMPAVELI) |
| Plasminogen, human-tvmh (RYPLAZIM) |
| Pozelimab-bbfg (VEOPOZ) |
| Ravulizumab-cwvz (ULTOMIRIS) |
| Remestemcel-L-rknd (RYONCIL) |
| Rezafungin (REZZAYO) |
| Rozanolixizumab-noli (RYSTIGGO) |
| Satralizumab-mwge (ENSPRYNG) |
| Seladelpar (LIVDELZI) |
| Sodium thiosulfate (PEDMARK) |
| Sutimlimab-jome (ENJAYMO) |
| Tofersen (QALSODY) |
| Trientine tetrahydrochloride (CUVRIOR) |
| Velmanase alfa-tycv (LAMZEDE) |
| Zilucoplan (ZILBRYSQ) |

| **Approval Criteria** | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the diagnosis funded by OHP? | **Yes:** Go to #4 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br>If eligible for EPSDT review: Go to #3 |
| 3. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical necessity. |
| 4. Is the request for a drug FDA-approved for the indication, age, and dose as defined in the FDA label (see links in **Table 1)**?<br><br>Note: This includes all information required in the FDA-approved indication, including but not limited to, the following as applicable: diagnosis, disease severity, biomarkers, place in therapy, and use as monotherapy or combination therapy. | **Yes**: Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 5. Is the request for continuation of therapy in a patient previously approved by FFS? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #6 |
| 6. Is baseline monitoring recommended for efficacy or safety (e.g., labs, baseline symptoms, etc) AND has the provider submitted documentation of recommended baseline and ongoing monitoring parameters described in the FDA label?*<br><br>*FDA pages for drugs and biologics:<br>https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm<br>https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 7. Is this medication therapy being prescribed by, or in consultation with, an appropriate medical specialist? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 8. Have other therapies been tried and failed? | **Yes:** Approve for up to 3 months (or length of treatment) whichever is less<br><br>Document therapies which have been previously tried | **No:** Approve for up to 3 months (or length of treatment) whichever is less<br><br>Document provider rationale for use as a first-line therapy |

| Renewal Criteria | | |
|---|---|---|
| 1. Is there documentation based on chart notes that the patient experienced a significant adverse reaction related to treatment? | **Yes:** Go to #2 | **No:** Go to #3 |
| 2. Has the adverse event been reported to the FDA Adverse Event Reporting System? | **Yes:** Go to #3<br><br>Document provider attestation | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is baseline efficacy monitoring available? | **Yes:** Go to #4 | **No:** Go to #5 |

| Renewal Criteria | | |
|---|---|---|
| 4. Is there objective documentation of improvement from baseline OR for chronic, progressive conditions, is there documentation of disease stabilization or lack of decline compared to the natural disease progression? | **Yes:** Approve for up to 6 months<br><br>Document benefit | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is there documentation of benefit from the therapy as assessed by the prescribing provider (e.g., improvement in symptoms or quality of life, or for progressive conditions, a lack of decline compared to the natural disease progression)? | **Yes**: Approve for up to 6 months<br><br>Document benefit and provider attestation | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 8/25; 6/25; 4/25; 2/25; 12/24; 10/24; 8/24; 4/24; 12/23; 10/23; 6/23; 2/23; 12/22; 6/22; 4/22; 12/21; 10/21; 6/21; 2/21; 8/20; 6/20; 2/20*
*Implementation: 9/15/25; 5/12/25; 3/10/25; 1/1/25; 9/1/24; 5/1/24; 1/1/24; 11/1/23; 7/1/23; 4/1/23; 1/1/23; 7/1/22; 5/1/22; 1/1/2022; 7/1/2021; 3/1/21; 11/1/20; 9/1/20; 7/1/20*

# Oxazolidinone Antibiotics

**Goal(s):**
- To optimize treatment of infections due to gram-positive organisms such as methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *Enterococcus faecium* (VRE)

**Length of Authorization:**
- 6 days

**Requires PA:**
- Non-preferred Oxazolidinone antibiotics

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD-10 code. | |
| 2. Does the patient have an active infection with suspected or documented MRSA (e.g. B95.8, B95.61, B95.62, J15212) or VRE (e.g. Z16.20, Z16.21, Z16.22, Z16.31, Z16.32, Z16.33, Z16.39) or other multi-drug resistant gram-positive cocci (e.g. Z16.30, Z16.24)? | **Yes:** Go to #3. | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Does the patient have a documented trial of appropriate therapy with vancomycin or linezolid, or is the organism not susceptible? | **Yes:** Approve tedizolid for up to 6 days and other non-preferred drugs for prescribed course. | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review:* *5/15*
*Implementation* *10/13/16; 7/1/15*

# Palivizumab (Synagis®)

**Goal(s):**

- Promote safe and effective use of palivizumab in high-risk infants and children. Prophylaxis against RSV should cover up to 5 months during high viral activity season, usually spanning from November through March in Oregon.

**Length of Authorization:**

- Based on individual factors; may extend up to 5 months (5 total doses)

**Requires PA:**

- Synagis (palivizumab) pharmacy and provider administered claims

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Has the patient been receiving monthly palivizumab prophylaxis and been hospitalized for a breakthrough RSV infection? | **Yes:** Pass to RPh; deny for medical appropriateness. | **No:** Go to #3 |
| 3. Is the request consistent with the current Advisory Committee on Immunization Practices (ACIP) recommendations for combination prophylactic agents (outlined here)?<br><br>2023 ACIP update: if the patient, or birth mother of the patient, has received other therapies for the prevention of RSV during or prior to the RSV season, palivizumab is not indicated | **Yes:** Go to #4 | **No:** Pass to RPh; deny for medical appropriateness. |
| 4. Is the request for RSV prophylaxis to be administered during the typical high viral activity season from November through March? | **Yes:** Go to #6 | **No:** Go to #5 |
| 5. Is the request for prophylaxis starting in October due to interseasonal increase in RSV activity with season onset designated by the OHA*?<br><br>* Data provided by the Oregon's Weekly Respiratory Syncytial Virus Surveillance Report from the Oregon Public Health Division based on regions. Weekly updates are found at: https://public.health.oregon.gov/DiseasesConditions/DiseasesAZ/Pages/disease.aspx?did=40) | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness. Prophylaxis is indicated only during high viral activity. |

| Approval Criteria | | |
|---|---|---|
| 6. Is the current age of the patient < 24 months at start of RSV season? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. Not recommended for patients ≥24 months old. |
| 7. GROUP A<br>Does the patient have the CLD (chronic lung disease) of prematurity ICD10 Q331through Q339 **and** in the past 6 months has required medical treatment with at least one of the following:<br>a. diuretics<br>b. chronic corticosteroid therapy<br>c. supplemental oxygen therapy | **Yes:** Go to #19 | **No:** Go to 8 |
| 8. GROUP B<br>Has the patient received a cardiac transplant during the RSV season? | **Yes:** Go to #19 | **No:** Go to #9 |
| 9. GROUP C<br>Is the child profoundly immunocompromised during the RSV season (i.e. solid organ transplant or hematopoietic stem cell transplantation)? | **Yes:** Go to #19 | **No:** Go to #10 |
| 10. GROUP D<br>Does the infant have cystic fibrosis and manifestations of severe lung disease or weight or length less than the 10$^{th}$ percentile? | **Yes:** Go to #19 | **No:** Go to #11 |
| 11. GROUP E<br>Is the request for a second season of palivizumab prophylaxis for a child born <32 weeks, 0 days gestation who required at least 28 days of oxygen, chronic systemic corticosteroid therapy, or bronchodilator therapy within 6 months of start of second RSV season? | **Yes:** Go to #19 | **No:** Go to #12 |
| 12. Will the patient be <12 months at start of RSV season? | **Yes:** Go to #13 | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 13. GROUP F<br>Was the infant born before 29 weeks, 0 days gestation? | **Yes:** Go to #19 | **No:** Go to #14 |
| 14. GROUP G<br>Does the infant have pulmonary abnormalities of the airway or neuromuscular disease compromising handling of secretions? | **Yes:** Go to #19 | **No:** Go to #15 |
| 15. GROUP H<br>Does the patient have hemodynamically significant congenital heart disease (CHD) ICD10: P293, Q209, Q220-Q223, Q225, Q229-Q234, Q238, Q240-Q246, Q248-Q249, Q250-Q256, Q278-Q279,Q282-Q283,Q288-Q289, Q2560-Q2565,Q2568-Q2569, Q2570-Q2572, Q2579,Q2731-Q2732 and at least one of the following:<br>a. Acyanotic heart disease who are receiving treatment to control congestive heart failure and will require cardiac surgical procedures; OR<br>b. Have moderate to severe pulmonary hypertension; OR<br>c. History of lesions adequately corrected by surgery AND still requiring medication for congestive heart failure? | **Yes:** Go to #19 | **No:** Go to #16 |
| 16. GROUP I<br>Does the patient have chronic lung disease (CLD) of prematurity defined as gestational age <32 weeks, 0 days and requirement for >21% oxygen for at least the first 28 days after birth? | **Yes:** Go to #19 | **No:** Go to #17 |
| 17. GROUP J<br>Does the patient have cyanotic heart defects and immunoprophylaxis is recommended? | **Yes:** Go to #19 | **No:** Go to #18 |
| 18. GROUP K<br>Does the patient have cystic fibrosis with clinical evidence of CLD and/or nutritional compromise? | **Yes:** Go to #19 | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 19. Is the request for more than 5 doses within the same RSV season or for dosing <28 days apart? | **Yes:** Pass to RPh. Deny; medical appropriateness. Prophylaxis is indicated for 5 months maximum and doses should be administered ≥28 days apart.<br><br>May approve for the following on a case-by-case basis:<br>a. >5 doses;<br>b. Prophylaxis for a second / subsequent RSV season | **No:** Go to #20 |
| 20. Has the patient had a weight taken within the last 30 days? | **Yes:** Document weight and date and go to #21<br>Weight:_____<br>Date:_____ | **No:** Pass to RPh. Obtain recent weight so accurate dose can be calculated. |
| 21. Approve palivizumab for a dose of 15 mg/kg. Document number of doses received in hospital and total number approved according to month of birth (refer to Table 1):<br><br>Total number of doses approved for RSV season:_____<br>Number of doses received in the hospital:_____<br><br>Prior to each refill, the patient's parent/caregiver and prescriber must comply with all case management services, including obtaining current weight for accurate dosing purposes throughout the approved treatment period as required by the Oregon Health Authority. | | |

**Table 1**. Maximum Number of Doses for Palivizumab for RSV Prophylaxis

| MONTH | ALL GROUPS |
|---|---|
| April | 5 |
| May | 5 |
| June | 5 |
| July | 5 |
| August | 5 |
| September | 5 |
| October | 5 |
| November | 5 |
| December | 4 |
| January | 3 |
| February | 2 |
| March | 1 |

* Infant may require less doses than listed based on age at the time of discharge from the hospital. Subtract number of doses given in hospital from total number of approved doses.

Notes:
- Dose: 15 mg/kg via intramuscular injection once monthly throughout RSV season.
- The start date for Synagis® is November 1 each year (or sooner when the Oregon Public Health Division has determined that RSV season onset has occurred) for a total of up to 5 doses.
- Approval for more than 5 doses or additional doses after March 31 will be considered on a case-by-case basis. Results from clinical trials indicate that Synagis® trough concentrations greater than 30 days after the 5th dose are well above the protective concentration. Therefore, 5 doses will provide more than 20 weeks of protection.

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*P&T/DUR Review:* *8/23 (KS); 2/22 (KS); 11/16; 9/14; 5/11; 5/12*
*Implementation:* *11/1/23; 12/1/22; 4/1/22; 1/1/17; 3/30/12*

# Parkinson's Disease Drugs

**Goals:**

- Promote preferred drugs for Parkinson's disease.
- Restrict use for non-funded conditions (e.g., restless leg syndrome) and support individual review for EPSDT.
- To limit utilization of safinamide to FDA-approved indications.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Non-preferred drugs

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is the diagnosis Parkinson's disease or another chronic neurological condition? | **Yes:** Go to #5 | **No:** Go to #3 |
| 3. Is the request for a funded diagnosis?<br><br>Note: Restless Leg Syndrome is not currently funded. | **Yes:** Go to #5 | **No:** Not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>Eligible for EPSDT review: go to #4 |
| 4. Is there documentation of medical appropriateness and medical necessity?<br><br>Definitions for medical appropriateness include use for an FDA indication AND use, contraindication, or intolerance to preferred agents in the class.<br>Medical necessity includes documentation that the diagnosis impacts the patient's health. | **Yes:** Go to #5 | **No:** Pass to RPh; deny medical appropriateness or medical necessity |
| 5. Is this a request for continuation of therapy? | **Yes:** Go to **Renewal Criteria**. | **No:** Go to #6 |

| Approval Criteria | | |
|---|---|---|
| 6. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products do not require PA.<br>• Preferred products are reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&T) Committee. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** If for treatment of unfunded condition for patient covered under EPSDT, approve for 1 year.<br><br>For all other requests: Go to #7 |
| 7. Is the request for safinamide or istradefylline? | **Yes:** Go to #12 | **No:** Go to #8 |
| 8. Is the request for opicapone? | **Yes:** Go to #9 | **No:** Go to #10 |
| 9. Is the patient on a non-selective monoamine oxidase (MAO) inhibitor?<br><br>Note: selective MAO-B inhibitors are permitted (moclobemide; rasagiline; safinamide; selegiline) | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Approve for the shorter of 1 year or length of prescription. |
| 10. Is the request for foslevodopa/foscarbidopa? | **Yes:** Go to #11 | **No:** Go to #14 |
| 11. Is the agent being prescribed by or in consultation with a neurology specialist? | **Yes:** Go to #12 | **No:** Pass to RPh. Deny; medical appropriateness |
| 12. Is the patient currently taking a nonselective monoamine oxidase (MAO) inhibitor or have they recently (within 2 weeks) taken a nonselective MAO inhibitor? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #13 |
| 13. Has the prescriber submitted a calculation of the base continuous dosage, hourly infusion rate, optional loading dose, and extra dose according to FDA prescribing information? | **Yes:** Approve for requested length of therapy. | **No:** Pass to RPh. Deny; medical appropriateness. |
| 14. Is the request for apomorphine sublingual film? | **Yes:** Go to #15 | **No:** Go to #16 |
| 15. Is the patient on a 5-HT3 antagonist (eg., ondansetron, dolasetron, granisetron, palonosetron, etc.) | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Approve for the shorter of 1 year or length of prescription. |

| Approval Criteria | | |
|---|---|---|
| 16. Is the patient currently taking levodopa/carbidopa? | **Yes:** Approve for the shorter of 1 year or length of prescription. | **No:** Pass to RPh. Deny; medical appropriateness. |

| Renewal Criteria | | |
|---|---|---|
| 3. Has the patient's condition progressed slower than expected, stabilized, or improved or as assessed by the prescribing physician and physician attests to patient's status? | **Yes:** Approve for the shorter of 1 year or length of prescription. | **No:** Pass to RPh; Deny; medical appropriateness. |

*P&T Review:* *02/25 (DE); 10/20 (AG); 3/18; 7/16; 9/14; 9/13; 09/10*
*Implementation:* *3/10/25; 11/1/20; 4/16/18; 8/16, 1/1/14, 1/1/11*

# Patiromer and Sodium Zirconium Cyclosilicate

**Goals:**

- Restrict use of patiromer and sodium zirconium cyclosilicate (SZC) to patients with persistent or recurrent hyperkalemia not requiring urgent treatment.
- Prevent use in the emergent setting or in scenarios not supported by the medical literature.

**Length of Authorization:**

- 3 months

**Requires PA:**

- Patiromer and Sodium Zirconium Cyclosilicate

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. Is this a request for continuation of therapy previously approved by the FFS program (patient already on patiromer or Sodium Zirconium Cyclosilicate (SZC))? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #2 |
| 2. What diagnosis is being treated? | Record ICD10 code. Go to #3 | |
| 3. Does the patient have persistent or recurrent serum potassium of ≥5.5 mEq/L despite a review for discontinuation of medications that may contribute to hyperkalemia (e.g., potassium supplements, potassium-sparing diuretics, nonsteroidal anti-inflammatory drugs)? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Does the patient have hyperkalemia requiring emergency intervention (serum potassium ≥6.5 mEq/L)? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #5 |
| 5. Is the request for patiromer? | **Yes:** Go to #6 | **No:** Go to #7 |
| 6. Does the patient have hypomagnesemia (serum magnesium < 1.4 mg/dL)? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #7 |
| 7. Does the patient have a severe GI disorder (i.e., major GI surgery (e.g., large bowel resection), bowel obstruction/impaction, swallowing disorders, gastroparesis, or severe constipation)? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Approve up to 3 months |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the patient's potassium level < 5.1 mEq/L and has this decreased by at least 0.35 mEq/L from baseline? | **Yes:** Approve for up to 3 months | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T Review:* *05/19 (DM), 05/16*
*Implementation:* *7/1/2019, 8/16, 7/1/16*

# PCSK9 Modulators

**Goal(s):**

- Promote use of PCSK9 modulators that is consistent with medical evidence
- Promote use of high value products

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- All PCSK9 modulators (pharmacy and provider administered claims)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. Is this a request for the renewal of a previously approved prior authorization? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #2 |
| 2. What diagnosis is being treated? | Record ICD10 code; go to #3 | |

| Approval Criteria | | |
|---|---|---|
| 3. Does the patient have very high-risk clinical atherosclerotic cardiovascular disease (ASCVD), defined as documented history of multiple major ASCVD events **OR** one major ASCVD event and multiple high-risk conditions (See below)<br><br><u>Major ASCVD events</u><br>• Recent ACS (within past 12 months)<br>• History of MI (other than recent ACS from above)<br>• History of ischemic stroke<br>• Symptomatic peripheral artery disease<br><u>High-Risk Conditions:</u><br>• Age ≥ 65<br>• Heterozygous familial hypercholesterolemia<br>• History of prior CABG or PCI<br>• Diabetes Mellitus<br>• Hypertension<br>• Chronic Kidney Disease<br>• Current smoking<br>• Persistently elevated LDL-C ≥ 100 despite maximally tolerated statin therapy and ezetimibe<br>• History of congestive heart failure | **Yes:** Go to #4 | **No:** Go to #7 |
| 4. Has the patient taken a daily high-intensity statin (see table below) and ezetimibe 10 mg daily for at least 3 months with a LDL-C still ≥ 70 mg/dl?<br><br>Prescriber to submit chart documentation of:<br>1) Doses and dates initiated of statin and ezetimibe;<br>2) Baseline LDL-C (untreated);<br>3) Recent LDL-C | **Yes:** Confirm documentation; go to #5<br><br>1. Statin:<br>Dose:<br>Date Initiated:<br><br>2. Ezetimibe 10 mg daily<br>Date Initiated:<br><br>Recent LDL-C<br>_____ mg/dL<br>Date:_____ | **No:** Go to #6 |

| Approval Criteria | | |
|---|---|---|
| 5. Is the patient adherent with a high-intensity statin and ezetimibe? | **Yes:** Approve for up to 12 months<br><br>Note: pharmacy profile may be reviewed to verify >80% adherence (both lipid-lowering prescriptions refilled 5 months' supply in last 6 months) | **No:** Pass to RPh; deny for medical appropriateness |
| 6. Does the patient have:<br>• A history of rhabdomyolysis caused by a statin; or alternatively,<br>• a history of creatinine kinase (CK) levels >10-times upper limit of normal with muscle symptoms determined to be caused by a statin; or<br>• Intolerable statin-associated side effects that have been re-challenged with ≥ 2 statins<br><br>Note: Prescriber must provide chart documentation of diagnosis or CK levels. A recent LDL-C level (within last 12 weeks) must also be submitted. | **Yes:** Confirm chart documentation of diagnosis or labs and approve for up to 12 months<br><br>Recent LDL-C _____ mg/dL<br>Date:_____ | **No:** Pass to RPh; deny for medical appropriateness |
| 7. Does the patient have a diagnosis of homozygous or heterozygous familial hypercholesterolemia?<br><br>Note: Prescriber must provide chart documentation of diagnosis and recent LDL-C (within last 12 weeks). | **Yes:** Go to #8 | **No:** Pass to RPh; deny for medical appropriateness. |
| 8. Does the patient still have a LDL-C of ≥ 100 mg/dl while taking a maximally tolerated statin and ezetimibe? | **Yes:** Go to #9<br><br>Recent LDL-C _____ mg/dL<br>Date:_____ | **No:** Pass to RPh; deny for medical appropriateness. |
| 9. Is the request for inclisiran? | **Yes:** Go to #10 | **No:** Approve for up to 12 months |

| Approval Criteria | | |
|---|---|---|
| 10. Has the patient tried and failed a PCSK9 inhibitor with evidence of a reduction in cardiovascular events (i.e., evolocumab or alirocumab) or have a contraindication to one of these agents?<br><br>*Failure of a PCSK9 inhibitor includes adherence to PCSK9 inhibitor for at least 12 weeks with an LDL-C that remains > 70 mg/dl with evidence of clinical atherosclerotic cardiovascular disease (ASCVD) | **Yes:** Go to #11 | **No:** Pass to RPh; deny for medical appropriateness. |
| 11. Is the patient currently still receiving a PCSK9 inhibitor (alirocumab or evolocumab)? | **Yes:** Pass to RPh; deny for medical appropriateness. | **No:** Approve for up to 12 months.<br><br>Note: Any current PA approvals for PCSK9 inhibitors will be end-dated. |

| Renewal Criteria | | |
|---|---|---|
| 1. What is the most recent LDL-C (within last 12 weeks)? | Recent LDL-C _____ mg/dL<br>Date:_____ ; go to #2 | |
| 2. Has the patient experienced and maintained a reduction in LDL-C compared to baseline labs (prior to initiating PCSK9 modulator)? | **Yes:** Go to #3 | **No:** Pass to RPh; deny for medical appropriateness |
| 3. Is the patient adherent with PCSK9 modulator therapy? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh; deny for medical appropriateness |

**High- and Moderate-intensity Statins.**

| **High-intensity Statins** (≥50% LDL-C Reduction) | **Moderate-intensity Statins** (30 to <50% LDL-C Reduction) | |
|---|---|---|
| Atorvastatin 40-80 mg<br>Rosuvastatin 20-40 mg | Atorvastatin 10-20 mg<br>Fluvastatin 80 mg<br>Lovastatin 40-80 mg | Rosuvastatin 5-10 mg<br>Pravastatin 40-80 mg<br>Simvastatin 20-40 mg |

*P&T / DUR Review:* *8/22 (MH) 8/21; 8/20; 5/19; 1/18; 11/16; 11/15*
*Implementation:* *10/1/22; 7/1/2019; 3/1/18; 1/1/1*

# Preferred Drug List (PDL) – Non-Preferred Drugs in Select PDL Classes

**Goal(s):**
- Ensure that non-preferred drugs are used appropriately for OHP-funded conditions in adults.
- Allow case-by-case review for members covered under the EPSDT program.

**Initiative:**
- PDL: Preferred Drug List

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Non-preferred drugs

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is this a request for continuation of a drug and dose previously approved by the FFS program? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Is this an FDA approved indication? | **Yes**: Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the dosing consistent with FDA-approved labeling? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is this an OHP-funded diagnosis? | **Yes**: Go to #6 | **No**: If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #7. |

| Approval Criteria | | |
|---|---|---|
| 6. Will the prescriber consider a change to a preferred product?<br><br>Message: Preferred products do not generally require a PA. Preferred products are evidence-based and reviewed for comparative effectiveness and safety by the P&T Committee. | **Yes**: Inform prescriber of covered alternatives in class. | **No**: Approve until anticipated formal review by the P&T committee, for 6 months, or for length of the prescription, whichever is less. |
| 7. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical necessity. |
| 8. Has the patient failed to have benefit with, or have contraindications or intolerance to, at least 2 preferred products?<br><br>Message:<br>Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Approve for 12 months. | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Inform prescriber of covered alternatives in class and process appropriate PA. |

| Renewal Criteria | | |
|---|---|---|
| 1. Has the patient failed to have benefit with, or have contraindications or intolerance to, at least 2 available preferred products? | **Yes:** Approve for 12 months. | **No:** Go to #2 |
| 2. Will the prescriber consider a change to a preferred product?<br><br>Message: Preferred products do not generally require a PA. Preferred products are evidence-based and reviewed for comparative effectiveness and safety by the P&T Committee. | **Yes**: Inform prescriber of covered alternatives in class. | **No:** Approve until anticipated formal review by the P&T committee, for 6 months, or for length of the prescription, whichever is less. |

*P&T / DUR Review:* *4/23; 12/22; 4/22; 7/15, 9/10; 9/09; 5/09*
*Implementation:* *5/1/23; 1/1/23; 5/1/22; 10/13/16; 8/25/15; 8/15; 1/1/11, 9/16/10*

# Peanut (arachis hypogaea) Allergen Powder-dnfp (Palforzia)

**Goal(s):**
- To ensure appropriate use of desensitization products in patients with peanut allergies

**Length of Authorization:**
- 12 months

**Requires PA:**
- Peanut (arachis hypogaea) allergen powder-dnfp (Palforzia) (both pharmacy and provider administered claims)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request by, or in consultation with, an allergist or immunologist? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the request for continuation of current therapy previously approved by the FFS program? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #4 |
| 4. Is the request for an FDA-approved indication and age? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Does the patient have a history of serious peanut allergy or anaphylaxis? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical necessity |
| 6. Is there baseline documentation of number of epinephrine administrations and hospital/emergency department visits (if any) in past 12 months which were caused by presumed peanut exposure. | **Yes:** Go to #7<br><br>Epi administrations: _____<br>Hospital/ED visits: _____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Does the patient have a history of severe peanut reaction that included circulatory shock or need for mechanical ventilation? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #8 |
| 8. Does the patient have a peanut-specific positive IgE of ≥ 0.35 $kU_a/L$ OR a skin prick test wheal of ≥ 3 mm? | **Yes**: Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 9. Does the patient have uncontrolled asthma, history of eosinophilic esophagitis, or other eosinophilic gastrointestinal disease? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #10 |
| 10. Are the healthcare setting and the prescriber certified in the Palforzia REMS program AND will the patient be enrolled in the REMS program upon PA approval? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the request for the full 300 mg daily maintenance dose of peanut allergen powder? | **Yes**: Go to #3 | **No:** Go to #2 |
| 2. Is the patient new to OHA FFS and has the patient not yet completed the initial dose titration prior to FFS enrollment? | **Yes:** Approve for 12 months;<br>Document baseline epinephrine use and hospital/emergency department visits | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Has the patient had a reduced number of allergic attacks since beginning peanut allergen powder as evidenced by either:<br>• Absence of, or reduction in the number of needed epinephrine administrations due to presumed peanut exposure?<br>OR<br>• Absence of, or reduction in the number of hospital/emergency department visits due to presumed peanut exposure? | **Yes**: Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 8/24 (DM); 8/23 (DM); 2/21 (SF)*
*Implementation: 9/1/24; 3/1/21*

# Phenylketonuria

**Goal(s):**
- Promote safe and cost effective therapy for the treatment of phenylketonuria.

**Length of Authorization:**
- Initial: 1 to 9 months;
- Renewal: 16 weeks to 1 year

**Requires PA:**
- Sapropterin and pegvaliase (pharmacy and provider administered claims)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What is the diagnosis being treated? | Record ICD10 code | |
| 2. Is the request for renewal of therapy previously approved by the FFS system? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Is the drug prescribed by or in consultation with a specialist in metabolic disorders? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the request for sapropterin? | **Yes:** Go to #5 | **No:** Go to #8 |
| 5. Is the diagnosis tetrahydrobiopterin- (BH4-) responsive phenylketonuria? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is the patient currently compliant with a Phe-restricted diet and unable to achieve target blood phenylalanine level? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny and recommend Phe-restricted diet. |
| 7. Is the patient's baseline blood phenylalanine level provided in the request and above the target range (see Clinical Notes)? | **Yes:** Approve for 2 months if initial dose is 5-10 mg/kg/day (to allow for titration to 20 mg/kg/day). Approve for 1 month if initial dose is 20 mg/kg/day (adults and children). | **No:** Request information from provider. |
| 8. Is the request for pegvaliase? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 9. Is the patient 18 years of age or older with a diagnosis of phenylketonuria? | **Yes:** Go to #10 | **No:** Pass to RPh. Deny; medical appropriateness |
| 10. Is the patient's blood phenylalanine concentration documented in the request and greater than 600 µmol/L on existing management (such as dietary phenylalanine restriction or sapropterin)? | **Yes:** Go to #11 | **No:** Pass to RPh. Deny; medical appropriateness<br><br>If not documented, request information from provider. |
| 11. Is the medication prescribed concurrently with epinephrine based on claims history or chart notes? | **Yes:** Approve for 9 months based on FDA-approved induction, titration, and maintenance dosing* | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the request for sapropterin? | **Yes:** Go to #2 | **No:** Go to #4 |
| 2. Did the patient meet the target phenylalanine level set by the specialist (see Clinical Notes)? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny for lack of treatment response. |
| 3. Is the patient remaining compliant with the Phe-restricted diet? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny and recommend Phe-restricted diet. |
| 4. Is the request for pegvaliase? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Has there been a reduction from baseline phenylalanine concentration of 20% or greater? | **Yes:** Approve for 12 months | **No:** Go to #6 |
| 6. Has there been a reduction in blood phenylalanine concentration to less than or equal to 600 µmol/L? | **Yes:** Approve for 12 months | **No:** Go to #7 |

| Renewal Criteria | | |
|---|---|---|
| 7. Is the request for a first renewal of pegvaliase therapy and the patient had been on pegvaliase 20 mg daily for at least 24 weeks? | **Yes:** Approve for 16 weeks for trial of maximum dose of 40 mg once daily. Continued approval at this dose requires documentation of improvement (>20% reduction from baseline or less than 600 µmol/L in phenylalanine concentration). | **No:** Pass to RPh. Deny for lack of treatment response. |

**Clinical Notes:**
Target blood phenylalanine levels in the range of 120-360 µmol/L for patients in all age ranges.[1]
In addition to the recommended Phe concentrations, a 30% or more reduction in blood Phe is often considered a clinically significant change from baseline and should occur after the initial trial.[2] If not, the patient is a non-responder and will not benefit from sapropterin therapy.
Sapropterin doses above 20 mg/kg/day have not been studied in clinical trials.

***Pegvaliase FDA-Recommended Dosage and Administration:**

| Treatment | Pegvaliase Dosage | Duration* |
|---|---|---|
| Induction | 2.5 mg once weekly | 4 weeks |
| Titration | 2.5 mg twice weekly | 1 week |
| | 10 mg once weekly | 1 week |
| | 10 mg twice weekly | 1 week |
| | 10 mg four times per week | 1 week |
| | 10 mg once daily | 1 week |
| Maintenance | 20 mg once daily | 24 weeks |
| Maximum** | 40 mg once daily | 16 weeks*** |

*Additional time may be required prior to each dosage escalation based on patient tolerability.
**Individualize treatment to the lowest effective and tolerated dosage. Consider increasing to a maximum of 40 mg once daily in patients who have not achieved a response (≥20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600 µmol/L) with 20 mg once daily continuous treatment for at least 24 weeks.
***Discontinue pegvaliase treatment in patients who have not achieved a response (≥20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600 µmol/L) after 16 weeks of continuous treatment with the maximum dosage of 40 mg once daily.

References:
1. Vockley J, Andersson HC, Antshel KM, et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. Genet Med. 2014;16(2):188-200. doi:10.1038/gim.2013.157
2. Blau N., Belanger-Quintana A., Demirkol M. Optimizing the use of sapropterin ($BH_4$) in the management of phenylketonuria. *Molecular Genetics and Metabolism* 2009;96:158-163.

*P&T Review:* *9/18 (JP); 5/16; 11/13; 9/13; 7/13*
*Implementation:* *11/1/2018; 8/16; 1/1/14*

# Phosphate Binders and Absorption Inhibitors

**Goal(s):**
- Promote use of preferred drugs for OHP-funded diagnoses.
- Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Non-preferred phosphate binders

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is this an OHP-funded diagnosis? | **Yes:** Go to #3 | **No:** Go to #7 |
| 3. Is the request for an FDA-approved indication? | **Yes:** Go to #4 | **No:** Go to #7 |
| 4. Is the request for tenapanor? | **Yes:** Go to #5 | **No:** Go to #6 |
| 5. Is the request to use tenapanor as add-on therapy to a phosphate binder in an adult with chronic kidney disease receiving dialysis who has had an inadequate response to phosphate binders or who is intolerant of any dose of a phosphate binder? | **Yes:** Approve for 1 year | **No:** Pass to RPh. Deny; medical appropriateness. |
| 6. Has the patient tried or have contraindications to a preferred phosphate binder (i.e., calcium acetate, sevelamer carbonate)? | **Yes:** Approve for 1 year | **No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of preferred phosphate binder product. |

**Approval Criteria**

7. RPh only: All other indications need to be evaluated as to whether use is for an OHP-funded diagnosis.
   - If funded and clinic provides supporting literature, approve for up to 12 months.
   - If not funded:
     - If eligible for EPSDT review; Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? AND
     - Is the request for a preferred product OR has the patient failed to have benefit with, or have contraindications or intolerance to, at least 2 preferred products?
       - Is yes, may approve for up to 12 months.
       - If No, Deny (medical necessity and appropriateness)
     - If member is not eligible for EPSDT review: Deny; not funded by the OHP.

*P&T Review:* *4/24 (DM); 8/21 (DM); 1/16 (AG); 11/12; 9/12; 9/10*
*Implementation:* *5/1/24; 5/1/16; 2/21/13*

# Pimavanserin (Nuplazid™) Safety Edit

**Goals:**

- Promote safe use of pimavanserin in patients with psychosis associated with Parkinson's disease.

**Length of Authorization:**

- Up to 6 months

**Requires PA:**

- Pimavanserin

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is the treatment for hallucinations and/or delusions associated with Parkinson's disease? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Are the symptoms likely related to a change in the patient's anti-Parkinson's medication regimen? | **Yes:** Go to #4<br><br>Consider slowly withdrawing medication which may have triggered psychosis. | **No:** Go to #5 |
| 4. Has withdrawal or reduction of the triggering medication resolved symptoms? | **Yes:** Pass to RPh; Deny; medical appropriateness | **No:** Go to #5 |
| 5. Is the patient on a concomitant first- or second-generation antipsychotic drug? | **Yes:** Pass to RPh; Deny; medical appropriateness | **No:** Go to #6 |
| 6. Has the patient been recently evaluated for a prolonged QTc interval? | **Yes:** Approve for up to 6 months | **No:** Pass to RPh; Deny; medical appropriateness |

*P&T Review:* *8/25 (DM); 8/20 (SF); 3/19; 9/18; 3/18; 01/17*
*Implementation:* *4/1/17*

# Platelet Inhibitors

**Goal:**

- Approve antiplatelet drugs for funded diagnoses which are supported by medical literature.

**Length of Authorization:**

- Up to 12 months.

**Requires PA:**

- Non-preferred drugs

**Covered Alternatives:**

- Preferred alternatives listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Will the prescriber consider a change to a preferred product? | **Yes:** Inform provider of preferred alternatives. | **No:** Go to #3 |
| 3. Is this new therapy for a patient who was hospitalized and had an antiplatelet initiated in the hospital? | **Yes:** Approve for 30 days only and request a PA from the provider for continuation of therapy. | **No:** Go to #4 |
| 4. Is this a request for continuation of therapy for a patient that already received 30 days of therapy that was initiated in the hospital? | **Yes:** Approve for FDA-approved indication for up to 1 year. | **No:** Go to #5 |
| 5. Is the request for ticagrelor? | **Yes:** Go to #6 | **No:** Got to #7 |
| 6. Does the patient have a history of intracranial hemorrhage? | **Yes:** Deny for medical appropriateness | **No:** Approve for FDA-approved indication for up to 1 year. |

| Approval Criteria | | |
|---|---|---|
| 7. Is the request for vorapaxar AND does the patient have a history of stroke, TIA or intracranial hemorrhage? | **Yes:** Deny for medical appropriateness | **No:** Approve for FDA-approved indications for up to 1 year.<br><br>If vorapaxar is requested, it should be approved only when used in combination with aspirin and/or clopidogrel. There is limited experience with other platelet inhibitor drugs or as monotherapy. |

**FDA Approved Indications (April 2021)**

| | 1° Stroke | 2° Stroke | 2° PAD | 1° MI | 2° MI | ACS | |
|---|---|---|---|---|---|---|---|
| | | | | | | No PCI | PCI |
| ASA/DP ER | | x | | | | | |
| clopidogrel | | x | x | | x | x | x |
| ticagrelor | x | x | | x | x | x | x |
| vorapaxar | | CI | x | | x | | |

Abbreviations: 1 $^{o}$ = prevention, 2$^{o}$ = secondary prevention; ACS=Acute Coronary Syndrome; ASA/DP ER = aspirin/dipyridamole; CI=contraindication; PCI=Percutaneous Intervention; X = FDA-approved indication.

*P&T / DUR Review:* *6/21 (KS), 9/17 (MH); 7/15; 11/11*
*Implementation:* *7/1/21; 10/15, 8/15; 7/31/14; 4/9/12*

# Pompe Disease Agents

**Goal(s):**
- Ensure medically appropriate use of approved agents for the treatment of Pompe disease

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Alglucosidase alfa (pharmacy and provider administered claims)
- Avalglucosidase alfa (pharmacy and provider administered claims)
- Cipaglucosidase alfa (pharmacy and provider administered claims)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1: FDA-approved Dosage and Administration**

| Agent | Indication | Age Minimum | Dosing Regimen |
|---|---|---|---|
| **Al**glucosidase alfa | Early Onset Pompe Disease (EOPD)<br>Late Onset Pompe Disease (LOPD) | None | 20 mg/kg IV once every 2 weeks |
| **Aval**glucosidase alfa | Late Onset Pompe Disease (LOPD) | ≥ 1 year | < 30 kg: 40 mg/kg IV once every 2 weeks<br>≥ 30 kg: 20 mg/kg IV once every 2 weeks |
| Cipaglucosidase alfa* | Late Onset Pompe Disease (LOPD) | 18 years or older | <40 kg: not indicated<br>≥40 kg: 20 mg/kg IV once every 2 weeks<br>-plus-<br>Miglustat<br>260 mg orally (≥ 50 kg)<br>-or-<br>195 mg orally (≥40 kg to <50 kg)<br>(administer 1 hour before cipaglucosidase infusion) |

*must be administered with miglustat according to FDA labeled dosing parameters

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the requested agent for an approved indication and dosed appropriately based on age and weight taken within the past month? (**see Table 1**) | **Yes:** Document patient weight and go to #3.<br><br>Weight: _____ | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 3. Is there documentation that the provider has assessed the patient for signs or susceptibility to the following?<br>• Fluid volume overload<br>• Acute underlying respiratory illness<br>• Compromised cardiac or respiratory function necessitating fluid restriction | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the request for continuation of therapy previously approved by FFS? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #5 |
| 5. Is the treatment for the diagnosis of Pompe disease confirmed by either DNA testing or enzyme assay (e.g. acid alpha-glucosidase activity test)? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is this request from a metabolic specialist, biochemical geneticist, or has provider documented experience in the treatment of Pompe disease? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is the request for treatment of late-onset Pompe disease (LOPD)? | **Yes:** Go to #11 | **No:** Go to #8 |
| 8. Has the provider documented a baseline value for ALL the following assessments?<br>• Muscle weakness/Motor function? (e.g. AIMS, PDMS-2, Pompe PEDI, etc)<br>• Respiratory status (e.g. FEV, FVC, or other age-appropriate test of pulmonary function)?<br>• Cardiac imaging (e.g. chest x-ray, echocardiography)?<br>• CRIM status? | **Yes:** Document baseline results and go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Is the patient CRIM-negative? | **Yes:** Go to #10 | **No:** Approve for 3 months<br><br>If approved, a referral will be made to case management by the OHA. |

| Approval Criteria | | |
|---|---|---|
| 10. Is there documentation that concomitant immune tolerance induction (ITI) therapy will be initiated with enzyme replacement therapy (ERT)? | **Yes:** Approve for 3 months | **No:** Pass to RPh. Deny; medical appropriateness |
| 11. Is the request for cipaglucosidase alfa or miglustat for Pompe Disease? | **Yes:** Go to #12 | **No:** Go to #13 |
| 12. Does the provider plan to order combination treatment as outlined in Table 1? | **Yes:** Approve miglustat as combination treatment. Go to #16 | **No:** Pass to RPh. Deny; medical appropriateness |
| 13. Is the patient 5 years of age or older? | **Yes:** Go to #14 | **No:** Go to #15 |
| 14. Is there a baseline documentation for both of the following?<br>• Pulmonary function test (PFT) with spirometry including baseline percent predicted forced vital capacity (FVC)<br>• Demonstration of completed 6-minute walk test (6MWT)<br>-OR-<br>Muscle weakness in the lower extremities? | **Yes:** Approve for 6 months<br><br>Document baseline results.<br><br>If approved, a referral will be made to case management by the OHA. | **No:** Pass to RPh. Deny; medical appropriateness |
| 15. Has the provider documented a baseline value for both of the following assessments:<br>• Muscle weakness/Motor function? (e.g. AIMS, PDMS-2, Pompe PEDI, etc)<br>• Respiratory status (e.g. FEV, FVC, or other age-appropriate test of pulmonary function)? | **Yes:** Approve for 3 months<br><br>Document baseline results.<br><br>If approved, a referral will be made to case management by OHA. | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is there documented evidence of adherence and tolerance to the approved infusion therapy regimen through claims history and/or provider assessment? | **Yes:** Go to #2 | **No:** Pass to RPh, Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 2. Is this a request for **al**glucosidase alfa? | **Yes:** Go to #3 | **No:** Go to #5 |
| 3. Is this the <u>first</u> renewal for **al**glucosidase alfa? | **Yes:** Go to #4 | **No:** Go to #5 |
| 4. Is there documentation that the patient has recently been tested* for IgG antibody formation?<br>** Patients should be monitored for IgG antibody formation every 3 months for 2 years and then annually thereafter per manufacturer labeling.* | **Yes**: Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Compared to baseline measurements, is there documented evidence of improvement or stabilization in muscle, motor, and/or respiratory function? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is patient under 5 years old?<br><br>Note: Approve therapy per Table 1 (including miglustat if appropriate) | **Yes:** Approve for 3 months | **No:** Go to #7 |
| 7. Has the patient received the requested therapy for at least 6 months?<br><br>Note: Approve therapy per Table 1 (including miglustat if appropriate) | **Yes:** Approve for 12 months | **No:** Approve for 3 months |

*P&T/DUR Review: 6/24 (DE); 2/22; 4/21;*
*Implementation: 7/1/24; 4/1/22; 5/1/21*

# Potassium-Competitive Acid Blockers

**Goal(s):**
- Promote use of potassium-competitive acid blockers (PCABs) in adults that is consistent with medical evidence.
- Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**
- Up to 8 weeks for erosive esophagitis healing, up to 24 weeks for maintenance of erosive esophagitis healing, 14 days for treatment of *H.pylori*, and up to 4 weeks for treatment of non-erosive gastrointestinal reflux disease (GERD)

**Requires PA:**
- Vonoprazan (VOQUENZA) oral tablets

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. Recommended Vonoprazan Dose Based on Hepatic Impairment and Indication**

| Classification | Recommended Dosage for Healing of Erosive Esophagitis | Recommended Dosage for Treatment of *H. pylori* infection | Recommended Dosage for Relief of Heartburn Associated with Non-erosive GERD |
|---|---|---|---|
| Child-Pugh Class A | 20 mg once daily | 20 mg twice daily | 10 mg once daily |
| Child-Pugh Class B | 10 mg once daily | Use is not recommended | 10 mg once daily |
| Child-Pugh Class C | 10 mg once daily | Use is not recommended | 10 mg once daily |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this a request for continuation of therapy previously approved by the FFS program? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #4 |
| 3. Is the diagnosis for erosive esophagitis or heartburn associated with nonerosive GERD? | **Yes:** Go to #4 | **No:** Go to #5 |
| 4. Has the patient tried an 8-week course of a proton pump inhibitor (PPI) (e.g. lansoprazole, pantoprazole),<br>AND<br>Do they still have symptoms of erosive esophagitis? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the indication for treatment of *Heliobacter pylori*? | **Yes**: Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 6. Have baseline renal function tests been obtained? | **Yes:** Go to #7. Document results _____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is estimated glomerular filtration rate < 30 mL/min? | **Yes:** Go to #8 | **No:** Go to #9 |
| 8. If the indication is for healing of erosive esophagitis or heartburn associated with nonerosive GERD, is the dose of vonoprazan 10 mg once a day?<br><br>*Note, if GFR < 30 mL/min, vonoprazan is not recommended for treatment of *H. Pylori* | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Have baseline hepatic function tests been obtained? | **Yes:** Go to #10. Document results _____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 10. Does the patient have hepatic impairment (Child-Pugh Class A, B or C)?<br><br>*Child-Pugh score is determined from 5 factors: total bilirubin, serum albumin, prolonged INR, presence of ascites and/or presence of encephalopathy. | **Yes:** Go to #11 | **No:** Approve for the recommended duration of therapy based upon indication.<br>• H. pylori infection: 2 weeks<br>• Healing of erosive esophagitis: 8 weeks |
| 11. Has the vonoprazan dose been adjusted for indication and level of hepatic impairment as outlined in **Table 1**? | **Yes:** Approve for the recommended duration of therapy based upon indication.<br>• *H. pylori* infection: 2 weeks<br>• Healing of erosive esophagitis: 8 weeks<br>• Heartburn associated with nonerosive GERD: 4 weeks | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria |
|---|

| | | |
|---|---|---|
| 1. Is the request to maintain healing of erosive esophagitis and to provide relief of heartburn associated with erosive esophagitis? | **Yes:** Go to #2 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 2. Is the vonoprazan dose 10 mg once a day? | **Yes:** Approve for up to 24 weeks (6 months) for maximum duration therapy of 6 months. | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T/DUR Review: 10/24 (DM)*
*Implementation: 12/1/2024*

# Pregabalin

**Goal(s):**
- Provide coverage only for diagnoses that are supported by the medical literature.

**Length of Authorization:**
- 90 days to lifetime (criteria-specific)

**Requires PA:**
- Pregabalin and pregabalin extended release

**Covered Alternatives**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. Is this a request for renewal of a previously approved prior authorization for pregabalin? | **Yes**: Go to **Renewal Criteria** | **No**: Go to # 2 |
| 2. What diagnosis is being treated? | Record ICD10 code | |
| 3. Is the request for pregabalin immediate release? | **Yes:** Go to #4 | **No:** Go to #5 |
| 4. Does the patient have a diagnosis of epilepsy? | **Yes:** Approve for lifetime | **No:** Go to #5 |
| 5. Is the request for a diagnosis funded by OHP? | **Yes:** Go to #7 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #6 |
| 6. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.)? | **Yes:** Go to #7 | **No:** Pass to RPh; Deny; medical necessity. |
| 7. Is the request for an FDA-approved or evidence-supported diagnosis (see **Table 1** below for examples)? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 8. Is the request for generalized anxiety disorder? | **Yes:** Go to #9 | **No:** Go to #10 |

| Approval Criteria | | |
|---|---|---|
| 9. Has the patient tried and failed to have benefit from, or have a contraindication to, first line treatment with a selective serotonin reuptake inhibitor (SSRI) or serotonin norepinephrine reuptake inhibitor (SNRI)? | **Yes:** Approve for 6 months | **No:** Pass to RPh. Deny; medical appropriateness. |
| 10. Is the patient concurrently on short- or long-acting opioids?<br><br>Note: There is insufficient evidence for use of opioid products (e.g., long-acting opioid with short-acting opioid) in neuropathic conditions. | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #11 |
| 11. Is there documentation that the patient has inadequate response or contraindication to at least 2 non-pharmacologic treatments for the requested condition?<br><br>Relevant treatments may include: acupuncture, supervised exercise therapy, yoga, and meditative movement. | **Yes:** Go to #12 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 12. Has the patient tried and failed, or have contraindications or intolerance to, a preferred gabapentinoid for 90 days? | **Yes**: Approve for 90 days | **No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of a preferred product |

| Renewal Criteria | | |
|---|---|---|
| 1. Does the patient have documented improvement from pregabalin? | **Yes**: Approve for up to 12 months | No: Pass to RPh. Deny; medical appropriateness |

**Table 1. Pregabalin formulations for FDA-approved or evidence-supported indications**

| Condition | Pregabalin | Pregabalin Extended-Release |
|---|---|---|
| Funded | | |
| Diabetic Neuropathy | X | X |
| Postherpetic Neuropathy | X | X |
| Painful Polyneuropathy | X | |
| Spinal Cord Injury Pain | X | |
| Chemotherapy Induced Neuropathy | X | |
| Generalized Anxiety Disorder | X | |
| Nonfunded | | |
| Fibromyalgia | X | |

*P&T Review:* *4/25 (DM); 6/24 (MH); 4/23; 10/22; 10/21; 10/20; 1/19; 7/18; 3/18; 3/17*
*Implementation:* *5/12/25; 7/1/24; 10/1/18; 8/15/18; 4/1/17*

# Proton Pump Inhibitors (PPIs)

**Goals:**

- Promote PDL options
- Restrict PPI use to maximum doses and durations recommended by guidelines.

**Requires PA:**

- Preferred PPIs beyond 68 days' duration
- Non-preferred PPIs

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/
- Individual components for treatment of *H. pylori* that are preferred products

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for a preferred PPI? | **Yes:** Go to #6 | **No:** Go to #3 |
| 3. Will the prescriber consider changing to a preferred PPI product?<br><br>Message: Preferred products are reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&T) Committee. | **Yes:** Inform prescriber of covered alternatives. | **No:** Go to #4 |
| 4. Has the patient already received 68 days of PPI therapy in past year for either of the following diagnoses:<br>• Esophagitis or gastro-esophageal reflux disease with or without esophagitis (K20.0-K21.9); or<br>• Current *H. pylori* infection? | **Yes:** Go to #7 | **No:** Go to #5 |
| 5. Does the patient have recurrent, symptomatic erosive esophagitis that has resulted in previous emergency department visits or hospitalization? | **Yes:** Approve for 1 year | **No:** Go to #6 |

| | | |
|---|---|---|
| 6. Does the patient have a history of gastrointestinal ulcer or bleed and have one or more of the following risk factors?<br>a. Age 65 years or older<br>b. Requires at least 3 months of continuous daily:<br>i. Anticoagulant;<br>ii. Aspirin (all doses) or non-selective NSAID; or<br>iii. Oral corticosteroid | **Yes:** Approve for 1 year | **No:** Go to #7 |
| 7. Are the indication, daily dose and duration of therapy consistent with criteria outlined in **Table 1**? | **Yes:** Approve for recommended duration. | **No:** Pass to RPh. Deny; medical appropriateness<br><br>Message: Patient may only receive 8 weeks of continuous PPI therapy. RPh may approve a quantity limit of 30 doses (not to exceed the GERD dose in the **Table**) over 90 days if time is needed to taper off PPI. Note: No specific PPI taper regimen has proven to be superior. H2RAs may be helpful during the taper. Preferred H2RAs are available without PA. |

**Table 1.** Dosing and Duration of PPI Therapy

| Conditions | Maximum Duration Recommended by Clinical Guidelines | Maximum Daily Dose |
|---|---|---|
| GERD:<br>Esophageal reflux (K219)<br>Esophagitis (K208-K210) | 8 weeks | Dexlansoprazole 30 mg<br>Dexlansoprazole Solu Tab 30 mg<br>Esomeprazole 20 mg<br>Lansoprazole 15 mg<br>Omeprazole 20 mg<br>Pantoprazole 40 mg<br>Rabeprazole 20 mg |
| *H. pylori* Infection (B9681) | 2 weeks | Dexlansoprazole 60 mg<br>Dexlansoprazole 30 mg*<br>Esomeprazole 40 mg<br>Lansoprazole 60 mg<br>Omeprazole 40 mg<br>Pantoprazole 80 mg<br>Rabeprazole 40 mg |
| Duodenal Ulcer (K260-K269) | 4 weeks | |
| Gastric Ulcer (K250-K259) | 8 weeks | |
| Peptic ulcer site unspecified (K270-K279) | 12 weeks | |
| Achalasia and cardiospasm (K220)<br>Barrett's esophagus (K22.70; K22.71x)<br>Dyskinesia of esophagus (K224)<br>Esophageal hemorrhage (K228)<br>Eosinophilic Esophagitis (K200)<br>Gastritis and duodenitis (K2900-K2901; K5281)<br>Gastroesophageal laceration-hemorrhage syndrome (K226)<br>Gastrojejunal ulcer (K280-K289)<br>Malignant mast cell tumors (C962)<br>Multiple endocrine neoplasia [MEN] type I (E3121)<br>Neoplasm of uncertain behavior of other and unspecified endocrine glands (D440; D442; D449)<br>Perforation of Esophagus (K223)<br>Stricture & Stenosis of Esophagus (K222)<br>Zollinger-Ellison (E164) | 1 year | |

* Dexlansoprazole SoluTab 30 mg (given as 2 SoluTabs at once) are not recommended for healing of erosive esophagitis.

*P&T / DUR Review: 10/24 (DM); 10/22; 10/20 (KS), 5/17; 1/16; 5/15; 3/15; 1/13; 2/12; 9/10; 3/10; 12/09; 5/09; 5/02; 2/02; 9/01, 9/98*
*Implementation: 12/1/2024; 1/1/23; 11/1/20; 6/8/16; 2/16; 10/15; 7/15; 4/15; 5/13; 5/12; 1/11; 4/10; 1/10; 9/06, 7/06, 10/04, 3/04*

# Pulmonary Hypertension Agents, Oral/Inhaled

**Goals:**

- Restrict use to appropriate patients with World Health Organization (WHO) Functional Class II-IV symptoms and WHO pulmonary classifications with demonstrated clinical benefit in clinical trials (e.g., pulmonary arterial hypertension (PAH), chronic thromboembolic pulmonary hypertension, or interstitial lung disease).
- Restrict use to conditions covered by the Oregon Health Plan (OHP). Note: erectile dysfunction is not covered by the OHP.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Non-preferred drugs (pharmacy and provider administered claims)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the drug being prescribed by, or in consultation with, a pulmonologist or cardiologist? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is the request for riociguat (Adempas®) or ambrisentan (Letairis®)? | **Yes:** Go to #4 | **No:** Go to #5 |
| 4. Is there documentation that the patient has a medical history of PAH associated with idiopathic interstitial pneumonias or idiopathic pulmonary fibrosis? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #5 |
| 5. Is the patient classified as having World Health Organization (WHO) Functional Class II-IV symptoms? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 6. Is there a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1; ICD10 I27.0)? | **Yes:** Go to #7 | **No:** Go to #8 |
| 7. Will the prescriber consider a change to a preferred product?<br><br>Note: preferred products do not require PA. | **Yes:** Inform prescriber of preferred alternatives in class. | **No:** Approve for 12 months |

| Approval Criteria | | |
|---|---|---|
| 8. Is the request for riociguat in a patient with a diagnosis of chronic thromboembolic pulmonary hypertension (WHO Group 4; ICD10 I27.24)? | **Yes:** Approve for 12 months | **No:** Go to #9 |
| 9. Is the request for nebulized treprostinil (Tyvaso®) in a patient with WHO Group 3 pulmonary hypertension (ICD10 I27.23) and a diagnosis of interstitial lung disease (J84.0-J84.9)?<br><br>Note: treprostinil is not approved in patients with pulmonary hypertension due to chronic obstructive pulmonary disease and may increase risk of exacerbations. | **Yes:** Approve for 12 months | **No:** Go to #10 |
| 10. Is the request for treatment of erectile dysfunction, sexual dysfunction, or infertility? | **Yes:** Pass to RPh; Deny; not covered by OHP. | **No:** Go to #11 |
| 11. RPh Only: For other indications and other types of pulmonary hypertension, prescriber must provide supporting literature for use. | **Yes:** Approve for length of treatment. | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T Review:* *12/24; 10/21 (SS); 9/18; 3/16; 7/14; 3/14; 2/12; 9/10*
*Implementation:* *1/1/25; 1/1/22; 11/1/18; 10/13/16; 5/1/16; 5/14/12; 1/24/12; 1/1/11*

# Pulmonary Arterial Hypertension Agents, Injectable (IV/SC)

**Goals:**

- Restrict use to patients with pulmonary arterial hypertension (PAH) and World Health Organization (WHO) Functional Class III-IV symptoms.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Non-preferred drugs (pharmacy and provider administered claims)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Will the prescriber consider a change to a preferred product?<br><br>Note: preferred products do not require PA. | **Yes:** Inform prescriber of preferred alternatives in class. | **No:** Go to #3 |
| 3. Is there a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1; ICD 10 I27.0)?<br><br>Note: injectable PAH medications are not FDA-approved for other forms of pulmonary hypertension. | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 4. Is the request for a prostanoid or prostacyclin receptor agonist (e.g., treprostinil, epoprostenol, selexipag)? | **Yes:** Go to #5 | **No:** Go to #6 |
| 5. Is the patient classified as having World Health Organization (WHO) Functional Class III-IV symptoms? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 6. Is the request for a patient with World Health Organization (WHO) Functional Class II-IV symptoms? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 7. Is the drug being prescribed by, or in consultation with, a pulmonologist or a cardiologist? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T Review: 12/24 (SS); 10/2; 9/18; 3/16; 9/12*
*Implementation: 1/1/25; 10/13/16; 1/1/13*

# Low Dose Quetiapine

**Goal(s):**
- To promote and ensure use of quetiapine that is supported by the medical literature.
- To discourage off-label use for insomnia.
- Promote the use of non-pharmacologic alternatives for chronic insomnia.

**Initiative:**
- Low dose quetiapine, immediate- and extended-release

**Length of Authorization:**
- Up to 12 months (criteria-specific)

**Requires PA:**
- Quetiapine (HSN = 14015) doses ≤50 mg/day
- For any requests in children ≤6 years of age, see criteria for Antipsychotics in Children
- Auto-PA approvals for people 7 and older:
  - Patients with a claim for a second-generation antipsychotic in the last 6 months
  - Patients with prior claims evidence of schizophrenia or bipolar disorder
  - Prescriptions identified as being written by a mental health provider
  - Extended-release formulations in patients with claims for a selective serotonin reuptake inhibitor or serotonin norepinephrine reuptake inhibitor in the last 90 days

**Covered Alternatives:**
- Preferred alternatives listed at www.orpdl.org/drugs/

**Table 1. Adults (age ≥18 years) with FDA-approved or Compendia-supported Indications**

| | |
|---|---|
| Bipolar Disorder | |
| Major Depressive Disorder (MDD) | Adjunctive therapy with antidepressants for MDD |
| Schizophrenia | |
| Bipolar Mania | |
| Bipolar Depression | |
| Generalized Anxiety Disorder (GAD) | Adjunctive therapy with SSRI/SNRI |

**Table 2. Pediatric FDA-approved indications**

| | | |
|---|---|---|
| Schizophrenia | Adolescents (13-17 years) | |
| Bipolar Mania | Children and Adolescents (10 to 17 years) | Monotherapy |

| Approval Criteria | | |
|---|---|---|
| 1. Is the request for an evidence-supported diagnosis (Table 1 or Table 2)? | **Yes:** Go to #2 | No: Pass to RPh. Deny; medical appropriateness. |
| 2. Is the prescription for quetiapine less than or equal to 50 mg/day? (verify days' supply is accurate) | **Yes**: Go to #3 | **No:** Trouble-shoot claim processing with the pharmacy. |

| Approval Criteria | | |
|---|---|---|
| 3. Is planned duration of therapy (at ≤50 mg) longer than 90 days? | **Yes:** Go to #4 | **No:** Approve for titration up to maintenance dose (60 days). |
| 4. Is reason for dose ≤50 mg/day due to any of the following:<br>• low dose needed due to debilitation from a medical condition or age;<br>• unable to tolerate higher doses;<br>• stable on current dose; or<br>• impaired drug clearance? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Note: may approve up to 6 months to allow taper. |

*P&T/DUR Review:* *8/25; 6/23 (SS); 4/21 (SF); 8/20; 3/19; 9/18; 11/17; 9/15; 9/10; 5/10*
*Implementation:* *7/1/23; 1/1/18; 10/15; 1/1/11*

# Repository Corticotropin Injection

**Goal(s):**

- Restrict use to patient populations in which corticotropin has demonstrated safety and effectiveness.

**Length of Authorization:**

- 4 weeks

**Requires PA:**

- Repository Corticotropin Injection (H.P. Acthar Gel for Injection)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is the diagnosis monotherapy for infantile spasms in infants and children under 2 years of age? | **Yes:** Approve up to 4 weeks (2 weeks of treatment and 2-week taper) | **No:** Go to #3 |
| 3. Is the diagnosis for acute exacerbation or relapse of multiple sclerosis? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Has the patient tried and been unable to tolerate intravenous methylprednisolone or high-dose oral methylprednisolone? | **Yes:** Approve up to 5 weeks (3 weeks of treatment, followed by 2-week taper). | **No:** Go to #5 |

| Approval Criteria | | |
|---|---|---|
| 5. Is the prescription for adjunctive therapy for short-term administration in corticosteroid-responsive conditions, including:<br><br>• The following rheumatic disorders: psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis or ankylosing spondylitis;<br>**OR**<br>• The following collagen diseases: systemic lupus erythematosus or systemic dermatomyositis;<br>**OR**<br>• Dermatologic diseases such as erythema multiforme or Stevens-Johnson syndrome;<br>**OR**<br>• Ophthalmic diseases such as keratitis, iritis, uveitis, optic neuritis, or chorioretinitis;<br>**OR**<br>• For the treatment of respiratory diseases, including symptomatic sarcoidosis or for treatment of an edematous state? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is there a contraindication, intolerance, or therapeutic failure with at least one intravenous corticosteroid? | **Yes:** Approve for 6 months. | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T Review:* *11/16 (DM); 5/13*
*Implementation:* *1/1/17; 1/1/14*

# Resmetirom (REZDIFFRA)

**Goal(s):**
- To ensure appropriate use of resmetirom in patients with nonalcoholic steatohepatitis (NASH)/metabolic dysfunction-associated steatohepatitis (MASH).

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- All pharmacy point-of-sale claims

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this an FDA approved indication and age?<br><br>Note: resmetirom is currently approved for people 18 years and older | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the request for continuation of therapy previously approved by the fee-for-service program? | **Yes:** Go to Renewal Criteria | **No:** Go to #4 |
| 4. Does the patient have a diagnosis of NASH (or MASH) as confirmed by liver biopsy (lifetime)? | **Yes:** Go to #8 | **No:** Go to #5 |
| 5. Is there documentation that the patient does NOT have:<br>• Ongoing or recent (within 2 years) significant alcohol use<br>• Chronic or active viral hepatitis<br><br>Note: significant alcohol use can be patient-specific but is typically defined as greater than 21 drinks/week (or >30 g/day) in men and greater than 14 drinks/week (or >20 g/day) in women. | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 6. Is there provider attestation or documentation that other causes of hepatic steatosis are not suspected based on patient history/presentation or have been ruled out?<br><br>Examples of other secondary causes of hepatic steatosis: Wilson's disease, lipodystrophy, abetalipoproteinemia, medications (e.g., amiodarone, methotrexate, tamoxifen, corticosteroids). | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is there documentation that the patient has, or is receiving drug treatment for, at least 3 of the 5 metabolic risk factors associated with MASH?<br><br>Risk Factors:<br>• Overweight or obesity or increased waist circumference (BMI ≥ 25 kg/m$^2$ or ethnicity adjusted equivalent)<br>• Hypertension<br>• Type 2 diabetes mellitus<br>• Hypertriglyceridemia<br>• Decreased level of high density lipoprotein (HDL) | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Does the patient have fibrosis stage 2 or 3 as shown by appropriate diagnostic test within past 24 months?<br><br>Note: appropriate tests may include biopsy, vibration controlled transient elastography (VCTE), magnetic resonance elastography (MRE), enhanced liver fibrosis test (ELF). | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Is the medication being ordered by, or in consultation with, a hepatologist or gastroenterologist? | **Yes:** Go to #10 | **No:** Pass to RPh. Deny; medical appropriateness |
| 10. Will the patient be engaged in a weight management lifestyle modification program in addition to pharmacotherapy?<br><br>Note: Resmetirom is currently approved in conjunction with diet and exercise | **Yes:** Go to #11 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 11. Does the patient have comorbidities of:<br>• Hypertension OR<br>• Dyslipidemia OR<br>• Overweight with body mass index (BMI) ≥ 25 kg/m$^2$ or Obesity BMI ≥ 30 kg/m$^2$ | **Yes:** Go to #12 | **No:** Go to #13 |
| 12. Is there documentation that the patient is prescribed or has a contraindication to guideline directed medication or lifestyle therapy for <u>each</u> diagnosed comorbidity?<br><br>Example:<br>• Hypertension-blood pressure at goal range or receiving treatment with antihypertensives<br>• Dyslipidemia-lipid panel at goal or receiving statin therapy<br>• Overweight or obesity-lifestyle management and treatment with glucagon-like peptide-1 receptor agonists (GLP-1 RA) | **Yes:** Go to #13 | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Recommend optimize risk factor treatment. Avoid *simultaneous* initiation of treatments with overlapping side effect profile (diarrhea, nausea) as resmetirom (e.g., GLP-1 RA) |
| 13. Does the patient have comorbid type 2 diabetes mellitus? | **Yes:** Go to #16 | **No:** Go to #14 |
| 14. Is there documentation that the patient has been screened for type 2 diabetes mellitus within past 12 months? | **Yes:** Go to #15 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 15. Was the screening for type 2 diabetes mellitus negative?<br><br>Note: screening options include hemoglobin A1c (HbA1c, goal <6.5%), fasting blood glucose (goal <126 mg/dL), or oral glucose tolerance test (goal <200 mg/dL) | **Yes:** Approve for 12 months | **No:** Go to #16 |

| Approval Criteria | | |
|---|---|---|
| 16. Is there documentation that the patient:<br>• Has a HbA1C <7% within past 6 months OR<br>• Is prescribed or has a contraindication to metformin and a glucagon-like peptide 1 (GLP-1) receptor agonist, and a sodium-glucose cotransporter-2 (SGLT2) inhibitor. | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Recommend optimize risk factor treatment. Avoid *simultaneous* initiation of treatments with overlapping side effect profile (diarrhea, nausea) as resmetirom (e.g., metformin or GLP-1 RA) |

| Renewal Criteria | | |
|---|---|---|
| 1. Does the provider attest that the patient remains on, and is adherent to, pharmacotherapeutic or lifestyle therapy for any current metabolic comorbidities? | **Yes:** Go to #2 | **No:** Pass to RPh. Deny; medical appropriateness |
| 2. Does the provider attest that the patient has been adherent to therapy with resmetirom OR is adherence apparent from medication claims history? | **Yes:** Go to #3 | **No:** Pass to RPh. Approve once, for 3 months.<br><br>Request documentation of adherence. |
| 3. Has the patient had a complete metabolic panel, liver enzymes, or other appropriate biochemical or noninvasive imaging test within the past 12 months to assess for potential disease progression?<br><br>Additional example tests: fibrosis-4 index (FIB-4), enhanced liver fibrosis test (ELF), vibration controlled transient elastography (VCTE), magnetic resonance elastography (MRE) | **Yes:** Go to #4 | **No:** Pass to RPh. Approve once, for 3 months.<br><br>Recommend biochemical monitoring. |

| Renewal Criteria | | |
|---|---|---|
| 4. If resmetirom initiation was more than 3 years ago, has the patient had noninvasive imaging (e.g., VCTE or MRE) or repeat liver biopsy to assess for progression of fibrosis in the past 3 years?<br><br>If **not applicable** because resmetirom started less than 3 years ago skip to question #5 | **Yes:** Go to #5 | **No:** Pass to RPh. Approve once, for 3 months.<br><br>Recommend noninvasive imaging or repeat biopsy. |
| 5. Does the patient have evidence of stage F4 fibrosis (cirrhosis) OR has fibrosis stage worsened (e.g., stage F2 to F3) since starting resmetirom. | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #6 |
| 6. Is there documentation of a risk/benefit assessment for ongoing treatment with resmetirom with possible resolution of metabolic comorbidities? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Approve once, for 3 months.<br><br>Recommend provide additional documentation. |

*P&T/DUR Review: 8/24 (SF)*
*Implementation: 9/1/24*

# Rifaximin (Xifaxan®) and Rifamycin (Aemcolo®)

**Goal(s):**

- Promote use that is consistent with medical evidence and product labeling.

**Length of Authorization:**

- 3 days for traveler's diarrhea caused by non-invasive strains of *E. Coli* for rifaximin or rifamycin.
- Up to 12 months for hepatic encephalopathy for rifaximin.
- 14 days for irritable bowel syndrome with diarrhea – may repeat a 14-day course of treatment up to 2 additional times for rifaximin.

**Requires PA:**

- Rifaximin and Rifamycin

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this an FDA approved indication at the FDA-approved dose? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the diagnosis traveler's diarrhea caused by non-invasive strains of *E. Coli*? | **Yes:** Go to #4 | **No:** Go to #6 |
| 4. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products do not require a PA.<br>• Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee.<br>• Preferred products for traveler's diarrhea are dependent on traveler's destination and resistance patterns in that area. Refer to **Table 1** for adult treatment recommendations. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Go to #5 |
| 5. Does the patient have a contraindication or allergy to azithromycin or ciprofloxacin? | **Yes:** Approve at FDA indicated dose and day supply for requested drug (Refer to Table 1). | **No:** Pass to RPh Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 6. Is the request for rifaximin to prevent or treat hepatic encephalopathy? | **Yes**: Go to #7 | **No**: Go to #9 |
| 7. Is the patient currently managed with a regularly scheduled daily regimen of lactulose? | **Yes**: Approve for 12 months | **No**: Go to #8 |
| 8. Does the patient have a contraindication to lactulose?<br><br>Note: studies demonstrate effectiveness of rifaximin as add-on therapy to lactulose. | **Yes**: Approve for 12 months | **No**: Pass to RPh Deny; medical appropriateness |
| 9. Is the request for rifaximin to treat irritable bowel syndrome with diarrhea?<br><br>Note: Medications to treat IBS-D are only FDA-approved in adults | **Yes:** Not eligible for EPSDT review: Pass to RPh. Deny; diagnosis not covered by OHP.<br><br>Eligible for EPSDT review: Approve for 14-day course of therapy. for a total 3 courses in one year. | **No**: Pass to RPh: Deny; medical appropriateness. |

**Table 1. CDC Acute Traveler's Diarrhea Antibiotic Treatment Recommendations[1]**

| Antibiotic | Dose | Duration | Notes |
|---|---|---|---|
| Azithromycin | 1000 mg | Single or Divided dose | • Use empirically as first-line treatment for travelers' diarrhea in Southeast Asia or other areas if fluoroquinolone- resistant bacteria are suspected.<br>• Preferred treatment for dysentery or febrile diarrhea. |
| Azithromycin | 500 mg once daily | 3 days | |
| Ciprofloxacin | 750 mg | Single Dose | • If symptoms are not resolved after 24 hours, continue daily dosing for up to 3 days. |
| Ciprofloxacin | 500 mg once daily | 3 days | |
| Levofloxacin | 500 mg once daily | 1-3 days | • If symptoms are not resolved after 24 hours, continue daily dosing for up to 3 days. |
| Ofloxacin | 400 mg BID | 1-3 days | • If symptoms are not resolved after 24 hours, continue daily dosing for up to 3 days. |
| Rifamycin | 388 mg BID in adults | 3 days | • Do not use if clinical suspicion for *Campylobacter*, *Salmonella*, *Shigella*, or other causes of invasive diarrhea. Use may be reserved for patients unable to receive azithromycin or fluoroquinolones. |
| Rifaximin | 200 mg TID in patients 12 years and older | 3 days | |

Abbreviations: BID = twice daily; CDC = Centers for Disease Control and Prevention; QDay = once daily; TID = three times daily

1. Center for Disease Control. The Yellow Book, Chapter 2: Traveler's Diarrhea. https://wwwnc.cdc.gov/travel/yellowbook/2018/the-pre-travel-consultation/travelers-diarrhea. Accessed 11/4/24.

# Risperdal® Consta® Quantity Limit

**Goal(s):**

- To ensure the use of the appropriate billing quantity. This is a quantity initiative, **not a clinical initiative**. The vial contains 2 mL. The dispensing pharmacy must submit the quantity as 1 vial and not 2 mL.

**Length of Authorization:**

- Date of service or 12 months, depending on criteria

**Requires PA:**

- Risperdal® Consta®

| Approval Criteria | | |
|---|---|---|
| 1. Is the quantity being submitted by the pharmacy expressed correctly as # syringes? | **Yes:** Go to #2 | **No:** Have pharmacy correct to number of syringes instead of number of mL. |
| 2. Is the amount requested above 2 syringes per 18 days for one of the following reasons?<br>• Medication lost<br>• Medication dose contaminated<br>• Increase in dose or decrease in dose<br>• Medication stolen<br>• Admission to a long-term care facility<br>• Any other reasonable explanation? | **Yes:** Approve for date of service only (use appropriate PA reason) | **No:** Go to #3 |
| 3. Is the pharmacy entering the dose correctly and is having to dispense more than 2 syringes per 18 days due to the directions being given on a weekly basis instead of every other week. | **Yes:** Approve for 1 year (use appropriate PA reason) | Note: This medication should NOT be denied for clinical reasons. |

*P&T Review:* *8/25 (DM); 10/23; 2/22; 9/18; 9/17; 9/16; 5/05*
*Implementation:* *10/13/16; 11/18/04*

# Roflumilast, Oral

**Goals:**

- Decrease the number of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and with a history of exacerbations.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Oral roflumilast (Daliresp®) tablets.
- topical roflumilast (Zoryve®) is subject to separate clinical PA criteria.

**Covered Alternatives:**

- Preferred alternatives listed at http://www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is this a request for continuation of therapy previously approved by the FFS program? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Does the patient have documented severe or very severe COPD (e.g., $FEV_1$ of ≤ 50% predicted)? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny for medical appropriateness |
| 4. Does the patient have a diagnosis of chronic bronchitis (ICD10 J410-J42; J440-J449)? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny for medical appropriateness |
| 5. Does the patient have documented prior COPD exacerbations? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny for medical appropriateness |
| 6. Does the patient have an active prescription for a long-acting bronchodilator (long-acting anticholinergic agent or long-acting beta-agonist) and inhaled corticosteroid (ICS)? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; recommend trial of preferred long-acting bronchodilator and ICS |
| 7. Is the prescriber a specialist in respiratory medicine or is the request in consultation with a specialist? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny for medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Does the provider attest that the patient's condition improved with roflumilast treatment? | **Yes:** Approve for 12 months. | **No:** Pass to RPh. Deny for medical appropriateness |

*P&T/DUR Review:* *12/24 (DM); 10/20 (KS), 9/15; 5/13; 2/12*
*Implementation:* *1/1/25; 11/1/20; 10/15; 1/14; 5/12*

# Sacubitril/Valsartan (Entresto™)

**Goal(s):**
- Restrict use of sacubitril/valsartan in populations and at doses in which the drug has demonstrated efficacy.
- Encourage use of beta-blockers with demonstrated evidence of mortality reduction in heart failure with reduced ejection fraction.

**Length of Authorization:**
- 3 to 12 months

**Requires PA:**
- Sacubitril/valsartan (Entresto™)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. Is this a request for continuation of therapy previously approved by the FFS program? | **Yes:** Go to Renewal Criteria | **No:** Go to #2 |
| 2. What diagnosis is being treated? | Record ICD10 code. Go to #3 | |
| 3. Does the patient have chronic heart failure (New York Heart Association [NYHA] Class II-IV)? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the patient 17 years of age or younger? | **Yes:** Go to #5 | **No:** Go to # 7 |
| 5. Does the patient have left ventricular systolic dysfunction (ejection fraction less than 40% (LVEF ≤ 40%)? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is the medication prescribed by or in consultation by a cardiologist or heart failure provider? | **Yes:** Approve for 3 months | **No:** Pass to RPh. Deny, medical appropriateness |
| 7. Has the patient tolerated a minimum daily dose an ACE-inhibitor or ARB listed in Table 1 for at least 30 days?<br><br>*Note: ACE inhibitors must be discontinued at least 36 hours prior to initiation of sacubitril/valsartan* | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 8. Does the patient have heart failure with reduced ejection fraction less than 40% (LVEF ≤ 40%)? | **Yes:** Go to #9 | **No:** Approve for 3 months<br><br>*Note: Benefits of therapy are most clearly evident in patients with left ventricular ejection fraction below normal. Use judiciously with higher baseline ejection fraction* |
| 9. Is the patient currently on a maximally tolerated dose of carvedilol, sustained-release metoprolol succinate, or bisoprolol; and if not, is there a documented intolerance or contraindication to each of these beta-blockers?<br><br>*Note: the above listed beta-blockers have evidence for mortality reduction in chronic heart failure at target doses and are recommended by heart failure guidelines.[1,2] Carvedilol and metoprolol succinate are preferred agents on the PDL.* | **Yes:** Go to #10 | **No:** Pass to RPh. Deny, medical appropriateness |
| 10. Is there evidence of adherence and tolerance to goal directed heart failure therapy (beta-blocker and ACE-I/ARB) through pharmacy claims/refill history and provider assessment? | **Yes:** Approve for 3 months | **No:** Pass to RPh. Deny, medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the patient 18 years or older or at least 50 kg? | **Yes:** Go to #2 | **No:** Go to #3 |
| 2. Is the patient currently taking sacubitril/valsartan at the target dose of 97/103 mg 2-times daily to a maximum dose as tolerated by the patient? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh and go to #4 |
| 3. Is the patient currently taking sacubitril/valsartan at the target dose in Table 2 or to a maximum dose as tolerated by the patient? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh and go to #4 |

| Renewal Criteria | |
|---|---|
| 4. What is the clinical reason the drug has not been titrated to the target dose? | Document rationale and approve for up to 90 days. Prior authorization required every 90 days until target dose achieved. |

**Table 1. Minimum Daily Doses of ACE-inhibitors or ARBs Required.[1,2]**

| ACE-inhibitor | | Angiotensin-2 Receptor Blocker (ARB) | |
|---|---|---|---|
| Captopril | 100 mg/day | Candesartan | 16 mg/day |
| Enalapril | 10 mg/day | Losartan | 50 mg/day |
| Lisinopril | 10 mg/day | Valsartan | 160 mg/day |
| Ramipril | 5 mg/day | Olmesartan | 10 mg/day |
| Trandolapril | 2 mg/day | Irbesartan | 150 mg/day |
| Fosinopril | 20 mg/day | | |

Abbreviations: BID = twice daily; QDay = once daily; mg = milligrams; TID = three times daily.

Notes:

- Patients must achieve a minimum daily dose of one of the drugs listed for at least 30 days to improve chances of tolerability to the target maintenance dose of sacubitril/valsartan 97/103 mg 2-times daily.[3]
- Valsartan formulated in sacubitril valsartan 97/103 mg 2-times daily is bioequivalent to valsartan 160 mg 2-times daily.[4]
- It is advised that patients previously on an ACE-inhibitor have a 36-hour washout period before initiation of sacubitril/valsartan to reduce risk of angioedema.[3,4]

**Table 2: Target dose of sacubitril/valsartan in pediatric heart failure[4]**

| Population | Target Dose |
|---|---|
| Patients less than 40 kg | 3.1 mg/kg twice daily |
| Patients at least 40 kg, less than 50 kg | 72/78 mg twice daily |
| Patients at least 50 kg | 97/103 mg twice daily |

References:

1. Yancy CW, Jessup M, Bozkurt B, et al. 2017 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. *Circulation* 2017;136(6):e137-e161.
2. McMurray J, Adamopoulos S, Anker S, et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012. European Journal of Heart Failure. 2012;14:803-869. doi:10.1093/eurjhf/hfs105.
3. McMurray J, Packer M, Desai A, et al. Angiotensin-neprilysin inhibition versus enalapril in heart failure. *N Eng J Med*. 2014;371:993-1004. doi:10.1056/NEJMoa1409077.
4. ENTRESTO (sacubitril and valsartan) [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals, February 2021.

*P&T / DUR Review:* *6/21(MH); 05/17(DM), 09/15*
*Implementation:* *7/1/21; 10/13/16; 10/1/15*

# Sedatives

**Goals:**

- Restrict use of sedatives to OHP-funded conditions, with individual review for individuals covered under the EPSDT program. Long-term treatment of insomnia with sedatives is not funded.
- Encourage use of cognitive behavioral therapy for insomnia.
- Prevent concomitant use of sedatives, including concomitant use with benzodiazepines or opioids.
- Limit daily zolpidem dose to the maximum recommended daily dose by the FDA.
- Permit use of melatonin in children and adolescents 18 years of age or younger.

**Length of Authorization:**

- Up to 12 months or lifetime (criteria-specific)

**Requires PA:**

- All sedatives (e.g., sedative hypnotics, hypnotics-melatonin agonists) except melatonin in children and adolescents. Melatonin is not covered for adults over 18 years of age.

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Zolpidem Daily Quantity Limits

| Generic | Brand | Max Daily Dose |
|---|---|---|
| **Zolpidem** | Ambien | 10 mg |
| **Zolpidem ER** | Ambien CR | 12.5 mg |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for melatonin in an adult over 18 years of age? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #3 |
| 3. Is the request for zolpidem at a higher dose than listed in the quantity limit chart? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #4 |
| 4. Is the request for a non-preferred product and will the prescriber consider a change to a preferred product?<br><br>Message: Preferred products are evidence-based and reviewed for comparative effectiveness and safety by the P&T Committee. | **Yes:** Inform prescriber of preferred alternatives in class. Go to #5 | **No:** Go to #5 |

| Approval Criteria | | |
|---|---|---|
| 5. Is the patient being treated under palliative care services (ICD10 Z51.5) with a life-threatening illness or severe advanced illness expected to progress toward dying? | **Yes:** Approve for 5 years | **No:** Go to #6 |
| 6. Has the patient been treated with a different non-benzodiazepine sedative, benzodiazepine, or opioid within the past 30 days? | **Yes:** Go to #7 | **No:** Go to #9 |
| 7. Is this a switch in sedative therapy due to intolerance, allergy or ineffectiveness? | **Yes:** Go to #9. Document reason for switch. | **No:** Go to #8 |
| 8. Is concurrent sedative therapy part of a plan to switch and taper off a long-acting benzodiazepine (such as diazepam, clonazepam, or chlordiazepoxide) AND has the provider included a detailed strategy to taper?<br><br>Note: a documented taper strategy should include planned dose reductions and length of time between each dose modification for at least the next few weeks. It should also include a documented follow-up plan to monitor progress and manage withdrawal symptoms (regular check-ins are essential for a successful taper). Triazolam may be discontinued without a taper in most cases (2-hour half-life prevents physical dependence). | **Yes:** Approve duplicate benzodiazepine therapy for the duration specified in the taper plan (not to exceed 6 months). | **No:** Pass to RPh. Deny; medical appropriateness. |
| 9. Does the patient have a diagnosis of insomnia with obstructive sleep apnea? | **Yes:** Go to #10 | **No:** Go to #11 |
| 10. Is the patient on CPAP? | **Yes:** Go to # 11 | **No:** Pass to RPh. Deny; medical appropriateness. Sedative/hypnotics are contraindicated due to depressant effect. |
| 11. Is the request for treatment of insomnia? | **Yes:** Go to #12 | **No:** Go to #13 |

| Approval Criteria | | |
|---|---|---|
| 12. Is the patient currently engaged in cognitive behavioral therapy focused on insomnia treatment (CBT-I), failed to have benefit in symptoms after 5-6 CBT interventions, OR have inability to access CBT-I? | **Yes: First request** Sedative treatment can be approved for 30 days. Long-term treatment must document that benefits outweigh risks.<br><br>**Subsequent request:** Go to **Renewal Criteria** | **No:** Pass to RPh. Deny; medical appropriateness. |
| 13. RPh only: Is diagnosis being treated a funded condition and is there medical evidence of benefit for the prescribed sedative? | **Yes:** Document supporting literature and approve 30 days with subsequent approvals dependent on follow-up and documented response. | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #14 |
| 14. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #15<br><br>Document baseline severity | **No:** Pass to RPh. Deny; medical necessity. |
| 15. Is the request for a melatonin agonist (e.g., melatonin, ramelteon, tasimelteon) for treatment of one of the following circadian rhythm sleep-wake disorders:<br>• People with delayed sleep-wake phase disorder<br>• Adults with non-24 hour sleep-wake disorder<br>• Children and adolescents with neurologic disorders and irregular sleep-wake rhythm disorder? | **Yes:** Approve for approve 30 days with subsequent approvals dependent on follow-up and documented response. | **No:** Pass to RPh. Deny; medical appropriateness. |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the request for a slow taper plan? | **Yes:** Approve for duration of taper (not to exceed 3 months). Subsequent requests should document progress toward discontinuation | **No:** Go to #2 |

| Renewal Criteria | | |
|---|---|---|
| 2. Is the request for treatment of an unfunded condition previously approved by FFS? | **Yes:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #3 | **No:** Go to #4 |
| 3. Is there documentation of improvement (e.g., of symptoms, function, quality of life, etc) since treatment was started? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 4. Is there documentation based on medical records that the patient and provider have discussed whether benefits of ongoing therapy (hospitalizations, function, quality of life) continue to outweigh risks (memory problems, dementia, cognitive impairment, daytime sedation, falls, fractures, dependence, and reduced long-term efficacy)? | **Yes:** Approve for 3 months | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T/DUR Review:* *12/22 (SS); 8/22; 12/20; 7/18; 3/17; 11/14, 3/14, 5/06, 2/06, 11/05, 9/05, 2/04, 2/02, 9/01*
*Implementation:* *1/1/24; 10/1/22; 1/1/21; 8/15/18; 1/1/15, 7/1/14; 1/1/07, 7/1/06, 11/15/05*

# Segesterone acetate and ethinyl estradiol yearly vaginal system (Annovera®)

**Goal(s):**

- To reduce waste associated with confusion between monthly and yearly vaginal birth control ring systems.

**Length of Authorization:**

- Up to 11 months

**Requires PA:**

- Any 2nd refill request (3rd total request) within any 12 month time period at pharmacy point of sale.

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. Has the provider attested that the patient has been counseled on the appropriate use, storage, and duration of use of this product since the most recent prescription fill? (include date of counseling)<br><br>Note: Product should be used continuously for 21 days followed by a 7 day ring free interval. One ring is effective for 13 total 28-day cycles (1 year). | **Yes**: Approve single ring for 11 months.<br><br>Previous fill date_____<br><br>Date of new counseling_____ | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 10/22 (SF)*
*Implementation: 1/1/23*

# Sodium-Glucose Cotransporter-2 Inhibitors (SGLT-2 Inhibitors)

**Goal(s):**
- Promote cost-effective and safe step-therapy for management of type 2 diabetes mellitus (T2DM).

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- All non-preferred SGLT-2 inhibitors require a PA

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. FDA Approved Indications of SGLT2 Inhibitors***

| Indication | Bexagliflozin | Canagliflozin | Dapagliflozin | Empagliflozin | Ertugliflozin | Sotagliflozin |
|---|---|---|---|---|---|---|
| **Adults with Type 2 Diabetes Mellitus** | | | | | | |
| Glucose lowering | X | X | X | X | X | |
| Heart failure | | X | X | X | | X |
| Kidney disease | | X | X | X | | X |
| **Children with Type 2 Diabetes Mellitus** | | | | | | |
| Patients 10 years and older | | X | | X | | |
| **Adults without Diabetes Mellitus** | | | | | | |
| Heart failure | | | X | X | | X |
| Kidney disease | | | X | X | | |
| * FDA indications are current as of November 2024 | | | | | | |

| Approval Criteria | | |
|---|---|---|
| 1. What is the diagnosis being treated? | Record ICD10 code | |
| 2. Will the prescriber consider switching to a preferred product?<br><br>Message:<br>• Preferred products do not require a PA.<br>Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Go to #3 |
| 3. Does the patient have type 2 diabetes? | **Yes:** Approve for up to 12 months | **No:** Go to #4 |

| Approval Criteria | | |
|---|---|---|
| 4. Does the patient have heart failure and is requesting an SGLT-2 inhibitor with demonstrated cardiovascular benefit (see Table 1 above)? | **Yes:** Approve for up to 12 months | **No:** Go to #5 |
| 5. Does the patient have chronic kidney disease and is requesting an SGLT-2 inhibitor with demonstrated renal and cardiovascular benefits (see Table 1 above)? | **Yes:** Approve for up to 12 months | **No: No:** Pass to RPh. Deny; medical appropriateness |

*P&T Review:* *2/25 (KS), 10/23 (KS), 10/22 (KS), 8/21 (KS), 8/20 (KS), 6/20, 7/18, 9/17; 9/16; 3/16; 9/15; 1/15; 9/14; 9/13*
*Implementation:* *11/1/23; 1/1/23; 9/1/20; 8/15/18; 10/13/16; 2/3/15; 1/1/14*

# Sickle Cell Disease, Gene Therapy

**Goal(s):**
- Approve Exagamglogene autotemcel (CASGEVY) and Lovotibeglogene autotemcel (LYFGENIA) for conditions supported by evidence of benefit

**Length of Authorization:**
- Once in a lifetime dose.

**Requires PA:**
- Exagamglogene autotemcel (billed as pharmacy or provider administered claim)
- Lovotibeglogene autotemcel (billed as pharmacy or provider administered claim)

**Covered Populations:**
- FFS and CCO enrolled populations beginning 1/1/26

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria for Sickle Cell Disease | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code.<br>• For sickle cell disease, continue to question #2<br>• For beta thalassemia and patient is enrolled in fee-for-service, go to "Approval Criteria for Beta Thalassemia" section below;<br>• For beta thalassemia and patient is enrolled in a coordinated care organization (CCO), request should be directed to that CCO. | |
| 2. Is this an FDA approved indication? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is there documentation that the patient has never received another gene therapy or hematopoietic stem cell transplant for any diagnosis? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the medication being ordered by, or in consultation with, a hematologist? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria for Sickle Cell Disease | | |
|---|---|---|
| 5. Does the patient have Sickle Cell Disease with recurrent vaso-occlusive crisis (VOC)?<br><br>Note: Recurrent VOC defined as at least 4 or moreVOC events in previous 24 months or receiving chronic transfusion therapy for recurrent VOC based on provider attestation. If lacking provider attestation, documentation of VOCs could include, but are not limited to, acute chest syndrome, priapism lasting > 2 hours and requiring visit to medical facility, acute pain event requiring visit to medical facility (with pain medications [e.g. opioids, injectable non-steroidal anti-inflammatory drugs] or red blood transfusion), acute splenic sequestration, or acute hepatic sequestration. | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is the patient 12 years old or older? | **Yes**: Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Does the prescriber attest that the patient's general health and comorbidities have been assessed and that the patient is expected to safely tolerate myeloablation? | **Yes**: Approve for one-time infusion treatment for lifetime of the patient. Approval is valid for 12 months and will be extended if needed to cover treatment journey.<br><br>Notify DMAP of approval. | **No:** Pass to RPh. Deny; medical appropriateness<br><br>Notify DMAP of denial. |

| Approval Criteria for Beta Thalassemia | | |
|---|---|---|
| 1. Is this an FDA approved indication? | **Yes**: Go to #2 | **No:** Pass to RPh. Deny; medical appropriateness |
| 2. Is there documentation that the patient has never received another gene therapy or hematopoietic stem cell transplant for any diagnosis? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the medication being ordered by, or in consultation with, a hematologist? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria for Beta Thalassemia | | |
|---|---|---|
| 4. Does patient have confirmed beta thalassemia? | **Yes**: Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the patient transfusion dependent, defined as requiring in each of the past 2 years:<br>• 100 mL/kg/year or more of packed red blood cells (any patient age) OR<br>• 8 transfusions or more of packed red blood cells per year | **Yes**: Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is the patient 12 years old or older? | **Yes**: Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is there documentation that the patient does not have cirrhosis or advanced liver disease? | **Yes**: Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Is there documentation that the patient does not have HIV or active infections (acute or chronic) of either hepatitis B or hepatitis C? | **Yes**: Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Does the prescriber attest that the patient's general health and comorbidities have been assessed and that the patient is expected to safely tolerate myeloablation? | **Yes**: Go to #10 | **No:** Pass to RPh. Deny; medical appropriateness |
| 10. Is the patient of childbearing potential OR capable of fathering a child? | **Yes:** Go to #11 | **No:** Go to #13 |
| 11. Is the patient pregnant, actively trying to conceive, or trying to father a child? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #12 |
| 12. Is there documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant or father a child during treatment and for at least 6 months after administration of the gene therapy? | **Yes:** Go to #13 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria for Beta Thalassemia | | |
|---|---|---|
| 13. Is there documentation that the provider and patient have discussed risks of myeloablative treatment on future fertility and options for fertility-preservation? | **Yes:** Approve for one-time infusion treatment for lifetime of the patient.<br><br>Approval is valid for 12 months and will be extended if needed to cover treatment journey. | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 8/25; 6/24 (SF)*
*Implementation: 9/15/25; 7/1/24*

# Sickle Cell Anemia Drugs

**Goal(s):**

- Approve the use of drugs for sickle cell disease for medically appropriate.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Non-preferred drugs or non-preferred formulations (pharmacy administered claims)
- Crizanlizumab (pharmacy or provider administered claims)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this an FDA-approved indication? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is this a renewal request for voxelotor, crizanlizumab or l-glutamine (ENDARI)? | **Yes:** Go to renewal criteria below. | **No:** Go to #4 |
| 4. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products/formulations do not require PA.<br>• Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Go to #5 |
| 5. Has the patient received a 3-month trial of hydroxyurea at stable doses or have contraindications to hydroxyurea? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; Recommend trial of hydroxyurea (stable dose for 3 months) |
| 6. Is the request for voxelotor and the patient is 4 years or older? | **Yes:** Go to #7 | **No:** Go to #8 |
| 7. Does the patient have a hemoglobin level of 10.5 g/dL or less? | **Yes:** Approve for up to 6 months. Record baseline hemoglobin value. | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 8. Is the request for crizanlizumab and the patient is 16 years or older? | **Yes:** Go to #9 | **No:** Go to #10 |
| 9. Has the patient had at least 2 pain crises in the last 12 months? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny; medical appropriateness |
| 10. Is the request for L-glutamine (ENDARI) and the patient is 5 years or older? | **Yes:** Go to #11 | **No:** Pass to RPh. Deny; medical appropriateness |
| 11. Has the patient had at least 2 pain crises in the last 12 months? | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the request for a first renewal of voxelotor? | **Yes**: Go to #2 | **No:** Go to #4 |
| 2. Has the patient had an increase in hemoglobin from baseline hemoglobin level since starting voxelotor? | **Yes:** Approve for up to 12 months. | **No:** Go to #3 |
| 3. Is the request for subsequent renewals (renewals beyond the first year) of voxelotor and the patient has stable hemoglobin levels? | **Yes:** Approve for up to 12 months. | **No:** Pass to RPh. Deny; medical appropriateness. |
| 4. Is the request for renewal of crizanlizumab? | **Yes**: Go to #5 | **No:** Go to #6 |
| 5. Has the patient demonstrated improvements in pain symptoms from baseline since starting crizanlizumab treatment? | **Yes:** Approve for up to 12 months. | **No:** Pass to RPh. Deny; medical appropriateness. |
| 6. Is the request for a renewal of L-glutamine (ENDARI)? | **Yes:** Go to #7 | **No:** See above for initial approval criteria. |
| 7. Has the patient demonstrated improvements in pain symptoms from baseline since starting L-glutamine treatment? | **Yes:** Approve for up to 12 months. | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T/DUR Review: 4//22 (KS), 6/20 (KS)*
*Implementation: 5/1/22; 7/1/20*

# Skeletal Muscle Relaxants

**Goal(s):**

- Cover non-preferred drugs only for funded conditions.
- Restrict carisoprodol to short-term use due to lack of long-term studies to assess safety or efficacy and high potential for abuse.

**Length of Authorization:**

- Up to 3 - 6 months

**Requires PA:**

- Non-preferred agents

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is the diagnosis funded by the Oregon Health Plan? | **Yes:** Go to #4 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #3 |
| 3. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical necessity. |
| 4. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products do not require PA<br>• Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&T) Committee. | **Yes:** Inform prescriber of covered alternatives in class | **No:** Go to #5 |

| Approval Criteria | | |
|---|---|---|
| 5. Is drug requested carisoprodol? | **Yes:** Go to #6 | **No:** Approve for up to 3 months |
| 6. Has an opioid been prescribed within the past 30 days? | **Yes:** Deny; medical appropriateness | **No:** Go to #7 |
| 7. Does total quantity of carisoprodol exceed 56 tablets in 90 days?<br><br>From claims, document product, dose, directions, and amount used during last 90 days. | **Yes:** Go to #8 | **No:** Approve for up to 3 months |
| 8. Does patient have a terminal illness (e.g. metastatic cancer, end stage Parkinson's disease, ALS)? | **Yes:** Approve for 6 months. | **No:** Pass to RPh. Go to #9 |
| 9. Pharmacist's statement:<br><br>• Carisoprodol cannot be approved for long term usage.<br>• Patients are limited to 56 tablets in a 90 day period.<br>• It is recommended that the patient undergo a "taper" of the carisoprodol product of which a supply may be authorized for this to occur.<br>• The amount and length of taper depends upon the patient's condition. Does the patient meet one or more of the following:<br>  ○ >65 years of age; or<br>  ○ renal failure; or<br>  ○ hepatic failure; or<br>  ○ take > 1400 mg per day? | **Yes:** Document reason and approve long taper:<br><br>• Authorize 18 tablets<br>• Reduce dose over 9 days<br>• 350 mg TID X 3 days, then<br>• 350 mg BID X 3 days, then<br>• 350 mg daily x 3 days then evaluate | **No:** Approve short taper:<br><br>• Authorize 10 tablets<br>• Reduce dose over 4 days<br>• 350 mg TID x 1 day, then<br>• 350 mg BID x 2 days, then<br>• 350 mg daily x1 day, then evaluate |

*P&T Review:* *9/19 (KS); 3/17 (DM); 3/17; 11/14; 9/09; 2/06; 2/04; 11/01; 2/01; 9/00; 5/00; 2/00*
*Implementation:* *4/1/17; 1/1/15, 1/1/14, 1/1/10, 11/18/04*

# Sleep-Wake Medications

**Goal(s):**
- To promote safe use of drugs for obstructive sleep apnea and narcolepsy.
- Limit use to diagnoses where there is sufficient evidence of benefit and uses that are funded by OHP. Excessive daytime sleepiness related to shift-work is not funded by OHP. Accommodate individual review for individuals under the EPSDT program.
- Limit use to safe doses.

**Length of Authorization:**
- Initial approval of 90 days if criteria met; approval of up to 12 months with documented benefit

**Requires PA:**
- Modafinil or armodafinil without previous claims evidence of narcolepsy
- Solriamfetol
- Pitolisant

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. Funded and Evidence-Supported Indications.**

| Indication | Modafinil (Provigil™) | Armodafinil (Nuvigil™) | Solriamfetol (Sunosi™) | Pitolisant (Wakix™) |
|---|---|---|---|---|
| • Excessive daytime sleepiness in narcolepsy | X | X | X | X |
| • Residual excessive daytime sleepiness in obstructive sleep apnea patients treated with CPAP | X | X | X | Not FDA approved; insufficient evidence |
| • Depression augmentation (unipolar or bipolar I or II acute or maintenance phase)<br>• Cancer-related fatigue<br>• Multiple sclerosis-related fatigue | X | Not FDA approved; insufficient evidence | | |
| • Drug-related fatigue<br>• Excessive daytime sleepiness or fatigue related to other neurological disorders (e.g. Parkinson's Disease, traumatic brain injury, post-polio syndrome)<br>• ADHD<br>• Cognition enhancement for any condition | Not FDA approved; insufficient evidence | | | |

**Table 2. Maximum Recommended Dose (consistent evidence of benefit with lower doses).**

| Generic Name | Minimum Age | Maximum FDA-Approved Daily Dose |
|---|---|---|
| Armodafinil | 18 years | 250 mg |
| Modafinil | 18 years | 200 mg |
| Solriamfetol | 18 years | 150 mg |
| Pitolisant | 6 years | 17.8 mg (poor CYP2D6 metabolizers) |

**Table 3. Recommended safety assessments**

| Modafinil or Armodafinil | Solriamfetol | Pitolisant |
|---|---|---|
| For people of childbearing potential, documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant. | Renal assessment. Dose adjustment is recommended for moderate impairment (EGFR <60 mL/min) and use in end stage renal disease is not recommended. | Renal assessment. Dose adjustment is recommended for moderate renal (EGFR <60 mL/min) and use in end stage renal disease is not recommended. |
| | Recent cardiovascular risk assessment (including blood pressure) within the past 3 months. Use of solriamfetol is not recommended in patients with uncontrolled hypertension or serious heart problems. | |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this a funded diagnosis?<br><br>Non-funded diagnoses:<br>• Shift work disorder (ICD10 G4720-4729; G4750-4769; G478)<br>• Unspecified hypersomnia (ICD10 G4710) | **Yes:** Go to #4 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #3 |

| Approval Criteria | | |
|---|---|---|
| 3. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc) despite lifestyle modifications (e.g., strategic bright light receipt or avoidance, sleep hygiene, dietary changes, etc)? | **Yes:** Document symptom severity. Go to #4<br><br>Evidence supports modafinil and armodafinil in moderate-severe shift work disorder (e.g., sleep latency ≤ 6 minutes) and risks likely outweigh benefits in patients with mild symptoms. | **No:** Pass to RPh. Deny; medical necessity |
| 4. Is the requested medication for an FDA-approved age (Table 2) and evidence-supported indication (Table 1)? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness. Providers for patients 7 to 17 years of age may also submit a request for sodium oxybate as it is FDA-approved for narcolepsy in this age group. |
| 5. Is the request for continuation of therapy at maintenance dosage previously approved by the FFS program? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #6 |
| 6. Is the drug prescribed by or in consultation with an appropriate specialist for the condition (e.g., sleep specialist, neurologist, or pulmonologist)? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Will prescriber consider a preferred alternative? | **Yes:** Inform prescriber of preferred alternatives (e.g., preferred methylphenidate) | **No:** Go to #8 |
| 8. Is the prescribed daily dose higher than recommended in Table 2? | **Yes:** Go to #9 | **No:** Go to #11 |
| 9. Is the request for modafinil 200 mg twice daily (total daily dose of 400 mg) with documentation of inadequate symptom improvement with lower doses? | **Yes:** Go to #11 | **No:** Go to #10 |

| Approval Criteria | | |
|---|---|---|
| 10. Is the request for pitolisant in a patient with documentation of all the following:<br>• CYP2D6 testing which indicates the patient is not a poor metabolizer<br>• Chart notes or provider attestation indicating lack of hepatic or renal impairment | **Yes:** Go to #11<br><br>Max dose for pitolisant is 35.6 mg daily. | **No:** Pass to RPh. Deny; medical appropriateness. |
| 11. Is there baseline documentation of fatigue severity using a validated measure (e.g., Epworth score, Brief Fatigue Inventory, or other validated measure)? | **Yes:** Go to #12<br><br>Document baseline scale and score | **No:** Pass to RPh. Deny; medical appropriateness |
| 12. Is there documentation or provider attestation of recent safety assessments for the requested drug (Table 3)? | **Yes:** Go to #13 | **No:** Pass to RPh. Deny; medical appropriateness |
| 13. Is the request for treatment of narcolepsy or fatigue secondary to major depression (MDD), MS, or cancer?<br><br>Note: Methylphenidate is recommended first-line for cancer. | **Yes:** Approve for 90 days and inform prescriber further approval will require documented evidence of clinical benefit. | **No:** Go to #14 |
| 14. Is the request for treatment of obstructive sleep apnea (OSA) (without narcolepsy)? | **Yes:** Go to #15 | **No:** Go to #16 |
| 15. Is the patient compliant with recommended first-line treatments (e.g., CPAP or other primary therapy)? | **Yes:** Approve for 90 days and inform prescriber further approval will require documented evidence of clinical benefit. | **No:** Pass to RPh; Deny; medical appropriateness |
| 16. All other diagnoses must be evaluated as to the OHP-funding level and evidence for clinical benefit.<br>• Evidence supporting treatment for excessive daytime sleepiness (EDS) or fatigue as a result of other conditions is currently insufficient and should be denied for “medical appropriateness”.<br>• Evidence to support cognition enhancement is insufficient and should be denied for “medical appropriateness”.<br>If new evidence is provided by the prescriber, please forward request to Oregon DMAP for consideration and potential modification of current PA criteria. | | |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the request for solriamfetol? | **Yes:** Go to #2 | **No:** Go to #3 |
| 2. Is there documentation of a recent blood pressure evaluation (within the last 3 months)? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the request for treatment of obstructive sleep apnea? | **Yes:** Go to #4 | **No:** Go to #5 |
| 4. Is the patient adherent to primary OSA treatment (e.g.,CPAP) based on chart notes? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is there documentation of clinical benefit and tolerability from baseline?<br><br>The same clinical measure used to diagnose excessive daytime sleepiness (EDS), fatigue secondary to MS and/or cancer, major depressive disorder (MDD) is recommended to document clinical benefit. For Epworth Sleepiness Scale, and improvement of at least 3 points is considered clinically significant. | **Yes:** Approve for up to 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T Review:* *8/25; 4/23; 10/20 (DE); 2/20; 7/19; 03/16; 09/15*
*Implementation:* *9/15/25; 5/1/23; 11/1/20; 3/1/2020; 8/19/19; 8/16, 1/1/16*

# Smoking Cessation

**Goal(s):**

- Promote use that is consistent with National Guidelines and medical evidence.
- Promote use of high value products

**Length of Authorization:**

- 6 months

**Requires PA:**

- Non-preferred drugs
- Varenicline for individuals younger than 17 years (safety edit)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is the diagnosis for tobacco dependence (ICD10 F17200)? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the request for varenicline for a patient less than 17 years old? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #4 |
| 4. Will the prescriber change to a preferred product?<br><br>Message:<br>• Preferred products do not require a PA.<br>• Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&T) Committee. | **Yes:** Inform prescriber of covered alternatives in class | **No:** Go to #5 |
| 5. Is the patient enrolled in a smoking cessation behavioral counseling program [e.g. Quit Line at: 800-QUIT-NOW (800-784-8669)]. | **Yes:** Approve NRT for 6 months | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T Review:* *2/2021 (DE); 9/19; 7/16; 4/12*
*Implementation:* *3/1/21;11/1/19; 8/16, 7/23/12*

# Sodium Phenylbutyrate/Taurursodiol (Relyvrio™)

**Goal(s):**
- To encourage use of riluzole which has demonstrated mortality benefits.
- To ensure appropriate use of sodium phenylbutyrate/taurursodiol.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- All pharmacy claims

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for continuation of therapy of previously approved FFS criteria (after which patient has completed 6-month trial)? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Is this a FDA approved indication? | **Yes**: Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the patient currently on riluzole therapy, OR have a documented contraindication or intolerance to riluzole? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the medication being prescribed by or in consultation with a neurologist? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Does the patient have documented percent-predicted slow vital capacity (%SVC) ≥ 60% within past 6 months? | **Yes:** Record lab result. _____ Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is there a baseline documentation of the revised ALS Functional Rating Scale (ALSFRS-R) score? | **Yes:** Record baseline score_____ Approve for 6 months based on FDA-approved dosing. | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 3. Has the prescriber provided documentation that anticipated decline of functional abilities as assessed by a Revised ALS Functional Rating Scale (ALSFRS-R) has slowed in a clinically meaningful way? | **Yes:** Got to #2 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 4. Has the patient progressed to permanent ventilation or received a tracheostomy since beginning medication? | **Yes:** Pass to RPh; Deny; medical appropriateness. | **No:** Approve for 12 months. |

*P&T/DUR Review: 4/23 (SF)*
*Implementation: 5/1/23*

# Sparsentan

**Goal(s):**
- To promote use that is consistent with medical evidence and product labeling in patients with immunoglobulin A nephropathy (IgAN).
- To ensure appropriate use of sparsentan in populations with clinically definite IgAN.
- To monitor for clinical response for appropriate continuation of therapy.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Sparsentan

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the patient ≥ 18 years of age with diagnosis of IgAN confirmed by biopsy? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Does the patient have an estimated glomerular filtration rate ≥ 30 mL/min/1.73 $m^2$? | **Yes**: Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the request for continuation of therapy for a patient who has received ≥ 6 months of initial therapy with this agent? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #5 |
| 5. Is the medication going to be used in combination with any renin-angiotensin-aldosterone antagonists (e.g. angiotensin converting enzyme inhibitors or angiotensin receptor blockers), endothelin receptor antagonists [ERAs], or aliskiren? | **Yes:** Pass to RPh. Deny; medical appropriateness<br><br>Use of sparsentan and any these agents is contraindicated. | **No:** Go to #6 |
| 6. Is the prescriber a specialist in the management of IgAN (e.g. nephrologist)? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 7. Is the patient at high risk of disease progression, defined as a 24-hour urine collection that indicates:<br>• Proteinuria > 1.0 g/day;<br>-OR-<br>• Urine protein-to-creatinine ratio ≥ 1.5 g/g? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Will the prescriber attest that the patient received the maximum or maximally tolerated dose of ONE of the following for ≥ 12 weeks prior to starting sparsentan:<br>• Angiotensin converting enzyme inhibitor<br>• Angiotensin receptor blocker<br>-OR-<br>is there documentation that the patient has an intolerance or contraindication to renin-aldosterone-angiotensin system (RAAS) inhibitors? | **Yes**: Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Has the patient received ≥ 3 months of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification, according to the prescriber? | **Yes**: Approve for 9 months | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Has the prescriber documented a positive patient response to sparsentan therapy such as:<br>• eGFR that is not declining?<br>• Stabilization or improvement of proteinuria?<br>• No progression to dialysis? | **Yes**: Approve for 1 year | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 12/23*
*Implementation: 1/1/24*

# Spinal Muscular Atrophy Drugs

**Goal(s):**
- Approve nusinersen (SPINRAZA), onasemnogene abeparvovec (ZOLGENSMA), or risdiplam (EVRYSDI) conditions supported by evidence of benefit (e.g., spinal muscular atrophy).

**Length of Authorization:**
- Nusinersen: Up to 8 months for initial approval and up to 12 months for renewal.
- Onasemnogene abeparvovec: Once in a lifetime dose.
- Risdiplam: Up to 6 months for initial approval and 12 months for renewal.

**Requires PA:**
- Nusinersen (billed as a pharmacy or provider administered claim)
- Onasemnogene abeparvovec (billed as a pharmacy or provider administered claim)
- Risdiplam (billed as pharmacy claim)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. FDA-Approved Dosing For Risdiplam**

| Age and Body Weight | Recommended Daily Dose of Risdiplam |
|---|---|
| Less than 2 months of age | 0.15 mg/kg |
| 2 months to less than 2 years of age | 0.2 mg/kg |
| 2 years of age and older weighing less than 20 kg | 0.25 mg/kg |
| 2 years of age and older weighing 20 kg or more | 5 mg |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD-10 code. Go to #2 | |
| 2. Is this a request for continuation of nusinersen or risdiplam therapy?<br><br>Note: Onasemnogene abeparvovec is only approved as a single, one-time dose per lifetime | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Does the patient have a diagnosis of spinal muscular atrophy (SMA), confirmed by SMN1 (chromosome 5q) gene mutation or deletion AND at least 2 copies of the SMN2 gene as documented by genetic testing? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 4. Is the requested medication prescribed by a pediatric neurologist or a provider with experience treating SMA? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the patient ventilator-dependent (using at least 16 hours per day on at least 21 of the last 30 days)?<br><br>Note: This assessment does not apply to patients who require ventilator assistance | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #6 |
| 6. Is a baseline motor assessment appropriate for age and/or intended population available? Examples include, but are not limited to, the following validated assessment tools:<br>• Hammersmith Infant Neurological Examination, Section 2 (HINE-2)<br>• Hammersmith Functional Motor Scale (HFMSE)<br>• Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)<br>• The Motor Function Measure 32 items (MFM-32)<br>• Upper Limb Module (ULM)<br>• 6-minute walk test (6MWT) | **Yes:** Document date and assessment results<br>Date: _____<br>Assessment:_____<br>Results:_____<br><br>Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 7. Has the patient had previous administration of onasemnogene abeparvovec (ZOLGENSMA), either in a clinical study or as part of medical care? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #8 |
| 8. Is the request for risdiplam? | **Yes**: Go to #9 | **No**: Go to #13 |
| 9. Is the prescribed dose within the limits defined in Table 1? | **Yes:** Go to #10 | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Recommended FDA-approved dosage is determined by age and body weight. |
| 10. In people of child-bearing potential, is there documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant? | **Yes:** Go to #11 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 11. Is the patient on concomitant therapy with nusinersen? | **Yes:** Pass to RPh. Deny; medical appropriateness**.** | **No:** Go to #12 |
| 12. For able patients, is there baseline documentation of pulmonary function measured by spirometry (FEV1, FVC, etc) or other validated pulmonary function test? | **Yes:** Document baseline results.<br><br>Approve for 6 months.<br><br>If approved, a referral will be made to case management by the Oregon Health Authority. | **No:** Pass to RPh. Deny; medical appropriateness. |
| 13. Is the request for nusinersen? | **Yes**: Go to #14 | **No**: Go to #15 |
| 14. Is the patient on concomitant therapy with risdiplam? | **Yes:** Pass to RPh. Deny; medical appropriateness**.** | **No:** Approve for up to 8 months. |
| 15. Is the request for onasemnogene abeparvovec? | Yes: Go to #16 | No: Pass to RPh. Deny; medical appropriateness |
| 16. Is the patient less than 2 years of age? | **Yes:** Go to #17 | **No:** Pass to RPh. Deny; medical appropriateness |
| 17. Have the following labs been obtained:<br><br>a) a baseline platelet count AND<br>b) baseline liver function tests (AST, ALT, total bilirubin, and PT) AND<br>c.) baseline troponin-I | **Yes:** Go to #18 | **No:** Pass to RPh. Deny; medical appropriateness |
| 18. Does the patient have a prescription on file for 30 days of on oral corticosteroid to begin one day before infusion of onasemnogene abeparvovec? | **Yes:** Approve for one time infusion | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is there evidence of adherence and tolerance to therapy through pharmacy claims/refill history and provider assessment? | **Yes:** Go to #2 | **No:** Pass to RPh; Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 2. Has the patient shown a positive treatment response in one of the following areas?<br>• Documented improvement from the baseline motor function assessment score with more areas of motor function improved than worsened<br>-OR-<br>• Documentation of clinically meaningful stabilization, delayed progression, or decreased decline in SMA-associated signs and symptoms compared to the predicted natural history trajectory of disease<br>-OR-<br>• Documentation of an improvement or lack of decline in pulmonary function compared to baseline | **Yes:** Approve for 12 months | **No:** Pass to RPh; Deny; medical appropriateness. |

*P&T Review: 2/23 (DM); 9/19 (DM); 7/17; 3/17*
*Implementation: 4/1/23; 11/1/19: 9/1/17; 5/17*

# Stiripentol

**Goal(s):**

- To ensure appropriate drug use and restrict to indications supported by medical literature.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Stiripentol capsules and powder for oral suspension

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for renewal of therapy previously approved by the FFS system? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Is the request for the FDA approved indication of Dravet syndrome in patients 6 months of age or older, weighing 7 kg or more, and taking clobazam? | **Yes**: Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is baseline white blood cell (WBC) and platelet counts on file within the past 3 months?<br><br>Note: Labs should be assessed every six months while receiving stiripentol therapy. | **Yes:** Approve for 12 months. Document results:<br>Date of lab work____<br>WBC_____<br>Platelets_____ | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Are recent WBC and platelet counts documented in patient records?<br><br>Note: Labs should be assessed every six months while receiving stiripentol therapy. | **Yes:** Go to #2<br>Document results here:<br>Date of lab work___<br>WBC_____<br>Platelets_____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 2. Has seizure frequency decreased since beginning therapy? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 4/25 (DM); 10/22 (SF); 10/21; 10/20; 6/20; 1/19*
*Implementation: 3/1/2019*

# Sublingual Immunotherapy

**Goal(s):**

- Restrict use of sublingual immunotherapy tablets for conditions funded by the OHP and where there is evidence of benefit. Treatment for allergic rhinitis is funded by the Oregon Health Plan only if there is a comorbidity such as asthma.
- Allow case-by-case review for members covered under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) program.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- All FDA-approved sublingual immunotherapy tablets (provider administered and pharmacy claims).

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. FDA-Approved Sublingual Immunotherapy Tablets**

| Product Name (BRAND NAME) | How Supplied | Approved Age Range | When to Initiate Therapy |
|---|---|---|---|
| Timothy Grass Pollen Allergen Extract (GRASTEK) | 2,800 BAU tablet | 5 to 65 yo | Start 12 weeks prior to expected onset of grass season and continue through grass season. |
| Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergy Extract (ORALAIR) | 100 IR and 300 IR tablets | | Start 16 weeks prior to expected onset of respective grass season and continue through grass season. |
| Short Ragweed Pollen Allergen Extract (RAGWITEK) | 12 Amb a 1-Unit tablet | | Start 12 weeks prior to expected onset of ragweed season and continue through ragweed season. |
| House Dust Mite Allergen Extract (ODACTRA) | 12 SQ-HDM tablet | 5 to 65 yo | Start anytime and once daily administration until discontinued by provider. |

Abbreviations: Amb a = Ambrosia artemisiifolia (short ragweed); BAUs = Bioequivalent Allergy Units; FDA = Food and Drug Administration; SQ-HDM = Standardized-Quality House Dust Mite units; IR = Index of Reactivity; SL = sublingual; yo = years old

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for an FDA-approved indication? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is the request for continuation of current therapy? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #4 |

| Approval Criteria | | |
|---|---|---|
| 4. Is the request for house dust mite immunotherapy (e.g., Odactra) and does the patient have co-morbid conditions funded by the OHP and listed in HERC guidance?<br>• Uncontrolled Mild to Moderate Asthma<br><br>Note: sublingual immunotherapy for grass and ragweed have insufficient evidence of benefit in allergic rhinitis and comorbid asthma | **Yes:** Go to #6 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #5 |
| 5. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes**: Go to #7 | **No**: Pass to RPh. Deny; medical necessity. |
| 6. If the patient has asthma, have they tried and failed to receive adequate benefit from or have a contradiction to a low to high dose orally inhaled corticosteroid treatment? | **Yes**: Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 7. Has the patient tried and failed to receive adequate benefit from or have a contraindication to oral antihistamines and/or nasal corticosteroids to manage allergic rhinitis? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical necessity. |
| 8. Does the patient meet the FDA-approved age range outlined in **Table 1**? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 9. Is the request by, or in consultation with, an allergist or immunologist? | **Yes:** Go to #10 | **No:** Pass to RPh. Deny; medical appropriateness |
| 10. Does the patient have severe, unstable, or uncontrolled asthma, a history of eosinophilic esophagitis, or other severe systemic allergic reaction? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #11 |

| Approval Criteria | | |
|---|---|---|
| 11. Has the patient undergone a properly performed skin test and/or is there serologic evidence of IgE-mediated antibody to a potent extract of the allergen? | **Yes:** Go to #12 | **No:** Pass to RPh. Deny; medical appropriateness |
| 12. Does the patient have a prescription on file for an epinephrine autoinjector in case of an adverse event? | **Yes:** Go to #13 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 13. Will the first dose be administered under medical supervision? | **Yes**: Approve for 12 months. | **No:** Pass to RPh. Deny; medical appropriateness. |

| Renewal Criteria | | |
|---|---|---|
| 1. Does the provider attest that patient's symptoms have improved with sublingual immunotherapy treatment and not experienced any adverse effects? | **Yes**: Approve for 12 months. | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T/DUR Review: 8/23 (DM)*
*Implementation: 9/1/23*

# Suzetrigine (Journavx™)

**Goal(s):**
- Allow use in accordance with available medical evidence for safety and efficacy.

**Length of Authorization:**
- Up to 14 days per acute injury/surgery

**Requires PA:**
- Suzetrigine quantities greater than 5 tablets total (50 mg tablets, a 48-hour supply) within 30 days

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the patient an adult 18 years or older? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is the request for treatment of acute pain?<br><br>Note: Acute pain is generally considered to last less than 30 days. | **Yes**: Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 4. Is the pain documented to be moderate to severe? | **Yes**: Go to #5<br>Record pain rating using visual analogue scale (VAS), numeric pain rating scale (NPRS) or other validated measure<br>_____ | **No:** Pass to RPh. Deny; medical appropriateness. |
| 5. Has the patient already received 14 days of suzetrigine for this indication? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #6 |
| 6. Is there documentation that the patient is failing to receive adequate pain relief from, or have contraindications to, both acetaminophen and a non-steroidal anti-inflammatory agent? | **Yes:** Approved requested doses up to maximum 30 tablets (total includes any doses received before prior authorization requirement). | **No:** Pass to RPh. Deny; medical necessity. |

# Targeted Immune Modulators for Autoimmune Conditions

**Goal(s):**

- Promote use that is consistent with national clinical practice guidelines and medical evidence.
- Restrict use of targeted immune modulators to OHP-funded diagnoses in adults.
- Allow case-by-case review for members covered under the EPSDT program.
- Promote use of cost-effective products.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- All targeted immune modulators for autoimmune conditions (both pharmacy and provider administered claims)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. Targeted Immune Modulators FDA-Approved for Ankylosing Spondylitis, Juvenile Idiopathic Arthritis, Rheumatoid Arthritis, and Non-Radiographic Axial Spondyloarthritis**

| Generic Name (BRAND NAME) | Ankylosing Spondylitis (AS) | Juvenile Idiopathic Arthritis (JIA) | Rheumatoid Arthritis (RA) | Non-Radiographic Axial Spondyloarthritis (NR-axSpA) |
|---|---|---|---|---|
| **Tier 1 (Preferred First-Line)** | | | | |
| **Adalimumab (HUMIRA)** | ≥18 y | ≥2 yo | ≥18 yo | |
| **Adalimumab-atto (AMJEVITA)** | ≥18 y | ≥2 yo | ≥18 yo | |
| **Adalimumab-fkjp 50 mg/mL (non-branded NDCs)** | ≥18 y | ≥2 yo | ≥18 yo | |
| **Adalimumab-ryvk (SIMLANDI)** | ≥18 y | ≥2 yo | ≥18 yo | |
| **Etanercept (ENBREL)** | ≥18 yo | ≥2 yo | ≥18 yo | |
| **Infliximab-axxq (AVSOLA)** | ≥18 yo | | ≥18 yo | |
| **Tier 2 (Preferred Second-Line)** | | | | |
| **Ixekizumab (TALTZ)** | ≥ 18 yo | | | ≥18 yo |
| **Tofacitinib (XELJANZ)** | ≥18 yo | ≥2 yo | ≥18 yo | |
| **Tier 3 (Non-Preferred Third-Line)** | | | | |
| **Abatacept (ORENCIA)** | | ≥2 yo | ≥18 yo | |
| **Anakinra (KINERET)** | | | ≥18 yo | |
| **Baricitinib (OLUMIANT)** | | | ≥18 yo | |
| **Bimekizumab (BIMZELX)** | ≥18 yo | | | ≥18 yo |
| **Canakinumab (ILARIS)** | | ≥2 yo | | |
| **Certolizumab (CIMZIA)** | ≥18 yo | ≥2 yo | ≥18 yo | ≥18 yo |
| **Golimumab (SIMPONI and SIMPONI ARIA)** | ≥18 yo | ≥2 yo (SIMPONI ARIA) | ≥18 yo | |
| **Infliximab (REMICADE)** | ≥18 yo | | ≥18 yo | |
| **Rituximab (RITUXAN)** | | | ≥18 yo | |
| **Sarilumab (KEVZARA)** | | | ≥18 yo | |
| **Secukinumab (COSENTYX)** | ≥18 yo | | | ≥18 yo |
| **Tocilizumab (ACTEMRA)** | | ≥2 yo | ≥18 yo | |
| **Upadacitinib (RINVOQ)** | ≥18 yo | ≥2 yo | ≥18 yo | ≥18 yo |

**Note: Biosimilar products are Tier 3 unless specifically mentioned**

**Table 2. Targeted Immune Modulators FDA-Approved for Plaque Psoriasis, Psoriatic Arthritis, and Hidradenitis Suppurativa**

| Generic Name (BRAND NAME) | Plaque Psoriasis (PsO) | Psoriatic Arthritis (PsA) | Hidradenitis Suppurativa (HS) |
|---|---|---|---|
| **Tier 1 (Preferred First-Line)** | | | |
| Adalimumab (HUMIRA) | ≥18 yo | ≥18 yo | ≥ 12 yo |
| Adalimumab-atto (AMJEVITA) | ≥18 yo | ≥18 yo | ≥18 yo |
| Adalimumab-fkjp 50 mg/mL (non-branded NDCs) | ≥18 yo | ≥18 yo | |
| Adalimumab-ryvk (SIMLANDI) | ≥18 yo | ≥18 yo | ≥18 yo |
| Etanercept (ENBREL) | ≥4 yo | ≥2 yo | |
| Infliximab-axxq (AVSOLA) | ≥18 yo | ≥18 yo | |
| **Tier 2 (Preferred Second-Line)** | | | |
| Ixekizumab (TALTZ) | ≥6 yo | ≥18 yo | |
| Tofacitinib (XELJANZ) | | ≥18 yo | |
| **Tier 3 (Non-Preferred Third-Line)** | | | |
| Abatacept (ORENCIA) | | ≥2 yo | |
| Apremilast (OTEZLA) | ≥ 6 yo and weighing ≥ 20 kg | ≥ 6 yo and weighing ≥ 20 kg | |
| Bimekizumab (BIMZELX) | ≥18 yo | ≥18 yo | ≥18 yo |
| Brodalumab (SILIQ) | ≥18 yo | | |
| Certolizumab (CIMZIA) | ≥18 yo | ≥18 yo | |
| Deucravacitinib (SOTYKU) | ≥18 yo | | |
| Golimumab (SIMPONI and SIMPONI ARIA) | | ≥2 yo (SIMPONI ARIA)<br>≥18 yo (SIMPONI) | |
| Guselkumab (TREMFYA) | ≥6 yo | ≥6 yo | |
| Infliximab (REMICADE) | ≥18 yo | ≥18 yo | |
| Risankizumab (SKYRIZI) | ≥18 yo | ≥18 yo | |
| Secukinumab (COSENTYX) | ≥6 yo | ≥2 yo | ≥18 yo |
| Tildrakizumab (ILUMYA) | ≥18 yo | | |
| Upadacitinib (RINVOQ) | | ≥2 yo | |
| Ustekinumab (STELARA) | ≥6 yo | ≥6 yo | |

**Note: Biosimilar products are Tier 3 unless specifically mentioned**

**Table 3. Targeted Immune Modulators FDA-Approved for Crohn's Disease and Ulcerative Colitis**

| Generic Drug Name (BRAND NAME) | Crohn's Disease | Ulcerative Colitis |
|---|---|---|
| **Tier 1 (Preferred First-Line)** | | |
| Adalimumab (HUMIRA) | ≥6 yo | ≥5 yo |
| Adalimumab-atto (AMJEVITA) | ≥6 yo | ≥18 yo |
| Adalimumab-fkjp 50 mg/mL (non-branded NDCs) | ≥6 yo | ≥18 yo |
| Adalimumab-ryvk (SIMLANDI) | ≥6 yo | ≥18 yo |
| Infliximab-axxq (AVSOLA) | ≥6 yo | ≥6 yo |
| **Tier 2 (Preferred Second-Line)** | | |
| Tofacitinib (XELJANZ) | | ≥18 yo |
| **Tier 3 (Non-Preferred Third-Line)** | | |
| Certolizumab (CIMZIA) | ≥18 yo | |
| Etrasimod (VELSIPITY) | | ≥18 yo |
| Golimumab (SIMPONI and SIMPONI ARIA) | | ≥18 yo (SIMPONI) |
| Guselkumab (TREMFYA) | ≥18 yo | ≥18 yo |
| Infliximab (REMICADE) | ≥6 yo | ≥6 yo |
| Mirikizumab (OMVOH) | ≥18 yo | ≥18 yo |
| Risankizumab (SKYRIZI) | ≥18 yo | ≥18 yo |
| Ozanimod (ZEPOSIA) | | ≥18 yo |

| Generic Drug Name (BRAND NAME) | Crohn's Disease | Ulcerative Colitis |
|---|---|---|
| **Upadacitinib (RINVOQ)** | ≥ 18 yo | ≥18 yo |
| **Ustekinumab (STELARA)** | ≥ 18 yo | ≥18 yo |
| **Vedolizumab (ENTYVIO)** | ≥18 yo | ≥18 yo |

**Note: Biosimilar products are Tier 3 unless specifically mentioned**

**Table 4. Targeted Immune Modulators FDA-Approved for Other Indications not Listed in Table 1, 2 or 3**

| Generic Drug Name (BRAND NAME) | Other Indications |
|---|---|
| **Adalimumab (HUMIRA) & biosimilars** | • Uveitis (non-infectious) ≥2 yo |
| **Abatacept (ORENCIA)** | • Acute Graft Versus Host Disease (aGVHD) ≥ 2 yo |
| **Anakinra (KINERET)** | • DIRA<br>• COVID ≥ 18 yo (hospitalized)<br>• NOMID |
| **Apremilast (OTEZLA)** | • Oral Ulcers associated with Behcet's Disease ≥ 18 yo |
| **Baricitinib (OLUMIANT)** | • COVID ≥ 18 yo (hospitalized) |
| **Canakinumab (ILARIS)** | • FCAS ≥4 yo<br>• FMF ≥ 4 yo<br>• Gout flares unresponsive to NSAIDs and colchicine ≥18 yo<br>• HIDS ≥ 4 yo<br>• MKD ≥ 4 yo<br>• MWS ≥ 4 yo<br>• Stills Disease ≥ 2 yo<br>• TRAPS ≥ 4 yo |
| **Rituximab (RITUXAN) and biosimilars** | • BL ≥ 6 mo<br>• BLL ≥ 6 mo<br>• B-AL ≥ 6 mo<br>• CLL ≥ 18 yo<br>• DLBCL ≥ 6 mo<br>• GPA ≥ 2yo<br>• MPA ≥ 2 yo<br>• NHL ≥18 yo<br>• Pemphigus Vulgaris ≥ 18 yo (RITUXAN only) |
| **Sarilumab (KEVZARA)** | • Polymyalgia Rheumatica (PMR) ≥ 18 yo |
| **Secukinumab (COSENTYX)** | • Enthesitis-Related Arthritis (ERA) ≥ 4 yo |
| **Spesolimab (Spevigo)** | • Generalized Pustular Psoriasis Flares >12 yo and weighing >40 kg<br>• Generalized Pustular Psoriasis after Flares >12 yo and weighing >40 kg |
| **Tocilizumab (ACTEMRA)** | • CRS ≥2 yo<br>• COVID ≥ 18 yo (hospitalized)<br>• GCA ≥18 yo<br>• SSc-ILD ≥ 18 yo |
| **Upadacitinib (RINVOQ)** | • Atopic Dermatitis ≥ 12 yo<br>• GCA ≥ 18 yo |

Abbreviations: BL = Burkitt Lymphoma; BLL = Burkitt-like Lymphoma; B-AL = mature B-cell acute leukemia; CLL = Chronic Lymphocytic Leukemia; COVID = Covid-19 infection; CRS = Cytokine Release Syndrome; DIRA = Deficiency of Interleukin-1 Receptor Antagonist; DLBCL = Diffuse Large B-Cell Lymphoma; FCAS = Familial Cold Autoinflammatory Syndrome; FMF = Familial Mediterranean Fever; GCA = Giant Cell Arteritis; GPA = Granulomatosis with Polyangiitis (Wegener's Granulomatosis); HIDS: Hyperimmunoglobulin D Syndrome; MKD = Mevalonate Kinase Deficiency; mo = months old; MPA = Microscopic Polyangiitis; MWS = Muckle-Wells Syndrome; NHL = Non-Hodgkin's Lymphoma; NOMID = Neonatal Onset Multi-Systemic Inflammatory Disease; NSAIDs = non-steroidal anti-inflammatory drugs; SSc-ILD = Systemic Sclerosis-Associated Interstitial Lung Disease; TRAPS = Tumor Necrosis Factor Receptor Associated Periodic Syndrome; yo = years old

**Table 5. First-Line Conventional Therapy Recommended for Select Conditions**

| Conditions | Recommended Conventional Therapy Prior To A Targeted Immune Modulator |
|---|---|
| **Arthritis (Juvenile Idiopathic,** | • DMARD therapy: Methotrexate, leflunomide, sulfasalazine or hydroxychloroquine for ≥ 6 months; AND |

| Conditions | Recommended Conventional Therapy Prior To A Targeted Immune Modulator |
|---|---|
| **Psoriatic, Rheumatoid)** | • Concurrent DMARD therapy with plans to continue concomitant use. Biologic therapy is recommended in combination with DMARDs (e.g. methotrexate) for those who have had inadequate response with DMARDs. |
| **Atopic Dermatitis** | • Moderate to high potency topical corticosteroid (e.g., clobetasol, desoximetasone, desonide, mometasone, betamethasone, halobetasol, fluticasone, or fluocinonide), in combination with a topical calcineurin inhibitor (e.g., tacrolimus) for at least 4 weeks OR<br>• Oral immunomodulator therapy (e.g., cyclosporine, methotrexate, or azathioprine) for at least 8 weeks |
| **Crohn's Disease** | • Mercaptopurine, methotrexate, or azathioprine for ≥6 months |
| **Generalized Pustular Psoriasis** | • Acitretin, methotrexate, or cyclosporine for ≥ 3 months |
| **Hidradenitis Suppurativa (HS)** | • 90-day trial of conventional HS therapy (e.g. oral antibiotics) |
| **Plaque Psoriasis** | • Topical high potency corticosteroid (e.g., betamethasone dipropionate 0.05%, clobetasol propionate 0.05%, fluocinonide 0.05%, halcinonide 0.1%, halobetasol propionate 0.05%; triamcinolone 0.5%) for a minimum of 4 weeks; AND<br>• At least one other topical agent: calcipotriene, tazarotene, anthralin for a minimum of 8 weeks; AND<br>• Phototherapy for at least 8 weeks; AND<br>• At least one other systemic therapy: acitretin, cyclosporine, or methotrexate for at least 16 weeks |
| **Ulcerative Colitis** | • 5-aminosalicylate products, mercaptopurine, or azathioprine for ≥6 months |
| **Abbreviations: DMARD=Disease Modifying Anti-Rheumatic Drug; HS=Hidradenitis Suppurativa** | |

**Table 6. FDA-recommended Baseline Safety Tests for Sphingosine 1-Phosphate Receptor Modulators**

| | Negative Pregnancy Test | LFTs | CBC with lymphocyte count | Ophthalmic Exam | Baseline ECG (see notes) | Skin Exam for Malignancy | Varicella Zoster Antibodies |
|---|---|---|---|---|---|---|---|
| **Etrasimod (VELSIPITY)** | X | X | X | X | X | X | X |
| **Ozanimod (ZEPOSIA)** | X | X | X | X | X | | X |
| Abbreviations: CBC=complete blood count; ECG=electrocardiogram; FDA =Food and Drug Administration; LFTs = liver function tests | | | | | | | |

**Sphingosine 1-Phosphate Receptor Modulators Clinical Notes:**

- Patients on antiarrhythmics, beta-blockers or calcium channel blockers or with risk factors for bradycardia (h/o MI, age >70 yrs., electrolyte disorder, hypothyroidism) may be more prone to development of symptomatic bradycardia and should be initiated on etrasimod or ozanimod with caution. A cardiology evaluation should be performed before considering treatment in patients with significant QT prolongation, heart disease, heart failure, history of cardiac arrest or myocardial infarction, cerebrovascular disease, and uncontrolled hypertension, a history of with second-degree Mobitz type II or higher AV block, sick-sinus syndrome, or sinoatrial heart block.
- An ophthalmology evaluation should be repeated 3-4 months after etrasimod or ozanimod initiation with subsequent evaluations based on clinical symptoms.

| Approval Criteria | |
|---|---|
| 6. What diagnosis is being treated? | Record ICD-10 code. |

| Approval Criteria | | |
|---|---|---|
| 7. Is the diagnosis funded by OHP?<br><br>Notes:<br>A. Mild-to-moderate psoriasis, plaque psoriasis, and atopic dermatitis are unfunded, severe forms are funded.<br>B. Mild Hidradenitis Suppurativa (HS) is unfunded, moderate-to-severe HS (e.g., Hurley Stage II or III) is funded.<br>C. Alopecia areata is unfunded.<br><br>Psoriasis and atopic dermatitis are severe in nature when resulting in functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's DLQI ≥ 13 (or severe score on other validated tool) AND one or more of the following:<br>• At least 10% body surface area involvement; OR<br>• Hand, foot, face, or mucous membrane involvement? | **Yes:** Go to # 4 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP.<br><br>If eligible for EPSDT review: Go to #3. |
| 8. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny, medical necessity. |
| 9. Is the request for a drug FDA-approved for this condition and age as defined in Table 1,2,3 or 4 above? | **Yes:** Go to #6 | **No:** Go to #5 |
| 10. Is there documentation of 1) inadequate response, contraindication or intolerance to FDA-approved targeted immune modulators AND 2) prescribing by, or in consultation with, a relevant specialist for the condition? | **Yes**: Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 11. Has the patient been annually screened for latent or active tuberculosis and if positive, started tuberculosis treatment?<br><br>*(Note: this requirement does not apply to requests for apremilast.) | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>If patient meets all other criteria, may approve once for up to 3 months to allow time for screening for ongoing therapy to avoid interruptions in care. |
| 12. Is this a request for continuation of therapy? | **Yes**: Go to **Renewal Criteria** | **No:** Go to #8 |
| 13. Is there documentation of one of the following:<br>• Treatment failure or inadequate response to conventional treatment in outlined Table 5 OR<br>• contraindication or intolerance to first-line conventional treatments outlined in Table 5 OR<br>• request is for a condition not outlined in Table 5? | **Yes:** Go to #9<br><br>Document each therapy with dates.<br><br>If applicable, document intolerance or contraindication(s). | **No**: Pass to RPh. Deny; medical appropriateness |
| 14. Is the request for 1) a preferred Tier 1 product in Table 1, 2 or 3 OR 2) a preferred Tier 2 product if there is no Tier 1 product listed for the indication? | **Yes:** Go to #11 | **No:** Go to #10 |

| Approval Criteria | | |
|---|---|---|
| 15. Is there documentation that therapy with an agent from each of the preferred tiers would be inappropriate?<br><br>Note: documentation could include inadequate response after ≥3 months with at least one product from each preferred tier, contraindication or intolerance to products from each preferred tier, or lack of products FDA-approved for the requested indication in tiers.<br><br>Message:<br>Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics Committee. | **Yes:** Go to #11 | **No**: Pass to RPh. Deny; medical appropriateness. Require trial of at least one product from each tier. |
| 16. Is the request for upadacitinib for severe atopic dermatitis? | **Yes:** Go to #12 | **No:** Go to #13 |
| 17. Has the provider submitted baseline assessment for the severity of atopic dermatitis:<br>Eczema Area and Severity Index score (EASI 50) OR<br>Dermatology Life Quality Index (DLQI) OR<br>Investigators Global Assessment (IGA) score? | **Yes:** Document date of baseline assessment and results here_____<br><br>Go to #14 | **No:** Pass to RPh. Deny; medical appropriateness |
| 18. Is the request for a JAK inhibitor (e.g., tofacitinib, baricitinib, or upadacitinib)? | **Yes:** Go to #14 | **No:** Go to #15 |

| Approval Criteria | | |
|---|---|---|
| 19. Is the patient currently on other biologic therapy or on a potent immunosuppressant like azathioprine, tacrolimus OR cyclosporine?<br><br>Note: Tofacitinib, baricitinib, and upadacitinib may be used concurrently with methotrexate or other nonbiologic DMARD drugs. Tofacitinib, baricitinib, or upadacitinib are not recommended to be used in combination with other JAK inhibitors, biologic DMARDs, azathioprine, or cyclosporine. | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Approve baricitinib or upadacitinib for up to 6 months.<br><br>Approve tofacitinib for up to 6 months at a maximum dose of 10 or 11 mg daily for Rheumatoid Arthritis OR<br>10 mg twice daily for 8 weeks then 5 or 10 mg twice daily for Ulcerative Colitis |
| 20. Is the prescription for a sphingosine 1-phosphate receptor modulator (etrasimod or ozanimod)? | **Yes:** Go to #16 | **No:** Go to #19 |
| 21. Have baseline safety assessments been completed as outlined in **Table 6**? | **Yes:** Go to #17 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 22. Does the patient have preexisting cardiac disease, risk factors for bradycardia, or is on an anti-arrhythmic, beta-blocker, or calcium channel blocker? | **Yes:** Go to #18 | **No:** Go to #19 |
| 23. Has the patient had a cardiology consultation before initiation (see clinical notes attached to **Table 6**)? | **Yes:** Go to #19 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 24. Duration of initial approval based on indication | AS, Plaque psoriasis, RA, AD: 6 months<br>HS: 12 weeks<br>UC/Crohn's: 12 months<br>Other: length of treatment or 1 year, whichever is longer | |

| Renewal Criteria | | |
|---|---|---|
| 4. Is the request to renew therapy for atopic dermatitis? | **Yes:** Go to #2 | **No:** Go to #3 |

| Renewal Criteria | | |
|---|---|---|
| 5. Have the patient's symptoms improved with upadacitinib therapy?<br>• at least a 50% reduction in the Eczema Area and Severity Index score (EASI 50) from when treatment started, OR<br>• at least a 4-point reduction in the Dermatology Life Quality Index (DLQI) from when treatment started, OR<br>• at least a 2-point improvement on the Investigators Global Assessment (IGA) score? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness. |
| 6. Is the request for continuation of adalimumab or secukinumab to treat moderate-to-severe Hidradenitis Suppurativa in an adult? | **Yes:** Go to #4 | **No:** Go to #5 |
| 7. Has the patient had clear evidence of response to adalimumab therapy as evidenced by:<br>• a reduction of 25% or more in the total abscess and inflammatory nodule count, AND<br>• no increase in abscesses and draining fistulas. | **Yes:** Approve for an additional 12 weeks of therapy | **No:** Pass to RPh. Deny; medical appropriateness. |
| 8. Has the patient been adherent to both biologic and DMARD therapy (if DMARD therapy has been prescribed in conjunction with the biologic therapy)? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 9. Has the patient's condition improved as assessed by the prescribing provider and provider attests to patient's improvement? | **Yes:** Approve for 12 months. Document baseline assessment and provider attestation received. | **No:** Pass to RPh; Deny; medical appropriateness. |

*P&T/DUR Review: 8/24(DM); 6/23; 10/22; 6/2; 10/21; 10/20; 2/20; 5/19; 1/19; 1/18; 7/17; 11/16; 9/16; 3/16; 7/15; 9/14; 8/12*
*Implementation: 1/1/25; 9/1/24; 7/1/23; 1/1/23; 7/1/22; 1/1/22; 1/1/2021; 7/1/2019; 3/1/19; 3/1/18; 9/1/17; 1/1/17; 9/27/14; 12/12*

# Targeted Immune Modulators for Severe Asthma and Atopic Dermatitis

**Goal(s):**

- Promote use that is consistent with national clinical practice guidelines, medical evidence, and OHP-funded conditions. Allow case-by-case review for members covered under the EPSDT program.
- Promote use of cost-effective products.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- All targeted immune modulators with indications for severe asthma, atopic dermatitis, or other indications (see **Table 1** below) for both pharmacy and physician-administered claims.
- This PA does not apply to topical agents for inflammatory skin conditions which are subject to separate clinical PA criteria.

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. FDA-Approved Indications and Ages**

| Generic Name/ BRAND NAME | Eosinophilic Asthma | Moderate to Severe Allergic Asthma | Difficult To Treat, Severe Asthma | Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) | Eosinophilic Esophagitis | Atopic Dermatitis (AD) | IgE-Mediated Food Allergy | Other |
|---|---|---|---|---|---|---|---|---|
| **Abrocitinib CIBINQO** | | | | | | ≥12 yrs | | |
| **Benralizumab FASENRA** | ≥6 yrs | | | | | | | EPGA ≥18 yrs |
| **Dupilumab DUPIXENT** | ≥6 yrs (or with oral corticosteroid dependent asthma) | | | ≥12 yrs | ≥1 yr & weighing ≥15 kg | ≥6 months | ≥18 yrs | PN ≥18 yrs COPD ≥18 yrs CSU ≥ 12 yrs |
| **Lebrikizumab EBGLYSS** | | | | | | ≥12 yrs | | |
| **Mepolizumab NUCALA** | ≥6 yrs | | | ≥18 yrs | | | | HES ≥ 12 yrs EPGA ≥18 yrs |
| **Nemolizumab NEMLUVIO** | | | | | | | | PN ≥ 18 yrs |
| **Omalizumab XOLAIR** | | ≥6 yrs | | ≥18 yrs | | | ≥ 1 yo | CSU ≥ 12 yrs |
| **Reslizumab CINQAIR** | ≥18 yrs | | | | | | | |
| **Tezepelumab TEZSPIRE** | | | ≥ 12 yrs | | | | | |
| **Tralokinumab ADBRY** | | | | | | ≥12 yrs | | |

Abbreviations: COPD = chronic obstructive pulmonary disease; CSU = chronic spontaneous urticaria; EGPA = eosinophilic granulomatosis with polyangiitis; HES = hypereosinophilic syndrome; PN = prurigo nodularis

**Table 2. Recommended First-Line Conventional Treatments**

| Indication | Conventional treatment |
|---|---|
| Atopic Dermatitis | 4-week trial of either one the following treatments:<br>• Moderate to high potency topical corticosteroid (e.g., clobetasol, desoximetasone, desonide, mometasone, betamethasone, halobetasol, fluticasone, or fluocinonide) in combination with a topical calcineurin inhibitor (e.g., tacrolimus) OR<br>• Oral immunomodulator therapy (e.g., cyclosporine, methotrexate, or oral corticosteroids)? |
| Eosinophilic granulomatosis with polyangiitis (EGPA) | 4-week trial of oral corticosteroid therapy (equivalent to oral prednisone or prednisolone 7.5 to 50 mg per day) |
| Nasal polyps | Intranasal corticosteroids (2 or more courses administered for at least 12 weeks each) |
| Asthma | Maximally dosed inhaled corticosteroid (**Table 3**) AND 2 additional controller drugs (i.e., long-acting inhaled beta-agonist, montelukast, zafirlukast, tiotropium) |
| Eosinophilic esophagitis | • Proton pump therapy for at least 8 weeks OR<br>• Corticosteroid therapy with local administration of fluticasone multi-use inhaler for at least 8 weeks (use nasal inhaler and swallow contents of the spray). |
| Chronic Obstructive Pulmonary Disease (COPD) | • Triple inhaler therapy (inhaled corticosteroid (ICS) with long-acting beta agonist (LABA) and long-acting muscarinic antagonist (LAMA) inhalers) for at least 3 months |
| Other | Documentation for conventional treatment(s) are not required |

**Table 3. Maximum Adult Doses for Inhaled Corticosteroids**

| High Dose Corticosteroids: | Maximum Dose |
|---|---|
| Qvar (beclomethasone) | 320 mcg BID |
| Pulmicort Flexhaler (budesonide) | 720 mcg BID |
| Alvesco (ciclesonide) | 320 mcg BID |
| Arnuity Ellipta (fluticasone furoate) | 200 mcg daily |
| Armonair (fluticasone propionate) | 232 mcg BID |
| Flovent HFA (fluticasone propionate) | 880 mcg BID |
| Flovent Diskus (fluticasone propionate) | 1000 mcg BID |
| Asmanex Twisthaler (mometasone) | 440 mcg BID |
| Asmanex HFA (mometasone) | 400 mcg BID |
| **High Dose Corticosteroid / Long-acting Beta-agonists** | **Maximum Dose** |
| Symbicort (budesonide/formoterol) | 320/9 mcg BID |
| Advair Diskus (fluticasone/salmeterol) | 500/50 mcg BID |
| Advair HFA (fluticasone/salmeterol) | 460/42 mcg BID |
| Wixela Inhub (fluticasone/salmeterol) | 500/50 mcg BID |
| AirDuo Digihaler (fluticasone/salmeterol) | 232/14 mcg BID |
| Airduo RespiClick (fluticasone/salmeterol) | 232/14 mcg BID |
| Breo Ellipta (fluticasone/vilanterol) | 200/25 mcg daily |
| Dulera (mometasone/formoterol) | 400/10 mcg BID |

**Table 4. Required baseline documentation of disease severity**

| Indication | Disease severity definitions |
|---|---|
| **Atopic dermatitis or prurigo nodularis** | Functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on another validated tool) AND one or more of the following:<br>• At least 10% body surface area involved, or<br>• Hand, foot, face, or mucous membrane involvement |
| **Asthma** | • At least 4 asthma exacerbations requiring systemic corticosteroids in the previous 12 months OR<br>• taking continuous oral corticosteroids at least the equivalent of prednisolone 5 mg per day for the previous 6 months OR<br>• at least 1 hospitalization or ≥ 2 emergency department (ED) visits in the past 12 months while on conventional treatment outlined in **Table 2 and 3** |
| **IgE-mediated food allergy** | • Number of epinephrine administrations and hospital/emergency department visits (if any) in past 12 months which were caused by presumed exposure to food that triggered an allergic response |
| **Hypereosinophilic syndrome (HES)** | • Duration of disease of at least 6 months without an identifiable non-hematologic secondary cause |
| **Chronic Obstructive Pulmonary Disease (COPD)** | • Blood eosinophil count ≥ 300 cells/μL AND<br>• at least 1 hospitalization or ≥ 2 emergency department (ED) visits in the past 12 months while on conventional treatment outlined in **Table 2 and 3** |

| **Approval Criteria** | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for an FDA-approved age and indication (**Table 1**)? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is the diagnosis an OHP-funded diagnosis?<br><br>Note: chronic idiopathic urticaria and mild-to-moderate atopic dermatitis are not OHP-funded conditions | **Yes**: Go to #5 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP.<br><br>If eligible for EPSDT review: Go to #4 |
| 4. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical necessity. |

| Approval Criteria | | |
|---|---|---|
| 5. Is this a request for continuation of therapy previously approved by the FFS program? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #6 |
| 6. Does the patient have a concurrent prescription for EpiPen® or equivalent so they are prepared to manage delayed anaphylaxis if it occurs after monoclonal antibody therapy? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 7. Is the medication being prescribed by, or in consultation with, an appropriate specialist?<br><br>Examples include allergist for any condition, dermatologist for atopic dermatitis, otolaryngologist for nasal polyps, or pulmonologist for asthma | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 8. Is there documentation of failure to have benefit with, or contraindication to, recommended conventional first-line treatments options (**Table 2 and 3**)? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 9. Is there documentation of disease severity prior to initiation of a targeted immune modulator (**Table 4**)? | **Yes:** Go to #10 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 10. Is the request for treatment of difficult to treat, severe asthma?<br><br>Note: Difficult to treat, severe asthma is defined as asthma with poor symptom control on high-dose inhaled corticosteroid-long-acting beta agonist (ICS-LABA) or maintenance oral corticosteroids (OCS). | **Yes:** Go to #11 | **No:** Go to #13 |
| 11. Has the patient been adherent to current asthma therapy in the past 12 months? | **Yes:** Go to #12 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 12. Is the patient currently receiving another monoclonal antibody (e.g., dupilumab, omalizumab, mepolizumab, benralizumab, reslizumab, tezepelumab etc.) without documentation indicating the patient is switching between treatments? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #13 |

| Approval Criteria | | |
|---|---|---|
| 13. Is the request for eosinophilic asthma, allergic asthma, or food allergies? | **Yes:** Go to #14 | **No:** Go to #15 |
| 14. Is there diagnostic documentation for the requested indication?<br>• Eosinophilic asthma: blood eosinophil count ≥150 cells/µL OR fractional exhaled nitric oxide (FeNO) ≥25 ppb in the past 12 months<br>• Allergic IgE-mediated asthma: positive skin test OR in vitro reactivity to perennial allergen<br>• Food allergy: IgE-mediated food allergy with skin testing to confirm allergy OR in vitro reactivity to perennial allergen | **Yes:** Approve for up to 12 months.<br><br>Document test and result:_____ | **No:** Pass to RPh. Deny; medical appropriateness. |
| 15. Is the request for a JAK inhibitor (e.g., abrocitinib)? | **Yes:** Go to #16 | **No:** Go to #17 |
| 16. Has the patient failed to have benefit with or have intolerance or contraindication to alternative targeted immunodulatory therapy? | **Yes:** Go to #17 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 17. Duration of approval based on indication: | Asthma, COPD, hypereosinophilic syndrome, eosinophilic granulomatosis with polyangiitis, and chronic spontaneous urticaria: 12 months<br><br>All other conditions: requested duration or 6 months, whichever is less | |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the request to renew therapy for inflammatory skin disease? | **Yes:** Go to #2 | **No:** Go to #3 |
| 2. Have the patient's symptoms improved with targeted immune modulator therapy?<br>• at least a 50% reduction in the Eczema Area and Severity Index score (EASI 50) from when treatment started OR<br>• at least a 4-point reduction in the Dermatology Life Quality Index (DLQI) or Children's Dermatology Life Quality Index (CDLQI from when treatment started OR<br>• at least a 2-point improvement on the Investigators Global Assessment (IGA) score? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is the request to renew therapy for asthma or COPD? | **Yes:** Go to #4 | **No:** Go to #6 |
| 4. Is the patient currently taking an inhaled corticosteroid and 2 additional controller drugs (i.e., long-acting inhaled beta-agonist, montelukast, zafirlukast, tiotropium) for asthma or triple inhaler therapy (ICS/LABA/LAMA) for COPD? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 5. Has the number of emergency department (ED) visits or hospitalizations in the last 12 months been reduced from baseline, or has the patient reduced their systemic corticosteroid dose by ≥50% compared to baseline or has the number of COPD exacerbations decreased? | **Yes:** Approve for up to 12 months. | **No:** Pass to RPh. Deny; medical appropriateness. |
| 6. Is the request to renew therapy for another FDA approved indication? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 7. Have the patient's symptoms improved with therapy? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness. |


1. *Oregon Health Evidence Review Commission. Coverage Guidance and Reports.* http://www.oregon.gov/oha/hpa/csi-herc/pages/index.aspx Accessed May 2, 2023.
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3. National Institute for Health and Care Excellence (NICE) Guidance. Dupilumab for Treating Severe Asthma with Type 2 Inflammation. https://www.nice.org.uk/guidance/ta751 December 2021
4. Global Initiative for Asthma. Global strategy for asthma management and prevention (2021 update). 2021. https://ginasthma.org/wp-content/uploads/2021/05/GINA-Main-Report-2021-V2-WMS.pdf

*P&T Review:* *12/24 (DM), 8/24; 6/23; 10/22; 6/22; 8/2; 10/20,7/19; 7/18; 7/16*
*Implementation:* *1/1/25; 9/1/24; 7/1/23; 1/1/23; 7/1/22; 1/1/22*

# Teplizumab

**Goal(s):**

- To promote safe and effective use in populations with established benefit:
  - Teplizumab has benefit for *prevention* of type 1 diabetes mellitus (T1DM) in members with stage 2 disease (defined below based on lab testing).
  - Benefit has not been established for symptomatic (stage 3) T1DM or members who do not meet the definition for stage 2 disease (defined below).

**Length of Authorization:**

- One 14-day treatment course.

**Requires PA:**

- All provider-administered and pharmacy point-of-sale claims for teplizumab

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. Is the request for an FDA approved age (e.g. 8 years of age or older)? | **Yes:** Go to #2 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 2. Has the patient previously been treated with teplizumab (use beyond the original 14 day infusion)? | **Yes:** Pass to RPh. Deny; medical appropriateness. No evidence to support additional doses. | **No:** Go to #3 |
| 3. Is the medication prescribed by or in consultation with an endocrinologist? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 4. Does the patient meet the standard criteria for the diagnosis of type 1 diabetes as determined as having one of the following:<br>- HbA1c of 6.5% or higher **OR**<br>- Fasting plasma glucose (FPG) of 126 mg/dL or higher **OR**<br>- Oral glucose tolerance test (OGTT) of 200 mg/dL or higher? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #5 |
| 5. Have baseline liver function tests and complete blood panel been evaluated in the past 2 months? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 6. Has the patient received, or have contraindications to, all routine immunizations recommended for their age based on provider attestation of immunization history?<br><br>Note:<br>- Teplizumab labeling recommends administration of live-attenuated vaccines at least 8 weeks prior to treatment and inactivated (killed) vaccines or mRNA vaccines at least 2 weeks prior to treatment.<br>- Routine vaccinations for patients at least 8 years of age typically include hepatitis B, hepatitis A, diphtheria, tetanus, pertussis, pneumococcal conjugate, inactivated poliovirus, influenza, and at least 2 doses of measles, mumps, rubella, and varicella. | **Yes:** Go to #7<br><br>Document provider attestation of immunization history. | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 7. Is the person at high risk of developing T1DM (e.g. Stage 2 diabetes) as determined by having the following:<br>- Presence of two or more diabetes-related autoantibodies (e.g. insulin autoantibodies (IAA), islet cell antibodies (ICA), glutamic acid decarboxylase 65 (GAD) autoantibodies, insulinoma-associated antigen 2 autoantibody (IA-2A), zinc transporter 8 autoantibody (ZnT8A)) **AND**<br>- Abnormal glucose confirmed within the last 2 months as determined by:<br>  - An abnormal glucose during an OGTT (140-199 mg/dL) **OR**<br>  - FPG 100-125 mg/dL **OR**<br>  - HbA1c 5.7-6.4% or ≥10% increase in HbA1c **OR**<br>  - 2-hour plasma glucose 140-199 mg/dL<br><br>Note: Teplizumab is preventative therapy and not approved at this time for people diagnosed with symptomatic T1DM (e.g. Stage 3) | **Yes:** Approve for one 14-day course. | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T/DUR Review: 4/23 (KS)*
*Implementation: 5/1/23*

# Teprotumumab

**Goal(s):**
- To ensure appropriate use of teprotumumab in patients with Thyroid Eye Disease (TED)

**Length of Authorization:**
- 8 total lifetime doses (approve for 9 months)

**Requires PA:**
- Teprotumumab (pharmacy and provider administered claims)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. Go to #2 | |
| 2. Is the patient an adult (18 years or older)? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the medication being ordered by, or in consultation with, an ophthalmologist or specialized ophthalmologist (e.g. neuro-ophthalmologist or ocular facial plastic surgeon)? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Does the patient have **moderate**, **severe**, or **sight-threatening** TED?<br>• Defined by the Graves' Orbitopathy Severity Assessment. Possible severity ratings are mild, moderate, severe, and sight-threatening. | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Does the patient have **active** TED?<br>• Defined as Clinical Activity Score (CAS) of 4 or higher on 7 point scale within past 3 months. | **Yes:** Go to #6<br><br>CAS score:_____<br>Score date:_____ | **No:** Go to #8 |

| Approval Criteria | | |
|---|---|---|
| 6. Does the patient have <u>any</u> of the following:<br>• active viral hepatitis, chronic liver disease, or a significant chronic infection <u>or</u><br>• a contraindication or severe side effect* to intermediate or high dose* corticosteroids <u>or</u><br>• failed to respond to 6 weeks of low-dose corticosteroid prophylaxis after radioactive iodine treatment <u>or</u><br>• failed to respond/relapsed after at least 3 weeks of intermediate or high dose* (IV or oral) corticosteroids<br><br>*Note:<br>• Teprotumumab is associated with hyperglycemia which may necessitate diabetic medication changes and may not be an appropriate alternative when avoiding steroids in patients with uncontrolled diabetes mellitus.<br>• Steroid regimens may vary. Example intermediate steroid regimen: 0.5 g/week for 6 weeks then 0.25 g/week for additional 6 weeks for cumulative dose 4.5 g IV methylprednisolone over ~ 3 months. Example high-dose steroid regimen: IV methylprednisolone 0.75 g/week for 6 weeks then 0.5 g/week for 6 weeks. | **Yes:** Go to #9 | **No:** Go to #7 |
| 7. Dose the patient have documentation of diplopia or significant proptosis*?<br><br>*Note: significant proptosis is defined as ≥ 3 mm above the upper limit for race and sex or < 3 mm but of sufficient severity to impact daily quality of life. | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Does the patient have **inactive** TED? | **Yes:** Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 9. Is the patient of childbearing potential?<br><br>Not considered of childbearing potential any of the following:<br>• Onset of menopause >2 years before current date or<br>• Non-therapy-induced amenorrhea >12 months before current date or<br>• Surgically sterile (absence of ovaries and/or uterus, or tubal ligation) or<br>• Not sexually active | **Yes:** Go to #10 | **No:** Go to #12 |
| 10. Is there documentation of negative pregnancy test within past 4 weeks? | **Yes:** Go to #11<br><br>Type of test (urine or serum): _____<br>Date of test:_____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 11. Has the provider attested that the patient has been counselled on risk of fetal harm AND agreed to use at least one reliable form of contraceptive for entire duration of drug therapy and for 180 days (6 months) after final dose?<br><br>• Reliable forms of birth control have less than 1% failure rate/year with consistent and correct use<br>• Examples include: implants, injectables, combined oral/intravaginal/transdermal contraceptives, intrauterine devices, sexual abstinence, or vasectomized partner<br>• Hormonal methods should be started at least one full menstrual cycle prior to initiation of teprotumumab. | **Yes:** Go to #12<br><br>Contraceptive method:_____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 12. Is there documentation that there has been a risk/benefit discussion with the patient related to risk of potentially permanent hearing impairment with teprotumumab AND documentation of a plan to assess/monitor hearing before, during, and after treatment? | **Yes:** Go to #13 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 13. Has the patient previously received any doses of teprotumumab? | **Yes:** Approve balance to allow 8 total lifetime doses†<br><br>(8 doses – previous # doses<br>= current approval #)<br><br>Previous number of doses_____ | **No:** Approve 8 doses† |

† All approvals will be referred for and offered optional case management

*P&T/DUR Review : 4/24 (SF); 12/20 (SF)*
*Implementation: 5/1/24; 1/1/2021*

# Tesamorelin (Egrifta®)

**Goal(s):**
- To ensure appropriate drug use and restrict to indications supported by medical literature.
- Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Tesamorelin (Egrifta and Egrifta SV®) subcutaneous injection

**Covered Alternatives:**
- No preferred alternatives

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the indicated treatment for reduction of excess abdominal fat in HIV-infected patients with lipodystrophy (ICD10 E881)? | **Yes:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #3. | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is there documentation that lipodystrophy has not sufficiently improved or cannot be managed by switching HIV antiretroviral therapy and lifestyle changes (e.g., diet and exercise)? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 4. Is there documentation that the condition is of sufficient severity that it impacts the patient's mental or physical health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.)? | **Yes:** Approve for 12 months. | **No:** Pass to RPh. Deny; medical necessity. |

*P&T/DUR Review:* *6/25 (DM); 9/15 (AG); 4/12*
*Implementation:* *8/1/2025; 10/15; 7/12*

# Testosterone

**Goal(s):**

- Restrict use to medically appropriate conditions funded under the Oregon Health Plan (use for sexual dysfunction or body-building is not covered)
- Allow case-by-case review for members covered under the EPSDT program.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- All testosterone products

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the medication requested for AIDS-related cachexia? | **Yes:** Go to #7 | **No:** Go to #3 |
| 3. Is the medication requested for one of the following diagnoses?<br>• Primary Hypogonadism (congenital or acquired): defined as testicular failure due to such conditions as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter's syndrome, chemotherapy, trauma, or toxic damage from alcohol or heavy metals OR<br>• Hypogonadotropic Hypogonadism (congenital or acquired): as defined by idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma or radiation | **Yes:** Go to #4 | **No:** Go to #6 |

| Approval Criteria | | |
|---|---|---|
| 4. Is there documentation of 2 morning (between 8 a.m. to 10 a.m.) tests (at least 1 week apart) demonstrating low testosterone levels at baseline as defined by the following criteria:<br>• Total serum testosterone level less than 300 ng/dL (10.4 nmol/L); OR<br>• Total serum testosterone level less than 350 ng/dL (12.1 nmol/L) AND free serum testosterone level less than 50pg/mL (or 0.174 nmol/L) | **Yes:** Go to #5 | **No:** Deny; medical appropriateness |
| 5. Is there documentation based on submitted chart notes of any of the following diagnoses:<br>• A recent major cardiovascular event (i.e., myocardial infarction, stroke or acute coronary syndrome) within the past 6 months<br>• Heart failure with uncontrolled symptoms (i.e., NYHA Class III-IV, presence of edema, or evidence of fluid retention)<br>• Benign prostate hyperplasia with uncontrolled symptoms or presence of severe lower urinary tract symptoms (i.e., frequent symptoms of incomplete emptying, increased frequency, intermittency, urgency, weak stream, straining, or nocturia)<br>• Breast cancer<br>• Prostate cancer (known or suspected) or elevated prostate specific antigen (PSA) with prior use of testosterone<br>• Untreated obstructive sleep apnea with symptoms<br>• Elevated hematocrit (>50%) | **Yes:** Deny; medical appropriateness | **No:** Go to #8 |
| 6. Is the medication requested for gender-affirming care? | **Yes:** Go to #7 | **No:** Go to #8 |

| Approval Criteria | | |
|---|---|---|
| 7. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products do not require a co-pay.<br>• Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics (P&T) Committee. | **Yes:** Inform prescriber of covered alternatives in class and approve the preferred product for up to 12 months. | **No:** Approve the requested agent for up to 12 months. |
| 8. RPh only: all other indications need to be evaluated for medical appropriateness under the OHP.<br><br>Note: Testosterone should not be prescribed to patients who have any contraindicated diagnoses listed in question #5.<br><br>Testosterone is FDA-approved only for primary hypogonadism and hypogonadotropic hypogonadism as defined in question #3. Safety and efficacy of testosterone therapy have not been established in people with late-onset (age-related) hypogonadism. | If not eligible for EPSDT review and prescriber provides evidence to supported off-label use: Approve for up to 12 months.<br><br>If eligible for EPSDT review: prescriber provides documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc) AND evidence supported off-label use: Approve for up to 12 months. | If there is not adequate documentation to support therapy: Deny; medical appropriateness. |

*P&T Review:* *10/24 (DE); 8/23 (SS); 11/18; 11/15; 2/12; 9/10; 2/06; 2/01; 9/00*
*Implementation:* *9/1/23; 1/1/19; 5/1/16; 1/1/16; 7/31/14; 5/14/12, 1/24/12, 1/1/11, 9/1/06*

# Tetracyclines (Oral)-Quantity Limit

**Goal(s):**

- Restrict use of oral tetracyclines to OHP-funded diagnoses in adults. Allow case-by-case review for members covered under the EPSDT program.
- Prevent inappropriate use beyond two, 14-day supplies within a 3-month time period
- Approve long-term use only for indications supported by the medical literature.

**Length of Authorization:**

- Up to 12 months

**Requires PA:**

- Long-term use of oral tetracyclines beyond two, 14-day supplies in a 3-month timeframe

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Is the request for an FDA-approved indication? | **Yes**: Go to #3 | **No:** Pass to RPh. If clinic provides supporting literature: Go to #3<br><br>If not supported by literature: Deny; medical appropriateness |
| 3. Is this an OHP-funded diagnosis? | **Yes**: Go to #4 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #6. |
| 4. Is the requested agent a preferred product? | **Yes:** Approve for duration of prescription or up to 6 months, whichever is less. | **No:** Go to #5 |

| Approval Criteria | | |
|---|---|---|
| 5. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>Preferred products are evidence-based and reviewed for comparative effectiveness and safety by the P&T Committee. | **Yes**: Inform prescriber of covered alternatives in class. | **No**: Approve until anticipated formal review by the P&T committee, for 6 months, or for length of the prescription, whichever is less. |
| 6. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical necessity. |
| 7. Is the request for a preferred product OR has the patient failed to have benefit with, or have contraindications or intolerance to, at least 2 preferred products?<br><br>Message:<br>Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Approve for 12 months. | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Inform prescriber of covered alternatives in class and process appropriate PA. |

*P&T / DUR Review:* *12/22; 5/17 (MH)*
*Implementation:* *1/1/23; 7/1/17*

# Thrombocytopenia Treatments

**Goal(s):**
- The goal of this initiative is to ensure thrombopoietin receptor agonists (TPOs) and tyrosine kinase inhibitors are used for their appropriate indications and for recommended treatment durations.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Non-preferred drugs

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this an FDA approved indication? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 3. Is this for a renewal therapy for a patient previously prescribed fostamatinib? | **Yes:** Go to Renewal Criteria | **No:** Go to #4 |
| 4. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• Preferred products do not require a PA.<br>• Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Inform prescriber of covered alternatives in class. | **No:** Go to #5 |
| 5. Is the request for avatrombopag (Doptelet®) or lusutrombopag (Mulpleta®) in a patient with chronic liver disease who is scheduled to undergo a procedure? | **Yes:** Approve for a maximum of 5 days for avatrombopag and for a maximum of 7 days for lusutrombopag. | **No:** Go to #6 |
| 6. Is the request for fostamatinib (Tavalisse™) and the patients has failed, or has contraindications to romiplostim and eltrombopag? | **Yes:** Approve for up to 3 months. | **No:** Pass to RPh. Deny; recommend trial of treatment(s) recommended in #6. |

| Renewal Criteria | | |
|---|---|---|
| 1. Is the renewal request for fostamatinib and the patient has had liver function tests within the previous 30 days? | **Yes:** Approve for up to 12 months. | **No:** Pass to RPh. Advise provider to monitor liver function tests as recommended by prescribing materials. |

*P&T/DUR Review: 1/2019 (KS)*
*Implementation: 3/1/2019*

# Topical Agents for Inflammatory Skin Disease

**Goal(s):**

- Restrict dermatological drugs only for funded OHP diagnoses for adults. Treatments are funded on the OHP for severe inflammatory skin diseases including: psoriasis, atopic dermatitis, lichen planus, Darier disease, pityriasis rubra pilaris, discoid lupus and vitiligo. Treatments for mild or moderate psoriasis, mild or moderate atopic dermatitis, seborrheic dermatitis, keratoderma and other hypertrophic and atrophic conditions of skin are not funded.
- Allow case-by-case review for members covered under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) program.

**Length of Authorization:**

- From 6 to 12 months

**Requires PA:**

- Non-preferred topical medications for inflammatory skin conditions.
- All topical medications approved for treatment of atopic dermatitis, psoriasis, and vitiligo for adults 21 years and older.
- This PA does not apply to oral or injectable targeted immune modulators for psoriasis or atopic dermatitis which are subject to separate clinical PA criteria.

**Covered Alternatives:**

- Preferred alternatives listed at www.orpdl.org/drugs/

**Table 1. FDA-Approved Ages and Evidence-supported Indications for Topical Drugs**

| Generic Drug Name | Brand Name | Minimum Age | Indication (severity) |
|---|---|---|---|
| Crisaborole 2% ointment | EUCRISA | 3 months | Atopic Dermatitis (Mild-to-Moderate) |
| Pimecrolimus 1% cream | ELIDEL | 2 years | Atopic Dermatitis (Mild-to-Moderate) |
| Ruxolitinib 1.5% cream | OPZELURA | 12 years | Atopic Dermatitis (Mild-to-Moderate)<br>Nonsegmental Vitiligo |
| Tacrolimus 0.03% ointment | PROTOPIC | 2 years | Atopic Dermatitis (Moderate-to-Severe) |
| Tacrolimus 0.1% ointment | PROTOPIC | 16 years | Atopic Dermatitis (Moderate-to-Severe) |
| Roflumilast 0.3% cream<br>Roflumilast 0.3% cream<br>Roflumilast 0.3% foam | ZORYVE | 6 years<br>6 years<br>9 years | Atopic Dermatitis<br>Plaque Psoriasis<br>Seborrheic Dermatitis |
| Tapinarof 1% cream | VTAMA | 18 years<br>2 years | Plaque Psoriasis<br>Atopic Dermatitis |
| Calcipotriene cream, solution, and ointment<br>Calcipotriene foam | DOVONEX<br>SORILUX | 18 years<br>4 years | Plaque Psoriasis |
| Tazarotene cream and gel | TAZORAC | 12 years | Plaque Psoriasis |
| Calcipotriene/Betamethasone ointment, suspension, foam<br>Calcipotriene/Betamethasone cream | TACLONEX<br>ENSTILAR<br>WYNZORA | 12 years<br><br>18 years | Plaque Psoriasis |
| Anthralin Shampoo<br>Anthralin Cream | ZITHRANOL | 12 years<br>18 years | Plaque Psoriasis |
| Halobetasol propionate/Tazarotene Lotion | DUOBRII | 18 years | Plaque Psoriasis |
| Calcitriol ointment | VECTICAL | 2 years | Plaque Psoriasis |

**Table 2. Topical First-Line Treatment Options Based on Disease Severity**

| | |
|---|---|
| Atopic Dermatitis (AD) | Mild to Moderate AD: Low-, Medium-, or High-Potency Corticosteroids* for 2-4 weeks or Calcineurin Inhibitors (pimecrolimus, tacrolimus)<br>Severe AD: High to Super-High Potency Corticosteroids for 2 weeks or Tacrolimus |
| Plaque Psoriasis | Mild to Moderate PsO: Moderate- to High-Potency Corticosteroids* for 4 weeks, Calcineurin Inhibitors (pimecrolimus, tacrolimus) for 8 weeks, Vitamin D Analogues (calcitriol, calcipotriene) for 4 |

| | |
|---|---|
| (PsO) | weeks, or Tazarotene for 8 weeks[1]<br>Severe PsO: High to Super-High Potency Corticosteroids for 4 weeks[1] |
| Nonsegmental Vitiligo | Mild to Severe Vitiligo: Moderate- to High-Potency Corticosteroids* for 2 months or Calcineurin Inhibitors (pimecrolimus, tacrolimus) for 3 months[2] |
| Note: *Strength of corticosteroid determined by patient age, site of inflammation, and severity of the condition | |

**Table 3. Potency of topical corticosteroid preparations using U.S. classification**[3]

| Potency Group | Corticosteroid | Strength | Formulation |
|---|---|---|---|
| **Lowest Potency (Group 7)** | Hydrocortisone Base and Hydrocortisone Acetate | 0.5%, 1.0%, 2.0% | cream, ointment, gel, lotion, solution |
| **Low Potency (Group 6)** | Alcometasone dipropionate | 0.05% | cream, ointment |
| | Betamethasone valerate | 0.05% | lotion |
| | Desonide | 0.05% | cream |
| | Fluocinolone acetonide | 0.01% | cream, oil, shampoo, solution |
| | Triamcinolone acetonide | 0.1% | cream |
| **Medium-Low Potency (Group 5)** | Betamethasone dipropionate | 0.05% | lotion |
| | Betamethasone valerate | 0.1% | cream |
| | Betamethasone valerate | 0.01% | cream, lotion |
| | Desonide | 0.05% | lotion, ointment |
| | Fluocinolone acetonide | 0.025% | cream |
| | Flurandrenolide | 0.05% | cream |
| | Fluticasone propionate | 0.05% | cream |
| | Hydrocortisone butyrate | 0.1% | cream |
| | Hydrocortisone valerate | 0.2% | cream |
| | Prednicarbate | 0.1% | cream |
| | Triamcinolone acetonide | 0.1% | lotion |
| **Medium Potency (Group 4)** | Betamethasone valerate | 0.12% | foam |
| | Desoximetasone | 0.05% | cream |
| | Fluocinolone acetonide | 0.025% | ointment |
| | Fluocinolone acetonide | 0.2% | cream |
| | Flurandrenolide | 0.05% | ointment |
| | Halcinonide | 0.025% | cream |
| | Hydrocortisone probutate | 0.1% | cream |
| | Hydrocortisone valerate | 0.2% | cream |
| | Mometasone furoate | 0.1% | cream, lotion, solution |
| | Prednicarbate | 0.1% | ointment |
| **Medium-High Potency (Group 3)** | Amcinonide | 0.1% | cream, lotion |
| | Betamethasone valerate | 0.1% | ointment |
| | Diflorasone diacetate | 0.05% | cream |
| | Fluocinonide | 0.05% | cream |
| | Fluticasone propionate | 0.005% | ointment |
| | Halcinonide | 0.1% | ointment, solution |
| | Triamcinolone acetonide | 0.5% | cream |
| | Triamcinolone acetonide | 0.1% | ointment |
| **High Potency (Group 2)** | Amcinonide | 0.1% | ointment |
| | Betamethasone dipropionate, augmented (Diprolene®) | 0.05% | cream, lotion |
| | Betamethasone dipropionate, unaugmented (Diprosone®) | 0.05% | cream, ointment |
| | Desoximetasone | 0.25% | cream, ointment, spray |
| | Desoximetasone | 0.05% | gel |
| | Diflorasone diacetate | 0.05% | ointment |
| | Fluocinonide | 0.05% | cream, gel, ointment, |

| | | | |
|---|---|---|---|
| | | | solution |
| | Halcinonide | 0.1% | cream |
| | Mometasone furoate | 0.1% | ointment |
| | Triamcinolone acetonide | 0.5% | ointment |
| **Super-High Potency (Group 1)** | Betamethasone dipropionate, augmented (Diprolene®) | 0.05% | gel, ointment |
| | Clobetasol propionate | 0.05% | cream, foam, gel, lotion, ointment, shampoo, spray |
| | Diflorasone diacetate | 0.05% | ointment |
| | Fluocinonide | 0.1% | cream |
| | Flurandrenolide | 4 mcg/cm$^2$ | tape |
| | Halobetasol propionate | 0.05% | cream, ointment |

| **Approval Criteria** | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD 10 code. | |
| 2. Is the request for treatment of severe inflammatory skin disease?<br>Severe disease is defined as:[4]<br>• Having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on other validated tool) AND one or more of the following:<br>3. At least 10% body surface area involved OR<br>4. Hand, foot, face, or mucous membrane involvement | **Yes:** Go to #4 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP<br><br>If eligible for EPSDT review: Go to #3 |
| 3. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical necessity |
| 4. Is the diagnosis plaque psoriasis, atopic dermatitis or nonsegmental vitiligo? | **Yes:** Go to #5 | **No:** Go to #8 |
| 5. Does the patient meet the age requirements per the FDA label?<br><br>Note: minimum ages for commonly prescribed drugs are listed in **Table 1** | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is the requested product preferred? | **Yes**: Approve for 6 months | **No**: Go to #7 |

| Approval Criteria | | |
|---|---|---|
| 7. Does the patient have a documented contraindication, intolerance or failed trials of at least 2 preferred first line agents (Table 2)? | **Yes:** Document drug and dates trialed, and intolerances or contraindications (if applicable):<br>1._____(dates)<br>2._____(dates)<br><br>Approve for length of treatment; maximum 6 months. | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Is the request for an FDA approved indication and age OR is supporting literature provided? | **Yes**: Approve for 1 year | **No:** Pass to RPh. Deny; medical appropriateness. |

**The Health Evidence Review Commission has stipulated via Guideline Note 21 that mild and moderate uncomplicated inflammatory skin conditions including psoriasis, atopic dermatitis, lichen planus, Darier disease, pityriasis rubra pilaris, and discoid lupus are not funded. Uncomplicated is defined as no functional impairment; and/or involving less than 10% of body surface area and no involvement of the hand, foot, or mucous membranes.*

*References:*


1. *Elmets CA, Korman NJ, Prater EF, 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. J Am Acad Dermatol. 2021;84(2):432-470.*
2. *Eleftheriadou, V., Atkar, R., Batchelor, J., McDonald, B., etal.., British Association of Dermatologists guidelines for the management of people with vitiligo 2021*. Br J Dermatol, 186: 18-29. https://doi.org/10.1111/bjd.20596*
3. *Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at http://www.micromedexsolutions.com. Accessed October 6, 2022.*
4. *Oregon Health Evidence Review Commission. Coverage Guidance and Reports. http://www.oregon.gov/oha/hpa/csi-herc/pages/index.aspx. Accessed March 1, 2022.*


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*P&T/DUR Review:* *12/22 (DM); 6/22; 12/20; 10/20; 7/19; 5/19; 3/18; 9/17; 7/15; 1/15; 09/10; 9/09; 3/09; 5/07; 2/06*
*Implementation:* *2/1/23; 7/1/22; 1/1/2021, 11/1/20; 8/19/19; 4/16/18; 10/15; 8/15; 9/13; 6/12; 9/10; 1/10; 7/09; 6/07; 9/06*

# Topiramate

**Goal(s):**

- Approve topiramate only for funded diagnoses which are supported by the medical literature (e.g. epilepsy and migraine prophylaxis).

**Length of Authorization:**

- 90 days to lifetime

**Requires PA:**

- Non-preferred topiramate products

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code | |
| 2. Does the patient have diagnosis of epilepsy? | **Yes:** Approve for lifetime. | **No:** Go to #3 |
| 3. Is the request for treatment of migraine? | **Yes:** Approve for 90 days with subsequent approvals dependent on documented positive response for lifetime. | **No:** Go to #4 |
| 4. Does the patient have a diagnosis of bipolar affective disorder or schizoaffective disorder? | **Yes:** Go to #5 | **No:** Go to #6 |
| 5. Has the patient tried or are they contraindicated to at least two of the following drugs?<br>• Lithium<br>• Valproate and derivatives<br>• Lamotrigine<br>• Carbamazepine<br>• Atypical antipsychotic<br><br>Document drugs tried or contraindications. | **Yes:** Approve for 90 days with subsequent approvals dependent on documented positive response for lifetime approval. | **No:** Pass to RPh; Deny; medical appropriateness. Recommend trial of 2 covered alternatives. |

| Approval Criteria | | |
|---|---|---|
| 6. Is the patient using the medication for weight loss? (Obesity ICD10 E669; E6601)? | **Yes:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP AND weight loss drugs excluded by state plan.<br><br>If eligible for EPSDT review: Go to #7 | **No:** Pass to RPh. Go to #9 |
| 7. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical necessity. |
| 8. Has the patient failed to have benefit with, or have contraindications or intolerance to, preferred topiramate products?<br><br>Message: Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. | **Yes:** Approve for 90 days with subsequent approvals up to 12 months dependent on documented positive response | **No:** Pass to RPh. Deny; medical appropriateness.<br><br>Inform prescriber of covered alternatives in class and process appropriate PA. |
| 9. All other indications need to be evaluated for appropriateness:<br>• Neuropathic pain<br>• Post-Traumatic Stress Disorder (PTSD)<br>• Substance abuse | Use is off-label: Deny; medical appropriateness. Other treatments should be tried as appropriate.<br><br>If clinically warranted: Deny; medical appropriateness. Use clinical judgment to approve for 1 month to allow time for appeal. MESSAGE: "Although the request has been denied for long-term use because it is considered medically inappropriate, it has also been APPROVED for one month to allow time for appeal." | |

*P&T Review:* *4/25 (DM);10/22 (SF); 10/21; 10/20; 6/20; 5/19; 1/19; 7/18; 3/18; 3/17; 7/16; 3/15; 2/12; 9/07; 11/07*
*Implementation:* *4/18/15; 5/12, 1/12*

# Drugs for Transthyretin-Mediated Amyloidosis (ATTR)

**Goal(s):**

- To limit utilization of medications for transthyretin mediated amyloidosis (ATTR) to FDA-approved indications and in populations with proven safety.

**Length of Authorization:**

- Up to 6 months

**Requires PA:**

- All medications indicated for ATTR (both pharmacy and provider-administered claims)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1: FDA approved therapies for ATTR amyloidosis**

| Drug | Indication |
|---|---|
| Acoramidis | Cardiomyopathy of wild-type or variant ATTR |
| Eplontersen | Polyneuropathy of hereditary ATTR |
| Inotersen | Polyneuropathy of hereditary ATTR |
| Patisiran | Polyneuropathy of hereditary ATTR |
| Tafamidis | Cardiomyopathy of ATTR (hereditary and wild type) |
| Vutrisiran | Cardiomyopathy or ATTR (hereditary and wild type)<br>Polyneuropathy of hereditary ATTR |

| Approval Criteria | | |
|---|---|---|
| 1. Is this a request for continuation of therapy previously approved by the FFS program? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #2 |
| 2. What diagnosis is being treated? | Record ICD10 code. | |
| 3. Is this an FDA approved indication of ATTR amyloidosis supported by transthyretin mutation proven by genetic testing (See Table 1)? | **Yes**: Go to #4<br><br>Document Genotype: _____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Does the patient have clinical signs and symptoms of disease (peripheral/autonomic neuropathy, motor disability, cardiovascular dysfunction)? | **Yes**: Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the request for or is the patient on concurrent use of more than one ATTR therapy (including diflunisal)? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #6 |

| Approval Criteria | | |
|---|---|---|
| 6. Has the patient had a liver transplantation? | **Yes:** Pass to RPh. Deny; medical appropriateness. | **No:** Go to #7 |
| 7. Is the request for patisiran or inoteren? | **Yes:** Go to #8 | **No:** Go to #15 |
| 8. Is baseline disease severity documented (polyneuropathy disability (PND) score and Familial amyloid polyneuropathy (FAP) stage)? | **Yes:** Document and Go to #9 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 9. Was the medication prescribed or in consultation with a neurologist? | **Yes:** Go to #10 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 10. Is the patient on Vitamin A supplementation or have a documented normal level? | **Yes:** Go to #11 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 11. Is the request for patisiran? | **Yes**: Approve for 6 months | **No**: Go #12 |
| 12. Is the request for inotersen? | **Yes:** Go to #13 | **No:** Go to #15 |
| 13. Has a baseline platelet count been obtained in the previous 3 months and are platelets ≥ 125 X $10^9$/L? | **Yes:** Go to #14<br><br>Document baseline platelet count:_____<br>Date of Lab:_____ | **No:** Pass to RPh. Deny; medical appropriateness. |
| 14. Has baseline renal function been evaluated in the previous 3 months? | **Yes:** Approve for 6 months<br><br>Document baseline serum creatinine and BUN:_____<br>Date of Lab:_____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 15. Is the request for tafamidis? | **Yes:** Go to #16 | **No:** Go to #18 |
| 16. Was the medication prescribed or in consultation with a cardiologist? | **Yes:** Go to #17 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 17. Does the patient have a medical history of heart failure (NYHA class I-III) with at least one prior hospitalization for heart failure? | **Yes:** Approve for 6 months | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 18. Is the request for a newly approved hATTR therapy and does the indication match the FDA approved indication? | **Yes:** Approve for 6 months | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Has the patient had a documented response to treatment including at least one of the following:<br>a. Improved neurologic impairment<br>b. Improved motor function<br>c. Improved quality of life<br>d. Improved cardiac function | **Yes:** Go to #2 | **No:** Pass to RPh; Deny (medical appropriateness) |
| 2. Is the prescribed medication tafamidis? | **Yes:** Approve for 12 months | **No:** Go to #3 |
| 3. Has the patient experienced stabilization OR improvement from baseline in one of the following:<br>a. Baseline polyneuropathy disability (PND) score<br>b. Familial amyloid polyneuropathy (FAP) stage | **Yes:** Go to #4 | **No:** Pass to RPh; Deny (medical appropriateness) |
| 4. Is the renewal for inotersen? | **Yes:** Go to #5 | **No:** Approve for 12 months |
| 5. Does the patient have a platelet count ≥ 100 X $10^9$/L? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 9/19; 7/19 (MH)*
*Implementation: 11/1/19*

# Tricyclic Antidepressants

**Goal(s):**
- Ensure safe and appropriate use of tricyclic antidepressants in children less than 12 years of age
- Discourage off-label use not supported by compendia

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Tricyclic antidepressants in children younger than the FDA-approved minimum age (new starts)
- Auto-PA approvals for:
  - Patients with a claim for an SSRI or TCA in the last 6 months
  - Prescriptions identified as being written by a mental health provider

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. FDA-Approved Indications of Tricyclic Antidepressants in Children**

| Drug | FDA-Approved Indications | Maximum Daily Dose | Minimum FDA-Approved Age |
|---|---|---|---|
| amitriptyline HCl | Depression | 50 mg | 12 |
| amoxapine | Depression | 400 mg | 18 |
| clomipramine HCl | Obsessive-compulsive disorder | 200 mg | 10 |
| desipramine HCl | Depression | 300 mg<br>(150 mg for 10-19 years of age) | 10 |
| doxepin HCl | Depression<br>Anxiety | 150 mg | 12 |
| imipramine HCl | Depression<br>Nocturnal enuresis | 75 mg | 6 |
| imipramine pamoate | Depression | 200 mg | 18 |
| maprotiline HCl | Depression<br>Bipolar depression<br>Dysthymia<br>Mixed anxiety and depressive disorder | 225 mg | 18 |
| nortriptyline HCl | Depression | 50 mg | 12 |
| protriptyline HCl | Depression | 60 mg | 12 |
| trimipramine maleate | Depression | 100 mg | 12 |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Does the dose exceed the maximum FDA-approved dose (**Table 1**)? | **Yes:** Go to #3 | **No:** Go to #4 |

| Approval Criteria | | |
|---|---|---|
| 3. Is there documentation that the prescriber is monitoring blood levels to support use of the prescribed dose? | **Yes:** Go to #4 | **No:** Go to #6 |
| 4. Is the request for an FDA-approved indication and age (**Table 1**)? | **Yes:** Approve for up to 6 months | **No:** Go to #5 |
| 5. Is the request for prophylactic treatment of headache or migraine and is the therapy prescribed in combination with cognitive behavioral therapy? | **Yes**: Approve for up to 6 months | **No:** Go to #6 |
| 6. Is the drug prescribed by or in consultation with an appropriate specialist for the condition (e.g., mental health specialist, neurologist, etc.)? | **Yes**: Approve for up to 6 months | **No:** Pass to RPh. Deny; medical appropriateness. |

*P&T/DUR Review: 6/24 (KS); 12/23 (KS), 2/23, 2/21(SS) 11/19*
*Implementation:7/1/24; 2/1/2020*

# Trofinetide (DAYBUE)

**Goal(s):**
- Promote use that is consistent with medical evidence and product labeling in patients with Rett syndrome.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Trofinetide oral solution

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. Recommended Weight-Based Trofinetide Oral Solution 200 mg/mL Dosing**

| Patient Weight | Trofinetide Dosage | Trofinetide Volume |
|---|---|---|
| 9 kg to less than 12kg | 5,000 mg twice daily | 25 mL twice daily |
| 12 kg to less than 20 kg | 6000 mg twice daily | 30 mL twice daily |
| 20 kg to less than 35 kg | 8,000 mg twice daily | 40 mL twice daily |
| 35 kg to less than 50 kg | 10,000 mg twice daily | 50 mL twice daily |
| 50 kg or more | 12,000 mg twice daily | 60 mL twice daily |
| Abbreviations: kg = kilograms; mg = milligrams; mL = millilters | | |

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for continuation of therapy previously approved by the FFS program? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Does the patient have a diagnosis of Rett syndrome? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is there documentation of genetic testing to confirm Rett syndrome diagnosis? | **Yes:** Go to #5 | **No:** Pass to RPh. Refer to Medical Director for review. |
| 5. Is the requested medication prescribed by a neurologist or a provider with experience in treating Rett syndrome? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is the request for an FDA approved age (e.g., 2 years of age and older)? | **Yes**: Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Is the request for an approved weight-based dosing regimen (see **Table 1**)? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 8. Has the provider documented specific and measurable goals of therapy?<br><br>Note: Documentation should include what will be assessed, how progress will be measured, and timeline for assessment. Goals should be attainable within 6 months and relevant to the condition or health of the patient. Documentation of progress toward or achievement of therapeutic goals will be required for renewal. | **Yes:** Document Assessment and Date:_____<br>_____<br><br>Approve for 6 months. Note: The first 2 pharmacy fills are limited to 14 days each to assess tolerance to therapy. Initial fills can overlap to ensure adequate time for delivery.<br><br>1.Approve Initial Request for enough units up to 14 days.<br>2. Approve enough units to cover subsequent 14-28 days.<br>3. Approve enough units for up to 6 months (5 to 24 weeks). | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Is there evidence of adherence and tolerance to therapy through pharmacy claims/refill history and/or provider assessment? | **Yes:** Go to #2 | **No:** Pass to RPh; Deny; medical appropriateness. |
| 2. Has the patient met the goals of therapy described in the initial authorization by the prescribing provider and provider attests to patient's stabilization on therapy? | **Yes:** Approve for 12 months. Document assessment and provider attestation received. | **No:** Pass to RPh; Deny; medical appropriateness. |

*P&T/DUR Review: 8/23 (DM)*
*Implementation: 9/1/23*

# Vadadustat (VAFSEO)

**Goal(s):**
- To limit utilization to FDA-approved indications and in populations with proven safety

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Pharmacy and provider administered claims

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this for anemia of chronic disease due to chronic kidney disease in an adult (18 years or older)? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Has the patient been on dialysis for at least 3 months? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Does the patient have a documented contraindication or intolerance to an erythropoiesis stimulating agent (ESA) (e.g., epoetin or darbepoetin)? | **Yes:** Go to #6 | **No:** Go to #5 |
| 5. Does the patient have documented a lack of response to an ESA after at least 3 months of therapy? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is there documentation of active malignancy? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #7 |
| 7. Is there documentation that the patient has uncontrolled hypertension (≥140mmHg/≥90mmHg)? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #8 |
| 8. Is there documentation of baseline ALT, AST, and bilirubin? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 2/25 (SF) Implementation: 3/10/25*

# Valoctocogene roxaparvovec-rvox

**Goal(s):**

- Approve valoctocogene roxaparvovec-rvox (ROCTAVIAN) for conditions supported by evidence of benefit.

**Length of Authorization:**

- Once in a lifetime dose.

**Requires PA:**

- Valoctocogene roxaparvovec (billed as pharmacy or provider administered claim)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is it the FDA approved indication? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is there documentation that the patient has never received another gene therapy for any diagnosis? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Does the patient have severe Hemophilia A with factor VIII activity of < 1 IU/dL? | **Yes**: Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is there documentation that the patient does not have factor VIII inhibitors? | **Yes:** Go to #6<br>Test date_____<br>Result_____ | **No**: Pass to RPh. Deny; medical appropriateness |
| 6. Is the patient 18 years or older? | **Yes**: Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Has the patient tested negative for adeno-associated virus serotype 5 (AAV5) antibodies as measured by an FDA approved test? | **Yes**: Go to #8<br>Test date_____<br>Result_____ | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 8. Has this patient had a liver health assessment (ALT, AST, bilirubin, alkaline phosphatase, INR, ultrasound or other radiologic assessment) and were all hepatic enzymes and hepatic radiological tests normal?<br><br>Note: Mild enzyme elevations which are transient and resolved on repeat testing may answer "Yes" to this question. | **Yes**: Go to # 11 | **No:** Go to #9 |
| 9. Does the patient have a history of severe liver fibrosis or cirrhosis? | **Yes**: Pass to RPh. Deny; medical appropriateness | **No:** Go to #10 |
| 10. Has the patient been evaluated and cleared for gene therapy treatment by a gastroenterologist or hepatologist? | **Yes**: Go to #11 | **No:** Pass to RPh. Deny; medical appropriateness |
| 11. Is the patient able and willing to abstain from alcohol for one year following receipt of gene therapy? | **Yes**: Go to #12 | **No:** Pass to RPh. Deny; medical appropriateness |
| 12. Is there documentation that the patient does not have any active, acute or chronic infections, including HIV, hepatitis B, or hepatitis C? | **Yes**: Go to #13 | **No:** Pass to RPh. Deny; medical appropriateness |
| 13. Is it anticipated that the patient will be able to safely use corticosteroids or other immunosuppressants for at least 8 weeks if needed? | **Yes**: Approve one lifetime does. | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 10/23 (SF)*
*Implementation: 11/1/23*

# Vericiguat (Verquvo®)

**Goal(s):**
- Restrict use of vericiguat in populations and at doses in which the drug has demonstrated efficacy.
- Encourage use of beta-blockers and inhibitors of the renin-angiotensin-aldosterone system with demonstrated evidence of mortality reduction in heart failure with reduced ejection fraction.

**Length of Authorization:**
- 6 to 12 months

**Requires PA:**
- Vericiguat (Verquvo®)

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. Is this a request for continuation of therapy previously approved by the FFS program? | **Yes:** Go to Renewal Criteria | **No:** Go to #2 |
| 2. What diagnosis is being treated? | Record ICD10 code. Go to #3. | |
| 3. Does the patient have symptomatic New York Heart Association (NYHA) Class II to IV chronic heart failure? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Does the patient have reduced ejection fraction (< 45%) assessed within the previous 12 months? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Does the patient have worsening heart failure defined as one of the following?<br>a. History of previous heart failure hospitalization within the last 6 months<br>b. Intravenous diuretic use within previous 3 months | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is the patient currently being seen by a cardiologist or heart failure specialist for management of advanced disease? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 7. Is the patient on an angiotensin system inhibitor at maximally tolerated dose, such as:<br>a. Angiotensin converting enzyme inhibitor (ACE-I)<br>b. Angiotensin receptor blocker (ARB)<br>c. Angiotensin receptor-neprilysin inhibitor (ARNI) | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Is the patient currently on a maximally tolerated dose of carvedilol, sustained-release metoprolol succinate, or bisoprolol; and if not, is there a documented intolerance or contraindication to each of these beta-blockers?<br><br>*Note: the above listed beta-blockers have evidence for mortality reduction in chronic heart failure at target doses and are recommended by national and international heart failure guidelines.[1,2] Carvedilol and metoprolol succinate are preferred agents on the PDL.* | **Yes:** Go to #9 | **No:** Pass to RPh. Deny, medical appropriateness |
| 9. Is there evidence of adherence and tolerance to goal directed heart failure therapy (beta-blocker and angiotensin inhibitor) through pharmacy claims/refill history and provider assessment? | **Yes:** Go to #10 | **No:** Pass to RPh. Deny, medical appropriateness |
| 10. Is the patient on long-acting nitrates such as isosorbide dinitrate, isosorbide 5-mononitrate, transdermal nitroglycerin, or other similar agents or phosphodiesterase-5 (PDE5) inhibitors (e.g. sildenafil, tadalafil)? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #11 |
| 11. Does the patient have stage 5 chronic kidney disease (eGFR < 15 ml/min or on hemodialysis/peritoneal dialysis)? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #12 |
| 12. Is the patient of childbearing potential? | **Yes:** Go to #13 | **No:** Approve for 6 months |
| 13. Is the patient pregnant or actively trying to conceive? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #14 |

| Approval Criteria | | |
|---|---|---|
| 14. Is there documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant? | **Yes:** Approve for 6 months | **No:** Pass to RPh. Deny, medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Has the patient developed symptomatic hypotension or syncope while on vericiguat? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #2 |
| 2. Has the patient experienced disease progression, defined as either worsening NYHA functional class or worsening signs and symptoms of heart failure requiring intensification of therapy? | **Yes:** Go to #3 | **No:** Approve for 12 months |
| 3. Is the patient currently being seen by a cardiologist or heart failure specialist for management of advanced disease? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

References:
1. Yancy CW, Jessup M, Bozkurt B, et al. 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;62(16):e147-239. doi: 10.1016/j.jacc.2013.05.019.
2. McMurray J, Adamopoulos S, Anker S, et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012. European Journal of Heart Failure. 2012;14:803-869. doi:10.1093/eurjhf/hfs105.

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*P&T / DUR Review:* *06/21 (MH)*
*Implementation:* *7/1/21*

# Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors

**Goal(s):**
- Promote safe use of VMAT2 inhibitors in adult patients.
- Promote use that is consistent with medical evidence.

**Length of Authorization:**
- Initial: Up to 3 months
- Renewal: Up to 12 months

**Requires PA:**
- All VMAT2 inhibitors

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. Go to #2 | |
| 2. Is the request for continuation of vesicular monoamine transporter 2 (VMAT2) inhibitor therapy previously approved by FFS criteria (patient has completed 3-month trial)? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Is the request for a patient 18 years or older with a diagnosis of chorea as a result of Huntington's disease? | **Yes:** Go to #4 | **No:** Go to #6 |
| 4. Does the patient have a baseline total maximal chorea score of 8 or higher as assessed by the Unified Huntington's disease Rating Scale–Total Chorea Movement subscore (UHDRS-TCS)? | **Yes:** Go to #5<br><br>Document baseline score: _____ | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Has it been determined that the patient does not have uncontrolled depression or at risk of violent or suicidal behavior? | **Yes:** Approve for 3 months. | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 6. Is the request for deutetrabenazine or valbenazine in a patient 18 years or older with a diagnosis of moderate to severe tardive dyskinesia? | **Yes:** Approve for 3 months.<br><br>Document baseline modified AIMS* score: _____ | **No:** Go to #7 |
| 7. Is the request for tetrabenazine in a patient with tics associated with Tourette syndrome? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Has the patient tried and failed an adequate trial of at least **2** of the following guideline directed medications[1]:<br>a. Clonidine or guanfacine OR<br>b. Topiramate OR<br>c. One of the following antipsychotics: pimozide, aripiprazole or risperidone?<br>OR<br>Does the patient have a documented intolerance, FDA-labeled contraindication, or hypersensitivity to the guideline directed medications? | **Yes:** Approve for 3 months<br><br>Document baseline Yale Global Tic Severity Score (YGTSS) Total Tic Severity (range 0 to 50)_____ _ | **No:** Pass to RPh. Deny; medical appropriateness |

* The dyskinesia score for the modified Abnormal Involuntary Movement Scale (AIMS) for numbers 1-7

| Renewal Criteria | | |
|---|---|---|
| 1. Is the request for a renewal of valbenazine or deutetrabenazine in a patient with tardive dyskinesia? | **Yes:** Go to #2 | **No:** Go to #3 |
| 2. Has the patient been taking the requested VMAT2 inhibitor for >3 months and has there been documented evidence of clinical improvement by a reduction in AIMS dyskinesia score from baseline? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the request for valbenazine, tetrabenazine or deutetrabenazine in a patient with chorea as a result of Huntington's disease? | **Yes:** Go to #4 | **No**: Go to #6 |

| Renewal Criteria | | |
|---|---|---|
| 4. Has the patient been taking the requested VMAT2 inhibitor for >3 months and has there been documented evidence of improvement in total maximal chorea score as assessed by the Unified Huntington's disease Rating Scale–Total Chorea Movement subscore **(**UHDRS-TCS**),** of at least 2 points from baseline? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Has it been determined that the mental status of the patient is stable and there is no indication of uncontrolled depression or risk of violent or suicidal behavior? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is the request for tetrabenazine in a patient with tics associated with Tourette syndrome? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Has the patient been taking tetrabenazine for >3 months and has there been documented evidence of reduced tic severity from baseline as assessed by the Yale Global Tic Severity Score (YGTSS) Total Tic Score (range 0-50) ? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

1. Pringsheim T, Okun MS, Müller-Vahl K, et al. Practice guideline recommendations summary: Treatment of tics in people with Tourette syndrome and chronic tic disorders. *Neurology.* 2019;92(19):896-906.

*P&T/DUR Review: 10/23 (DM); 1/2018(KS)*
*Implementation: 11/1/23; 3/1/18*

# Voclosporin

**Goal(s):**
- Promote use that is consistent with medical evidence.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Voclosporin pharmacy claims

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this an FDA approved indication? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is this a request for continuation of therapy previously approved by fee-for-service (FFS)? | **Yes:** Go to **Renewal Criteria** | **No:** Go to #4 |
| 4. Does the patient have Class III, Class IV, or Class V lupus nephritis AND is a baseline assessment with one of the following:<br>• Urinary protein to creatinine ratio<br>• eGFR | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |
| 5. Is the drug being prescribed by or in consultation with a rheumatologist, nephrologist, or a provider with experience treating lupus nephritis? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is the patient currently on cyclophosphamide?<br>Note: Voclosporin safety and efficacy has not been established in combination with cyclophosphamide and use is not recommended. | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #7 |

| Approval Criteria | | |
|---|---|---|
| 7. Is the patient currently taking or have a contraindication to ALL of the following:<br>• Mycophenolate OR Azathioprine<br>• Glucocorticoids (e.g. prednisone)<br>• Hydroxychloroquine | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Does the patient have proteinuria with a urine protein: creatinine ratio of >500 mg/g? | **Yes:** Go to #9 | **No:** Go to #10 |
| 9. Is the patient currently taking, or have a contraindication to, either an angiotensin-converting enzyme inhibitor (ACEI) OR an angiotensin II receptor blocker (ARB)? | **Yes:** Go to #10 | **No:** Pass to RPh. Deny; medical appropriateness. |
| 10. Is the patient of childbearing potential? | **Yes:** Go to #11 | **No:** Approve for 6 months |
| 11. Is the patient pregnant or actively trying to conceive? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #12 |
| 12. Is there documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant? | **Yes:** Approve for 6 months | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 1. Does the patient have an eGFR within past 60 days?<br>Note: Should be monitored monthly per package labeling. | **Yes:** Go to #2<br><br>Record eGFR value & date<br>_____ | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 2. Has the voclosporin dose been adjusted appropriately based on baseline eGFR and current eGFR?<br>• If eGFR <60 mL/min/1.73 m2 and reduced from baseline by >20% and <30%, reduce the dose by 7.9 mg twice a day. Reassess eGFR within two weeks; if eGFR is still reduced from baseline by >20%, reduce the dose again by 7.9 mg twice a day.<br>• If eGFR <60 mL/min/1.73 m2 and reduced from baseline by ≥30%, discontinue LUPKYNIS. Re-assess eGFR within two weeks; consider re-initiating LUPKYNIS at a lower dose (7.9 mg twice a day) only if eGFR has returned to ≥80% of baseline.<br>• For patients that had a decrease in dose due to eGFR, consider increasing the dose by 7.9 mg twice a day for each eGFR measurement that is ≥80% of baseline; do not exceed the starting dose. | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Has the patient's lupus nephritis improved or stabilized as assessed by one of the following:<br>• Urinary protein to creatinine ratio<br>• eGFR | **Yes:** Approve for 12 months. | **No:** Pass to RPh; Deny; medical appropriateness. |

*P&T/DUR Review: 2/22 (SF)*
*Implementation: 4/1/22*

# Voretigene neparvovec (Luxturna)

**Goal(s):**

- Restrict use of voretigene neparvovec to patients with retinal dystrophy associated with biallelic RPE65 mutations

**Length of Authorization:**

- Up to 6 months

**Requires PA:**

- Voretigene neparvovec (applies to both provider administered and pharmacy claims)

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request from a provider at a center of excellence who is trained for and following administration and treatment protocols for voretigene neparvovec? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the patient greater than 1 year of age? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Has the patient been previously enrolled in clinical trials of gene therapy for retinal dystrophy RPE65 mutations or been previously been treated with gene therapy for retinal dystrophy in the eye(s) receiving treatment? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #5 |
| 5. Does the patient have other pre-existing eye conditions or complicating systemic diseases that would eventually lead to irreversible vision loss and prevent the patient from receiving full benefit from treatment (eg. severe diabetic retinopathy)? | **Yes**: Pass to RPh. Deny; medical appropriateness | **No:** Go to #6 |
| 6. Does the patient have retinal dystrophy with confirmed biallelic RPE65 mutations? | **Yes:** Go to #7<br><br>Document genetic testing | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 7. Does the patient have a visual acuity of at least 20/800 OR have remaining light perception in the eye(s) receiving treatment? | **Yes:** Go to #8 | **No:** Pass to RPh. Deny; medical appropriateness |
| 8. Does the patient have visual acuity of less than 20/60 OR a visual field of less than 20 degrees? | **Yes:** Go to #9<br><br>Document baseline visual function | **No:** Pass to RPh. Deny; medical appropriateness |
| 9. Does the provider document presence of neural retina and a retinal thickness >100 microns within the posterior pole as assessed by optical coherence tomography with AND have sufficient viable retinal cells as assessed by the treating physician? | **Yes:** Approve up to 2 doses for up to 6 months.<br><br>Document retinal thickness and physician attestation | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 3/18 (SS)*
*Implementation: 4/16/18*

# Vosoritide

**Goal(s):**
- Ensure medically appropriate use of approved agents for the treatment of achondroplasia in pediatric patients

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Vosoritide

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1:**

| Actual Body Weight* | Dose | Injection Volume | Vial Strength for Reconstitution** |
|---|---|---|---|
| 3 kg | 0.096 mg | 0.12 mL | 0.4 mg |
| 4 kg | 0.12 mg | 0.15 mL | 0.4 mg |
| 5 kg | 0.16 mg | 0.2 mL | 0.4 mg |
| 6 to 7 kg | 0.2 mg | 0.25 mL | 0.4 mg |
| 8 to 11 kg | 0.24 mg | 0.3 mL | 0.4 mg |
| 10-11 kg | 0.24 mg | 0.3 mL | 0.4 mg |
| 12-16 kg | 0.28 mg | 0.35 mL | 0.56 mg |
| 17-21 kg | 0.32 mg | 0.4 mL | 0.56 mg |
| 22-32 kg | 0.4 mg | 0.5 mL | 0.56 mg |
| 33-43 kg | 0.5 mg | 0.25 mL | 1.2 mg |
| 44-59 kg | 0.6 mg | 0.3 mL | 1.2 mg |
| 60-89 kg | 0.7 mg | 0.35 mL | 1.2 mg |
| ≥90 kg | 0.8 mg | 0.4 mL | 1.2 mg |

*=Intermediate body weights that fall within these weight bands should be rounded to the nearest whole number.
**=The concentration of vosoritide in reconstituted 0.4 mg vial and 0.56 mg vial is 0.8 mg/mL. The concentration of vosoritide in reconstituted 1.2 mg vial is 2 mg/mL.

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this an FDA approved indication based on diagnosis and current age restrictions? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the prescribed agent being dosed according to actual body weight (ABW) as outlined in Table 1? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is the request for continuation of therapy in a patient previously approved by FFS? | **Yes:** Go to Renewal Criteria | **No:** Go to #5 |
| 5. Is the agent prescribed by, or in consultation with, a pediatric endocrinologist, neurologist, or other prescriber specialized in the care of patients with achondroplasia or skeletal dysplasia? | **Yes:** Go to #6 | **No:** Pass to RPh. Deny; medical appropriateness |
| 6. Is there documented evidence of a baseline measurement of annualized growth velocity (AGV) within the last 90 days AND, if male ≥15 years or female ≥13 years old, evidence of non-closure of epiphyseal plates? | **Yes:** Go to #7 | **No:** Pass to RPh. Deny; medical appropriateness |
| 7. Does the patient have a history of bone-related surgery or fracture of long bone or spine within the previous 6 months or planned bone surgery? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Go to #8 |
| 8. Does the patient have a diagnosis of recurrent symptomatic hypotension with or without orthostasis? | **Yes:** Pass to RPh. Deny; medical appropriateness | **No:** Approve for 6 months |

| Renewal Criteria | | |
|---|---|---|
| 1. Is this an FDA approved indication based on diagnosis and current age restrictions? | **Yes**: Go to #2 | **No:** Pass to RPh. Deny; medical appropriateness |
| 2. Is there documented evidence that the regimen is well tolerated with no adverse effects or drug toxicity? | **Yes:** Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 3. Is there documented evidence of adherence of at least 85% to the approved therapy regimen verified through claims history and/or provider assessment<br>OR<br>If adherence less than 85% of the time, there is documentation that the discontinuation was temporary due to the need for surgery or treatment of an infection? | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Is this the first renewal request? | **Yes:** Approve for 6 months | **No:** Go to #5 |
| 5. Is there documented evidence of an improvement in annualized growth velocity (AGV) ≥ 1.0 cm/year from baseline AND, if male ≥15 years or female ≥13 years old, evidence of non-closure of epiphyseal plates? | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 4/22 (DE)*
*Implementation: 5/1/22*

# Weight Management Drugs

**Goal(s):**

- To provide guidance for the use of weight management therapies to ensure they are used in the most appropriate patient populations in which evidence supports efficacy and safety.
- Allow case-by-case review for members covered under the EPSDT program. Recommend use of GLP-1 receptor agonists only for FDA-approved indications supported by the evidence.
- To provide guidance for the use of weight management drugs, like semaglutide (WEGOVY) and tirzepatide (ZEPBOUND), to ensure coverage for the most appropriate patient populations in which evidence supports efficacy and safety for reduction in cardiovascular (CV) outcomes, nonalcoholic steatohepatitis (NASH, also called metabolic dysfunction-associated steatohepatitis [MASH]) and obstructive sleep apnea (OSA).

**Length of Authorization:**

- Up to 6 months
- Renewal up to 12 months

**Requires PA:**

- All drugs used for weight management.
- Refer to the Glucagon-like Peptide-1 (GLP-1) Receptor Agonists and Glucose Dependent Insulinotropic Polypeptide (GIP) Receptor Agonist PA Criteria for approval of semaglutide (OZEMPIC and RYBELSUS) and tirzepatide (MOUNJARO) for type 2 diabetes.

  Note: Semaglutide is not currently covered for adults who do not have established cardiovascular disease, non-alcoholic steatohepatitis (NASH), or type 2 diabetes. Tirzepatide is not currently covered for adults who do not have established obstructive sleep apnea or type 2 diabetes.

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

**Table 1. Drugs FDA Approved for Weight Management**

| Drug | Adults | Pediatrics |
|---|---|---|
| Liraglutide (SAXENDA) | Yes | Yes – 12 years and older |
| Naltrexone/bupropion (CONTRAVE) | Yes | No |
| Phentermine/topiramate (QSYMIA) | Yes | Yes – 12 years and older |
| Semaglutide (WEGOVY) | Yes | Yes – 12 years and older |
| Tirzepatide (ZEPBOUND) | Yes | No |
| Setmelanotide (IMCIVREE) | Yes | Yes – 2 years and older |
| Orlistat (Xenical) | Yes | Yes – 12 years and older |

**Table 2. BMI Cutoffs for Obesity by Sex and Age for Pediatric Patients Aged 12 Years and Older (CDC Criteria)**

| Age (years) | Body mass index (kg/m2) at 95% percentile | |
|---|---|---|
| | Males | Females |
| 12 | 24.2 | 25.2 |
| 12.5 | 24.7 | 25.7 |
| 13 | 25.1 | 26.3 |

| | | |
|---|---|---|
| 13.5 | 25.6 | 26.8 |
| 14 | 26.0 | 27.2 |
| 14.5 | 26.4 | 27.7 |
| 15 | 26.8 | 28.1 |
| 15.5 | 27.2 | 28.5 |
| 16 | 27.5 | 28.9 |
| 16.5 | 27.9 | 29.3 |
| 17 | 28.2 | 29.6 |
| 17.5 | 28.6 | 30 |

**Table 3. Evidence-Supported Indications**
Note: Drugs prescribed for only weight management (overweight or obesity) are NOT currently covered

| Drug | Indications |
|---|---|
| Liraglutide | • Non-alcoholic steatohepatitis (NASH) with stage 2 or 3 fibrosis in adults 18 years and older* |
| Semaglutide | • Established cardiovascular disease (e.g., history of myocardial infarction, stroke, or symptomatic peripheral arterial disease)<br>• Non-alcoholic steatohepatitis (NASH) with stage 2 or 3 fibrosis in adults 18 years and older* |
| * NASH Requirements:<br>• Diagnosis by liver biopsy OR all of the following:<br>○ documentation that the patient does NOT have ongoing or recent (within 2 years) significant alcohol use or chronic or active viral hepatitis. Significant alcohol use can be patient-specific but is typically defined as greater than 21 drinks/week (or >30 g/day) in men and greater than 14 drinks/week (or >20 g/day) in women.<br>○ provider attestation or documentation that other causes of hepatic steatosis are not suspected based on patient history/presentation or have been ruled out. Examples of other secondary causes of hepatic steatosis include, but are not limited to, Wilson's disease, lipodystrophy, abetalipoproteinemia, medications (e.g., amiodarone, methotrexate, tamoxifen, corticosteroids).<br>○ documentation that the patient has, or is receiving drug treatment for, at least 3 of the 5 metabolic risk factors associated with MASH. Risk factors include:<br>▪ Overweight or obesity or increased waist circumference (BMI ≥ 25 kg/m$^2$ or ethnicity adjusted equivalent)<br>▪ Hypertension<br>▪ Type 2 diabetes mellitus<br>▪ Hypertriglyceridemia<br>▪ Decreased level of high density lipoprotein (HDL)<br>• fibrosis stage 2 or 3 as shown by appropriate diagnostic test within past 24 month [appropriate tests may include biopsy, vibration controlled transient elastography (VCTE), magnetic resonance elastography (MRE), enhanced liver fibrosis test (ELF)]<br>• medication being ordered by, or in consultation with, a hepatologist or gastroenterologist | |
| Tirzepatide | • Moderate to severe obstructive sleep apnea (OSA) in adults with obesity |

| Approval Criteria | |
|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. |

| Approval Criteria | | |
|---|---|---|
| 2. Is this a request for continuation of therapy after an initial approval by FFS? | **Yes**: Go to **Renewal Criteria** | **No:** Go to #3 |
| 3. Does the patient have a BMI corresponding to one of the following:<br>1) ≥30 kg/m$^2$ or<br>2) ≥25 kg/m$^2$ and comorbid conditions [e.g., diabetes mellitus, hypertension, dyslipidemia, fatty liver disease, or cardiovascular disease] or<br>3) a BMI at the 95$^{th}$ percentile or greater for age and sex (Table 2 above)? | **Yes:** Go to #4<br><br>Record baseline BMI | **No:** Deny; medical appropriateness |
| 4. Will the patient be engaged in a weight management lifestyle modification program in addition to pharmacotherapy?<br><br>See clinical notes below | **Yes:** Go to #5 | **No:** Deny; medical appropriateness. All drugs approved for weight loss are indicated as an adjunct to diet and exercise. |
| 5. Is the member eligible for EPSDT review AND is the requested medication FDA-approved for their age (Table 1)? | **Yes:** Go to #6 | **No:** Go to #11 |
| 6. Is the request for setmelanotide? | **Yes**: Go to #7 | **No:** Go to #9 |
| 7. Does the patient have obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance OR does the patient have Bardet—Biedl syndrome (BBS)? | **Yes**: Go to #8 | **No:** Deny; medical appropriateness. |
| 8. Does the patient have a history of depression and/or suicidal ideation? | **Yes**: Deny; medical appropriateness. | **No:** Approve for up to 6 months. |
| 9. Does the patient have comorbidities (e.g., hypertension, dyslipidemia, diabetes, fatty liver disease, depression, or sleep apnea)? | **Yes:** Approve for 6 months | **No:** Go to #10 |

| Approval Criteria | | |
|---|---|---|
| 10. Has the patient previously tried a weight loss treatment plan administered by a health care provider (e.g., diet and exercise program, nutritional counseling, and/or a calorie restricted diet) for a time period of at least 3 months within the previous 6-month timeframe*?<br><br>* See Clinical Notes Below | **Yes:** Approve for 6 months. | **No:** Deny; medical appropriateness. Lifestyle modifications are recommended by guidelines. |
| 11. Is the request for an indication in Table 3?<br><br>Note: drugs when prescribed for weight management (e.g., obesity or overweight) in the absence of another evidence-supported indication are not currently covered. | **Yes:** Go to #12 | **No:** Pass to RPh. Deny; drugs are not covered by OHP for adults when indicated for weight loss. |
| 12. Has the patient previously tried a weight loss treatment plan administered by a health care provider (e.g., diet and exercise program, nutritional counseling, and/or a calorie restricted diet) for a time period of at least 3 months within the previous 6-month timeframe? | **Yes**: Go to #13 | **No:** Deny; medical appropriateness |
| 13. Is there documentation of a type 2 diabetes diagnosis? | **Yes:** Go to #15 | **No:** Go to #14 |
| 14. Has the patient been screened for diabetes within the past year and do screening results indicate they do not have diabetes (e.g., HbA1c <6.5% or fasting blood glucose <126 mg/dl (7 mmol/L)? | **Yes:** Go to #15 | **No:** Pass to RPh; Deny; medical appropriateness.<br><br>Recommend screening and if positive recommend a GLP-1 RA indicated for glucose lowering (see GLP-1 RA/GIP RA PA criteria) |
| 15. Is the request for tirzepatide (ZEPBOUND)? | **Yes:** Go to #19 | **No:** Go to #16 |
| 16. Is the request for semaglutide (WEGOVY)? | **Yes:** Go to #17 | **No:** Approve for up to 6 months |

| Approval Criteria | | |
|---|---|---|
| 17. Is the patient currently taking semaglutide (OZEMPIC) 2.0 mg weekly and is able to tolerate the medication and is still desiring additional weight loss? | **Yes**: Approve for up to 6 months | **No:** Go to #18 |
| 18. Will the patient try semaglutide (OZEMPIC) for at least 4 months to ensure tolerability/compliance? | **Yes**: Approve Ozempic for up to 6 months<br><br>* Load PA for OZEMPIC | **No:** Pass to RPh. Deny; medical appropriateness. |
| 19. Does the patient have obesity (BMI of 30 kg/m$^2$ or greater) and moderate to severe obstructive sleep apnea (OSA)?<br>- Moderate OSA is defined as an apnea-hypopnea index (AHI) of 15 events/hour or more<br>- Severe OSA is defined as an AHI of 30 events/hour or more | **Yes:** Approve tirzepatide (ZEPBOUND) for up to 6 months | **No:** Pass to RPh. Deny; medical appropriateness. |

| Renewal Criteria | | |
|---|---|---|
| 1. Is this a request for continuation of therapy with a weight loss medication previously approved by FFS? | **Yes**: Go to #2 | **No:** Go to **Approval Criteria** above |
| 2. Is the person requesting the medication less than 18 years of age? | **Yes:** Go to #3 | **No:** Go to #4 |
| 3. Has the patient lost at least 1% of BMI from baseline or maintained at least a 1% BMI weight loss? | **Yes:** Go to #7 | **No:** Deny; medical appropriateness |
| 4. Is the request for ongoing treatment for someone with established cardiovascular disease (e.g., history of myocardial infarction, stroke, or symptomatic peripheral arterial disease), NASH or OSA? | **Yes:** Go to #5 | **No:** If not eligible for EPSDT review: Pass to RPh. Deny; drugs are not covered by OHP for adults when indicated for weight loss.<br><br>If eligible for EPSDT review: Go to #5 |
| 5. Has the patient lost or maintained a BMI reduction of 5% or more? | **Yes**: Go to #6 | **No:** Deny; medical appropriateness |
| 6. Has the patient been adherent to therapy based on provider attestation? | **Yes:** Go to #7 | **No:** Deny; medical appropriateness |

| Renewal Criteria | | |
|---|---|---|
| 7. Is the patient continuing with a weight loss treatment plan (e.g., diet and exercise program, nutritional counseling, and/or a calorie restricted diet)? | **Yes:** Approve for up to 12 months. | **No:** Deny; medical appropriateness. All drugs approved for weight loss are indicated as an adjunct to diet and exercise. |

***Clinical Notes**

Adapted from the following guideline on the treatment of adolescents with obesity:

- American Academy of Pediatrics. *Pediatrics*. 2023;151(2): e2022060640. Available at: https://publications.aap.org/pediatrics/article/151/2/e2022060640/190443/Clinical-Practice-Guideline-for-the-Evaluation-and?autologincheck=redirected

Recommended Behavior Strategies

| Strategy | Description |
|---|---|
| 1. Reduction in sugar-sweetened beverages (SSBs) | Higher intake of sugar-sweetened beverages (carbonated beverages, sweetened beverages, soda, sports drinks, and fruit drinks) is associated with greater weight gain in adults and children. The American Heart Association (AHA) recommends not more than 25 g (6 tsp) each day of added sugar and not more than 1, 8-oz serving of SSB per week. The AAP discourages the consumption of sports drinks and energy drinks for children and adolescents. The AAP statement on fruit juice notes that it is a poor substitute for whole fruit because of its high sugar and calorie content and pediatricians should advocate for elimination of fruit juice in children with excessive weight gain. |
| 2. Choose My Plate | MyPlate is the US Department of Agriculture's (USDA) broad set of recommendations for healthy eating for Americans. These recommendations include multiple healthy diet goals: low in added sugar, low in concentrated fat, nutrient dense but not calorie dense, within an appropriate calorie range without defined calorie restriction, and with balanced protein and carbohydrate. The principles can be adapted to different food cultures. There is a surprising dearth of literature on the impact of these guidelines on health and BMI outcomes and on the most effective education practices. **Available at: USDA choose my plate.gov** |
| 3. 60 minutes daily of moderate to vigorous physical activity | Aerobic exercise, especially for 60 min at a time, is associated with improved body weight in youth although its effect may be small and variable. It is also associated with better glucose metabolism profiles. High-intensity interval training in youth with obesity may improve body fat, weight, and cardiometabolic risk factors, although the effect is variable. The Physical Activity Guidelines for Americans recommends 60 min per day for children and adolescents. |
| 4. Reduction in sedentary behavior | Reduction in sedentary behavior, generally defined as reduced screen time, has consistently shown improvement in BMI measures, although impact is small. Early studies focused on reduced television, a discrete activity that is simpler than current multifunctional electronic devices. The AAP recommends no media use under age 18 month, a 1-hour limit for ages 2–5 years, and a parent- monitored plan for media use in older children, with a goal of appropriate, not- excessive use but without a defined upper limit. |

The activities most commonly associated with positive behavior change are: parental involvement in goal setting, problem solving, social support, demonstrating desired behaviors, and home environment modifications to support positive change.

Abbreviations: AAP – American Academy of Pediatrics; BMI = body mass index; oz = ounce; tsp = teaspoon; USDA = United States Department of Agriculture

*P&T/DUR Review: 4/25 (KS); 8/24 (SS/SF); 6/24 (KS)*
*Implementation: 5/12/25; 9/1/24; 7/1/24*

# Xanomeline-trospium (COBENFY) Safety Edit

**Goal(s):**
- Promote safe use of xanomeline-trospium in combination with other mental health drugs for schizophrenia.

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- Xanomeline-trospium
- Auto-approval requests for people with a claim for xanomeline-trospium in the last 6 months

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is xanomeline-trospium prescribed for an FDA-approved indication? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Is the intent to prescribe xanomeline-trospium in conjunction with another antipsychotic medication? | **Yes:** Go to #4 | **No:** Go to #5 |
| 4. Is there documentation or provider attestation that the benefits of therapy (e.g. symptom improvement, social function, number of hospitalizations, etc) outweigh potential risks of combination treatment (e.g. hepatic impairment, biliary disease, gastrointestinal and anticholinergic effects, etc)? | **Yes:** Go to #5 | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 5. Is there documentation or provider attestation that the patient does not have any of the following conditions?<br>• Concurrent antidepressant that inhibits CYP2D6 (e.g., bupropion, fluoxetine, paroxetine, or duloxetine)<br>• Urinary retention (e.g., benign prostatic hyperplasia, diabetic cystopathy)<br>• Untreated narrow-angle glaucoma<br>• Impaired gastric motility (e.g., gastrointestinal obstructive disorders)<br>• Mild, moderate or severe hepatic impairment, biliary disease, or elevated liver function tests<br>• Moderate or severe renal impairment or estimated glomerular filtration rate (eGFR) <60 mL/min | **Yes:** Approve for 12 months | **No:** Pass to RPh. Deny; medical appropriateness |

*P&T/DUR Review: 8/25; 2/25 (SS)*
*Implementation: 3/10/25*

# Zuranolone (Zurzuvae)

**Goal(s):**
- To ensure appropriate use of zuranolone in patients with post-partum depression.

**Length of Authorization:**
- One time use only.

**Requires PA:**
- Zuranolone requires a prior authorization approval due to safety concerns.

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is this an FDA approved indication and age (e.g., ≥18 years)? | **Yes**: Go to #3 | **No:** Pass to RPh. Deny; medical appropriateness |
| 3. Does the patient have moderate to severe post-partum depression?<br><br>Note: Zuranolone is not indicated for major depressive disorder but can be covered for depression meeting the clinical diagnosis of post-partum depression (e,g., moderate to severe depression with peripartum onset). | **Yes:** Go to #4 | **No:** Pass to RPh. Deny; medical appropriateness |
| 4. Has the patient been previously treated with zuranolone for severe post-partum depression related to their most recent pregnancy? | **Yes:** Pass to RPh. Deny; medical appropriateness. Multiple courses of zuranolone have not been studied. | **No:** Approve for a single 14-day treatment. |

*P&T/DUR Review: 6/24 (KS); 12/23 (KS)*
*Implementation: 1/1/24*