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

May 1, 2022

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 May 1, 2022

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

- Botulinum Toxins
- Emergency drug coverage for CWM
- Drugs for nonfunded conditions
- Efgartigimod
- Fabry Disease
- Preferred drug list – nonpreferred drugs in select PDL classes
- Orphan Drugs
- Sickle Cell Disease
- Vosoritide

Clerical changes

- Analgesics, Non-Steroidal Anti-Inflammatory Drugs
- Exclusion list
- Oncology agents
- Proton pump inhibitors
- Sleep wake medications

For questions, contact the Division's Pharmacy Program at dmap.rxquestions@state.or.us.

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.

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 • FQHC/RHC and AI/AN providers - Also enter the pharmacy or clinic NPI for your facility
Section II	Type of PA Request: Mark "Pharmacy" • 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 • 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
Section VIII:	Complete for oral nutritional supplements only

HEALTH SYSTEMS DIVISION
Medicaid Programs

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 Prior Authorization 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 have received this Prior Authorization 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 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 __/__/____

OHP 3978 (12/2021)

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? ☐ Yes ☐ No
- 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 bone fracture)*? ☐ Yes ☐ No
- Malabsorption difficulties *(e.g., Crohn's disease, cystic fibrosis, bowel resection/removal, short gut syndrome, 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 assessment indicating adequate intake is not obtainable through regular, liquefied or pureed foods:

Serum protein level: Date taken:

Albumin level: Date taken:

Current weight: Normal weight:

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 http://www.oregon.gov/OHA/HSD/OHP/Pages/PT-Committee.aspx
- For summaries of P&T Committee recommendations approved by OHA for policy implementation, view the OHA Recommendations posted at http://www.oregon.gov/OHA/HSD/OHP/Pages/PT-Committee.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@state.or.us

Voicemail: 503-947-5220
Fax: 503-947-1119

Acne Medications

Goal(s):
- Ensure that medications for acne are used appropriately for OHP-funded conditions.

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? 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:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP.
4. Will the prescriber consider a change to a preferred product? Message: • 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 process appropriate PA.	**No:** Approve for 12 months.

P&T/DUR Review: 02/21 (SF); 06/2020 (SF); 11/18 (JP)
Implementation: 7/1/20; 1/1/1

Aducanumab

Goal(s):
- To support medically appropriate 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 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/

Table 1. Aducanumab Dosing and ARIA Monitoring

IV Infusion (every 4 weeks)	Dose	ARIA Monitoring
Infusion 1 and 2	1 mg/kg	MRI 90 days prior to Infusion 1
Infusion 3 and 4	3 mg/kg	MRI 28 days prior to Infusion 7
Infusion 5 and 6	6 mg/kg	
Infusion 7 to 11	10 mg/kg	MRI 28 days prior to Infusion 12
After Infusion 12	10 mg/kg	MRI annually

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

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is this being 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 diagnosis funded by OHP?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP.

Approval Criteria		
4. Will the prescriber consider a change to a preferred product? Message: • 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:** Go to #5
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 the therapy prescribed by or in consultation with a neurologist?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness
7. 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: • Clinical Dementia Rating (CDR)-Global Score of 0.5; **AND** • Objective evidence of cognitive impairment at screening; **AND** • Mini-Mental Status Exam (MMSE) score between 24 and 30 (inclusive); **AND** • Positron Emission Tomography (PET) scan positive for amyloid beta plaque or presence of amyloid confirmed in cerebrospinal fluid (CSF)?	**Yes:** Go to #8 Document test results.	**No:** Pass to RPh. Deny; medical appropriateness There is insufficient evidence for use of this agent in treating moderate or severe AD
8. Has the patient received a baseline brain magnetic resonance imaging (MRI) within 90 days 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 assessed and documented baseline disease severity within the last 6 months utilizing an objective measure/tool (e.g., MMSE, Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13], 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], or other validated AD patient monitoring tool)?	**Yes:** Record baseline measurement. Go to #10	**No:** Pass to RPh. Deny; medical appropriateness
10. 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 [**ARIA-E**]-edema (brain swelling) and/or [**ARIA-H**]-hemosiderin deposition (brain bleeding or protein deposits on brain/spinal cord)?	**Yes:** Record scheduled appointment dates: _____ Go to #11	**No:** Pass to RPh. Deny; medical appropriateness
11. Has the prescriber ruled out the presence of any vascular abnormalities which may increase bleeding risk/ARIA **AND** has the patient been screened to ensure they are not currently receiving anticoagulant or antiplatelet therapy (excluding aspirin 81 mg)?	**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: • Clinical Dementia Rating (CDR)-Global Score of 0.5; AND • Objective evidence of cognitive impairment at screening; AND • Mini-Mental Status Exam (MMSE) score between 24 and 30 (inclusive)	**Yes:** Go to #2	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
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
3. Is there documented evidence of beta-amyloid reduction compared to baseline confirmed by post-infusion brain imaging or CSF testing?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Was there an adverse event (ARIA-H or ARIA-E [brain microhemorrhage, superficial siderosis, or edema], hypersensitivity reaction, etc.) observed or reported with aducanumab therapy?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #5
5. Has the patient received at least 6 months of uninterrupted aducanumab therapy?	**Yes:** Go to #6	**No:** Approve remaining duration of the 6-month titration period
6. Is there documentation that, compared to baseline assessment, aducanumab therapy has resulted in: • cognitive or functional improvement **OR** • disease stabilization **OR** • reduction in clinical decline compared to the natural disease progression? The same clinical measure used to assess AD (e.g., CDR-SB, MMSE, ADAS-Cog-13, ADCS-ADL-MCI, etc) is recommended to document clinical benefit.	**Yes:** Approve for up to 6 months Document benefit	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 10/21 (DE)
Implementation: 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®	≥ 18		20 mg	80 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

Approval Criteria		
4. Is the request for a non-preferred product and will the prescriber consider a change to a preferred product? Message: • 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
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 Document baseline results.	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
11. Does the patient have follow-up appointments scheduled during weeks 1 and 2 after the proposed therapy initiation date?	**Yes:** Go to #12 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 Go to #2	**No:** Pass to RPh. Deny; medical appropriateness
2. Is the amifampridine dose within appropriate limits? (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; not funded by the OHP.
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. Go to # 5	**No:** Pass to RPh. Deny; medical appropriateness. 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. Dose not to exceed 1 vial per day (590 mg/8.4 ml vial). Renewal consideration will require documentation of monthly MAC sputum cultures and regimen adherence.	**No:** Pass to RPh. Deny; medical appropriateness. 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. Approve for additional 3 months. 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.
- 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 #3	**No:** Pass to RPh. Deny; not funded by the OHP
3. 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 #4.	**No:** Go to #5
4. 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 #5
5. Will the prescriber consider switching to a preferred product? Message: • Preferred products do not require PA. • 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: *2/21 (KS), 3/16 (MH); 11/14; 9/13; 2/12; 9/09; 2/06*
Implementation: *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 physician 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. Is the diagnosis funded by OHP?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP.
4. 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 #5
5. Is this a request for continuation of therapy previously approved by fee-for-service (FFS)?	**Yes**: Go to **Renewal Criteria**	**No:** Go to #6
6. Is the patient currently on other biologic therapy?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**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?	**Yes:** Go to # 8	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
8. Does the patient have a baseline assessment of SLE disease activity available using one of the following functional assessment tools: • SLE Index Score (SIS) • British Isles Lupus Assessment Group (BILAG) • Systemic Lupus Activity Measure (SLAM) • Systemic Lupus Erythematosus Disease Activity Score (SLEDAI or modified versions, e.g. SLEDAI-2K, SELENA-SLEDAI) • Physicians Global Assessment (PGA) • Systemic Lupus International Collaborating Clinic (SLICC) Damage Index	**Yes:** Go to # 9. Document baseline assessment _____.	**No:** Pass to RPh. Deny; medical appropriateness
9. Is the patient currently taking ALL of the following or have a documented contraindication: • Hydroxychloroquine • Glucocorticoids (e.g. prednisone) • 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: • SLE Index Score (SIS) • British Isles Lupus Assessment Group (BILAG) • Systemic Lupus Activity Measure (SLAM) • Systemic Lupus Erythematous Disease Activity Score (SLEDAI or modified versions, e.g. SLEDAI-2K, SELENA-SLEDAI) • Physicians Global Assessment (PGA) • 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

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 will be subject to PA criteria.

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

Approval Criteria		
1. What is the diagnosis being treated?	Record ICD10 Code.	
2. Will the prescriber consider a change to the preferred product? Message: • Preferred products do not require a PA. • 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? Message: • Preferred vitamin B products do not require a PA. • 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	**Yes:** Approve for up to 6	**No:** Go to #8

diagnosis AND receiving chemotherapy or radiation?	months.	
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.

Length of Authorization:

- See criteria

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/

Table 1: Examples of FUNDED indications (12/16/21)

ICD-10	Description
B37.3	Candidiasis of vulva and vagina
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
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, B48.8, 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, N75.9, N76.0-N77.1	Inflammatory disease of cervix vagina and vulva
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

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, L23.0, L23.81, L24.81, L25.0, L25.2, L25.8-25.9, L55.1-55.2 ,	Contact dermatitis and other eczema

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
B35.1	Tinea unguium (onychomycosis)
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 (12/16/21)

ICD-10	Description
B35.0	Dermatophytosis of scalp and beard (tinea capitis/ tinea barbae)
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 #4
3. Will the prescriber consider a change to a preferred product? Message: • Preferred products do not require PA. • 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.
4. 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 #5

<table>
<tr><th colspan="3">Approval Criteria</th></tr>
<tr><td>5. Is the diagnosis not funded by OHP? (see examples in Table 2).</td><td>Yes: Pass to RPh. Deny; not funded by OHP</td><td>No: Got to #6</td></tr>
<tr><td>6. Is the diagnosis funded by OHP if criteria are met? (see examples in Table 3).</td><td>Yes: Go to #7</td><td>No: Go to #9</td></tr>
<tr><td>7. Is the patient immunocompromised (examples below)?
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
Does the patient have a diagnosis of HIV/AIDS? OR
Does the patient have sickle cell anemia?
Poor nutrition, elderly or chronically ill?
Other conditions as determined and documented by a RPh.</td><td>Yes: Record ICD-10 code. Approve as follows: (immunocompromised patient)

ORAL & TOPICAL
Course of treatment.
If length of therapy is unknown, approve for 3 months.</td><td>No: Go to #8</td></tr>
<tr><td>8. Is the patient currently taking an immunosuppressive drug? Document drug.

Pass to RPh for evaluation if drug not in list.

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)

ORAL & TOPICAL
Course of treatment.

If length of therapy is unknown, approve for 3 months.</td><td>No: Pass to RPh. Deny; not funded by the OHP</td></tr>
</table>

Approval Criteria

9. 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: 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: *2/22 (KS); 11/19 (KS); 7/15; 09/10; 2/06; 11/05; 9/05; 5/05*
Implemented: *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.
- 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:

- 6 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? Message: • 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:** 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 inhaled corticosteroid, leukotriene antagonist, etc.) and/or inhaled rescue beta-agonist (e.g. albuterol) within the last 6 months? *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. *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? • Acute or chronic inflammation of the orbit • Chronic Sinusitis • Acute Sinusitis • Sleep apnea • Wegener's Granulomatosis	**Yes:** Document ICD-10 codes. Go to #7	**No:** Pass to RPh. Deny; not funded by the OHP
7. Does patient have contraindications (e.g. pregnancy), or had insufficient response to available alternatives? 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 Chronic Bronchitis?	**Yes:** Pass to RPh. Deny; not funded by the OHP	**No:** Pass to RPh. Go to #10
10. RPh only: Is the diagnosis above the line or below the line? • Above: Deny; medical appropriateness • Below: Deny; not funded by the OHP (e.g., acute upper respiratory infections or urticaria).		

P&T Review: *5/15 (AG); 9/10; 9/08; 2/06; 9/04; 5/04; 2/02*
Implementation: *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 Month
Almotriptan	Axert	25 mg	6.25 mg tab 12.5 mg tab	12 tabs
Eletriptan	Relpax	80 mg	20 mg tab 40 mg tab (blister pack 6, 12)	6 tabs
Frovatriptan	Frova	7.5 mg	2.5 mg tab (blister pack 9)	9 tabs
Lasmiditan	Reyvow	200 mg	50 mg tab 100 mg tab	8 tabs
Naratriptan	Amerge	5 mg	1 mg tab 2.5 mg tab (blister pack 9)	9 tabs
Rizatriptan	Maxalt Maxalt MLT	30 mg	5 mg tab 10 mg tab (blister pack 6, 12)	12 tabs
Sumatriptan tablets	Imitrex & generics	200 mg	25 mg tab, 50 mg tab, 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

Generic	Brand	Max Daily Dose	Dosage Form	Quantity Limit Per Month
Sumatriptan injectable	Imitrex & generics	12 mg	6 mg/0.5 mL	6 vials
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	10 mg	2.5 mg tab (blister pack, 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? Message: • Preferred products do not require PA within recommended dose limits. • 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. • May recommend use of migraine prophylactic therapy and reinforce that doses above those recommended by the manufacturer increase the incidence of medication overuse headache. • One lifetime 90-day taper may be approved at pharmacist's discretion. • Document.	**No:** Trouble-shoot claim payment (e.g., days' supply?). 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*

Anti-Parkinson's Agents

Goals:

- Promote preferred drugs for Parkinson's disease.
- Restrict use for non-funded conditions (e.g., restless leg syndrome).
- 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 diagnosis Restless Leg Syndrome?	**Yes:** Pass to RPh. Deny; not funded by the OHP.	**No:** Go to #4
4. RPh only: All other indications need to be evaluated to determine if treatment is for a funded condition.	**Funded:** Go to #5	**Not Funded:** Deny; not funded by the OHP.
5. Is this a request for continuation of therapy?	**Yes:** Go to **Renewal Criteria**.	**No:** Go to #6
6. Will the prescriber consider a change to a preferred product? Message: • Preferred products do not require PA. • 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:** 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

Approval Criteria		
9. Is the patient on a non-selective monoamine oxidase (MAO) inhibitor? 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 apomorphine sublingual film?	**Yes:** Go to #11	**No:** Go to #12
11. 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.
12. 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		
1. Has the patient's condition improved as assessed by the prescribing physician and physician attests to patient's improvement?	**Yes:** Approve for the shorter of 1 year or length of prescription.	**No:** Pass to RPh; Deny; medical appropriateness.

P&T Review: *10/20 (AG); 3/18; 7/16; 9/14; 9/13; 09/10*
Implementation: *11/1/20; 4/16/18; 8/16, 1/1/14, 1/1/11*

Antipsychotic Use 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 30 days in children 3-5 years of age
- All antipsychotic use in children 2 years of age or younger

Note: use of olanzapine as an antiemetic for chemotherapy does not require 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 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 Tourette's Disorder ≥6 yrs
asenapine maleate	≥18 yrs	≥10 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
4. Is there documented clinical rationale for lack of metabolic monitoring (e.g. combative behaviors requiring sedation)? 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. Annual metabolic screening is required for chronic use of antipsychotics. Refer denied requests to the OHA for follow-up. A single 90 day continuation of therapy may be granted upon request to allow for laboratory testing.

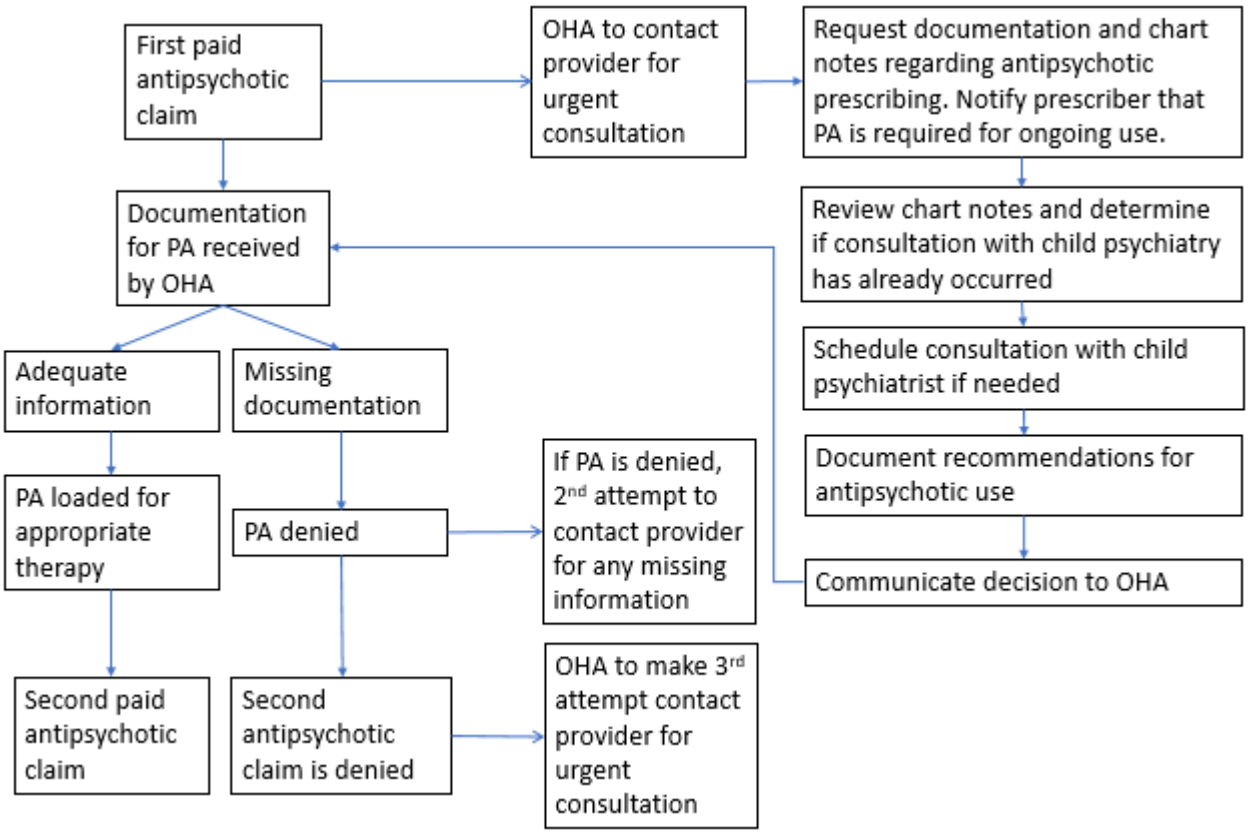
Approval Criteria		
5. Is the patient engaged in, been referred for, or have documented inability to access evidence based first-line non-pharmacological therapy (e.g., applied behavior analysis therapy for autism, parent behavioral therapy, or parent child interaction therapy)?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness. Refer denied requests to the OHA for follow-up. A single 90 day continuation of therapy may be granted upon request to allow time for engagement.
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? A thorough assessment should include ALL the following: a. Multidisciplinary review including a mental health specialist b. Mental health assessment including documentation of diagnoses, symptoms, and disease severity c. Discussion and consideration of first-line non-pharmacological therapies d. Assessment of antipsychotic risks and monitoring strategies 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) f. Anticipated duration of therapy 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. Refer denied requests to the OHA for follow-up. A single 90 day continuation of therapy may be granted upon request to allow for submission of required documentation.

P&T/DUR Review: 6/21(SS)
Implementation: TBD

Appendix 2. Provider notification Retrospective safety program to facilitate review of antipsychotic use in children less than 5 years of age

Figure A1. Notification process



Provider Notification

- Inclusion criteria will target 3 basic patient populations:
    1. Patients with a soon-to-expire PA based on the following criteria OR
        - Patients <= 5 years of age AND
        - a prior authorization for an antipsychotic with an expiration date within the next 30 days (PDL classes: antipsychotics, 1st gen; antipsychotics, 2nd gen; antipsychotics, parenteral) AND
        - a recent paid FFS claim for an antipsychotic in past 45 days AND
        - no subsequent prior authorization request approved for an antipsychotic
    2. Patients with a new start of an antipsychotic in the past 2 weeks defined based on the following criteria OR
        - Patients <= 5 years of age AND
        - with a paid FFS antipsychotic claim in the past 2 weeks AND
        - no currently active prior authorization for the antipsychotic AND
        - no paid claims for the same HSN within the prior 3 months.
    3. Patients with a denied claim for an antipsychotic defined based on the following criteria
        - Patients <= 5 years of age AND
        - with a denied FFS antipsychotic claim in the past 2 weeks due to the safety edit AND
        - with no currently active prior authorization for the antipsychotic AND
        - with no subsequent paid claims for the same HSN
- Exclusion criteria:

1. Providers with notifications sent for the same patient and drug (based on HSN) in the past 3 months
2. Patients not currently enrolled in Medicaid
3. Patients who are deceased

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 5 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 this an OHP-funded diagnosis?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP
3. Is the antiviral agent to be used to treat a current influenza infection?	**Yes:** Go to #4	**No:** Go to #5
4. Will the prescriber consider a change to a preferred product? Message: • Preferred products do not require 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 and approve for length of therapy or 5 days, whichever is less.	**No:** Approve based on standard FDA dosing for influenza treatment Note: baloxavir and peramivir are FDA approved as a single dose for treatment of influenza.
5. Is the antiviral prescribed oseltamivir or zanamivir?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
6. Does the patient have any of the following CDC[1] and IDSA[2] criteria that may place them at increased risk for complications requiring chemoprophylaxis? • 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) • 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 • Persons at high risk for complications from influenza who cannot receive influenza vaccine after exposure to an infectious person • Residents of institutions, such as long-term care facilities, during influenza outbreaks in the institution. • Pregnancy and women up to 2 weeks postpartum 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. 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:** Pass to RPh. Deny; medical appropriateness.

References:
1. Centers for Disease Control and Prevention. Influenza Antiviral Medications: Summary for Clinicians. http://www.cdc.gov/flu/pdf/professionals/antivirals/antiviral-summary-clinician.pdf. Accessed June 2, 2015.
2. Harper SA, Bradley JS, Englund JA, et al. Seasonal influenza in adults and children – diagnosis, treatment, chemoprophylaxis, and institutional outbreak management: clinical practice guidelines of the Infectious Diseases Society of America. *Clinical Infectious Diseases*. 2009; 48:1003-32.

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

Antivirals for Herpes Simplex Virus

Goal(s):
- Cover oral and/or topical antivirals only for covered diagnoses.
- HSV infections are covered only when complicated by an immunocompromised host.

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? Message: • 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:** 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: • Diagnosis of cancer AND currently undergoing chemotherapy or radiation. Document therapy and length of treatment. • Solid organ transplant • HIV/AIDS	**Yes:** Approve for up to 12 months	**No:** Go to #5

Approval Criteria		
5. Is the patient currently taking an immunosuppressive drug? 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: **Immunosuppressants** Abatacept Adalimumab Anakinra Apremilast Azathioprine Basiliximab Certolizumab pegol Cyclosporine Cyclosporine Etanercept Golimumab Hydroxychloroquine Infliximab Leflunomide Methotrexate Natalizumab Rituximab Secukinumab Sirolimus Tacrolimus Tocilizumab Tofacitinib Ustekinumab 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.	If funded and clinic provides supporting literature, approve for length of treatment. If length of treatment is not provided, approve for 3 months. Note: deny non-viral diagnoses (medical appropriateness)	If non-funded, deny (not funded by the OHP). Note: Deny viral ICD-10 codes that do not appear on the OHP funding list pending a more specific diagnosis code (not funded by the OHP).

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

Atopic Dermatitis and Topical Antipsoriatics

Goal(s):

- Restrict dermatological drugs only for funded OHP diagnoses. Severe psoriasis and severe atopic dermatitis treatments are funded on the OHP. Treatments for mild or moderate psoriasis, seborrheic dermatitis, keratoderma and other hypertrophic and atrophic conditions of skin are not funded.

Length of Authorization:

- From 6 to 12 months

Requires PA:

- Non-preferred antipsoriatics
- All atopic dermatitis drugs
- STC = 92 and HIC = L1A, L5F, L9D, T0A
- This PA does not apply to biologics for psoriasis, or dupilumab which are subject to separate clinical PA criteria.

Covered Alternatives:

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

Table 1. FDA-approved ages for atopic dermatitis drugs

Drug	Minimum Age
Crisaborole	3 months
Pimecrolimus	2 years
Ruxolitinib	12 years
Tacrolimus 0.03%	2 years
Tacrolimus 0.1%	16 years

Approval Criteria		
1. What diagnosis is being treated?	Record ICD 10 code.	
2. Is the diagnosis for seborrheic dermatitis, keratoderma or other hypertrophic and atrophic conditions of skin?	**Yes:** Pass to RPh; deny, not funded by the OHP.	**No:** Go to #3

Approval Criteria		
3. Is the request for treatment of severe inflammatory skin disease? Severe disease is defined as:[1] • 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: 1. At least 10% body surface area involved 2. Hand, foot or mucous membrane involvement	**Yes:** Go to #4	**No:** Pass to RPh; deny, not funded by the OHP
4. Is the diagnosis psoriasis?	**Yes:** Go to #8	**No:** Go to #5
5. Is the diagnosis atopic dermatitis?	**Yes:** Go to #6	**No:** Go to #10
6. Does the patient meet the age requirements per the FDA label (Table 1)?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness
7. Does the patient have a documented contraindication, intolerance or failed trials of at least 2 first line agents indicated for the treatment of severe AD (topical corticosteroids)?* *Note ruxolitinib, pimecrolimus and crisaborole are FDA approved to manage mild to moderate AD, while tacrolimus is FDA approved to manage moderate to severe AD.	**Yes:** Document drug and dates trialed, and intolerances or contraindications (if applicable): 1._____(dates) 2._____(dates) Approve for length of treatment; maximum 6 months.	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
8. Is the requested product preferred?	**Yes:** Approve for length of treatment; maximum 1 year.	**No:** Go to #9
9. Will the prescriber consider a change to a preferred product? **Message:** Preferred products are evidence-based reviewed for comparative effectiveness & safety by the Pharmacy and Therapeutics (P&T) Committee.	**Yes:** Inform provider of preferred alternatives. Approve for length of treatment; maximum 1 year.	**No**: Approve for length of treatment; maximum 1 year.
10. RPH only: All other indications need to be evaluated as to whether they are funded by the OHP.*	**If funded, or clinic provides supporting literature:** Approve for 1 year.	**If not funded:** Deny, not funded by the OHP.

P&T/DUR Review: *12/20 (DM); 10/20; 7/19 (DM); 5/19 (DM) 3/18 (DM); 9/17; 7/15; 1/15; 09/10; 9/09; 3/09; 5/07; 2/06*
Implementation: *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*

**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.Oregon Health Evidence Review Commission. Coverage Guidance and Reports. http://www.oregon.gov/oha/hpa/csi-herc/pages/index.aspx Accessed October 14, 2020.

Attention Deficit Hyperactivity Disorder (ADHD) Safety Edit

Goals:

- Cover ADHD medications only for diagnoses funded by the OHP and medications consistent with current best practices.
- Promote care by a psychiatrist for patients requiring therapy outside of best-practice guidelines.
- 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. FDA-approved and OHP-funded Indications.

	STIMULANTS		NON-STIMULANTS			
Indication	**Methylphenidate and derivatives****	**Amphetamine and derivatives**	**Atomoxetine**	**Clonidine ER**	**Guanfacine ER**	**Viloxazine**
ADHD	**Age ≥6 years**	**Age ≥3 years**	**Age ≥6 years**	**Children age 6-17 years only**	**Children age 6-17 years only**	**Children age 6- 17 years only**
Narcolepsy	**Age ≥6 years**	**Age ≥6 years**	**Not approved**	**Not approved**	**Not approved**	**Not approved**

See **Table 2 for off-label methylphenidate IR dosing for age ≥ 4 years

Table 2. Standard Age and Maximum Daily Doses.

Drug Type	Generic Name	Minimum Age	Maximum Age	Maximum Daily Dose (adults or children <18 years of age unless otherwise noted)
CNS Stimulant	amphetamine ER	3		20 mg
CNS Stimulant	amphetamine/dextroamphetamine salts IR	3		40 mg
CNS Stimulant	amphetamine/dextroamphetamine salts ER	6		60 mg
CNS Stimulant	dexmethylphenidate IR	6		20 mg
CNS Stimulant	dexmethylphenidate LA	6		40 mg for adults or 30 mg if age <18 years
CNS Stimulant	dextroamphetamine IR	6		40 mg
CNS Stimulant	dextroamphetamine LA	6		60 mg
CNS Stimulant	lisdexamfetamine	4		70 mg
CNS Stimulant	methamphetamine	6	17	not established
CNS Stimulant	methylphenidate IR	4		60 mg
CNS Stimulant	methylphenidate LA	6		72 mg
CNS Stimulant	methylphenidate transdermal	6	17	30 mg
CNS Stimulant	serdexmethylphenidate/dexmethylphenidate	6		52.3 mg/ 10.4 mg
Non-Stimulant	atomoxetine	6		100 mg

Non-Stimulant	clonidine LA	6	17	0.4 mg
Non-Stimulant	guanfacine LA	6	17	4 mg for adjunctive therapy in ages 6-17 years and for monotherapy in ages 6-12 years 7 mg for monotherapy in ages 13-17 years
Non-Stimulant	viloxazine	6	17	400 mg

Abbreviations: IR = immediate-release formulation; LA = long-acting formulation (extended-release, sustained-release, etc.)

Table 3. Standard Combination Therapy for ADHD

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

Abbreviations: IR = immediate-release formulation; LA = long-acting formulation (extended-release, sustained-release, etc.)
* As recommended by the American Academy of Pediatrics 2011 Guidelines www.pediatrics.org/cgi/doi/10.1542/peds.2011-2654
**As identified by Drug Class Review: Pharmacologic Treatments for Attention Deficit Hyperactivity Disorder: Drug Effectiveness Review Project, 2011.

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:** Pass to RPh. Deny; not funded by OHP.
3. Is the requested drug on the PDL?	**Yes:** Go to #5	**No:** Go to #4
4. Will the prescriber consider a change to a preferred agent? Message: • Preferred drugs are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics (P&T) Committee.	**Yes:** Inform prescriber of preferred alternatives	**No:** Go to #5
5. Is the request for an approved FDA diagnosis defined in Table 1?	**Yes:** Go to #6	**No:** Go to #9
6. Are the patient's age and the prescribed dose within the limits defined in Table 2?	**Yes:** Go to #7	**No:** Go to #9
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

Approval Criteria		
8. Is the multi-drug regimen considered a standard combination as defined in Table 3?	**Yes:** Approve for up to 12 months	**No:** Go to #9
9. Was the drug regimen developed by, or in consultation with, a psychiatrist, developmental pediatrician, psychiatric nurse practitioner, sleep specialist or neurologist?	**Yes:** Document name and contact information of consulting provider and approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness. Doses exceeding defined limits or non-recommended multi-drug regimens of stimulants and/or non-stimulants are only approved when prescribed by a psychiatrist or in consultation with a mental health specialist. May approve continuation of existing therapy once up to 90 days to allow time to consult with a mental health specialist.

P&T Review: *8/20 (DE); 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: *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*

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: (Both pharmacy and physician-administered claims)

- All medications indicated for ATTR

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
Inotersen	Polyneuropathy of hereditary ATTR
Patisiran	Polyneuropathy of hereditary ATTR
Tafamidis	Cardiomyopathy of ATTR (hereditary and wild type)

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 the diagnosis funded by OHP?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP.
4. Is this an FDA approved indication of ATTR amyloidosis supported by transthyretin mutation proven by genetic testing (See Table 1)?	**Yes**: Go to #5 Document Genotype: _____	**No:** Pass to RPh. Deny; medical appropriateness
5. Does the patient have clinical signs and symptoms of disease (peripheral/autonomic neuropathy, motor disability, cardiovascular dysfunction)?	**Yes**: Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. 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 #7

Approval Criteria		
7. Has the patient had a liver transplantation?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #8
8. Is the request for patisiran or inoteren?	**Yes:** Go to #9	**No:** Go to #16
9. Is baseline disease severity documented (polyneuropathy disability (PND) score and Familial amyloid polyneuropathy (FAP) stage)?	**Yes:** Document and Go to #10	**No:** Pass to RPh. Deny; medical appropriateness.
10. Was the medication prescribed or in consultation with a neurologist?	**Yes:** Go to #11	**No:** Pass to RPh. Deny; medical appropriateness.
11. Is the patient on Vitamin A supplementation or have a documented normal level?	**Yes:** Go to #12	**No:** Pass to RPh. Deny; medical appropriateness.
12. Is the request for patisiran?	**Yes**: Approve for 6 months	**No**: Go #13
13. Is the request for inotersen?	**Yes:** Go to # 14	**No:** Go to #16
14. Has a baseline platelet count been obtained in the previous 3 months and are platelets ≥ 125 X 10^9/L?	**Yes:** Go to #15 Document baseline platelet count:_____ Date of Lab:_____	**No:** Pass to RPh. Deny; medical appropriateness.
15. Has baseline renal function been evaluated in the previous 3 months?	**Yes:** Approve for 6 months Document baseline serum creatinine and BUN:_____ Date of Lab:_____	**No:** Pass to RPh. Deny; medical appropriateness
16. Is the request for tafamidis?	**Yes:** Go to #17	**No:** Go to #19
17. Was the medication prescribed or in consultation with a cardiologist?	**Yes:** Go to #18	**No:** Pass to RPh. Deny; medical appropriateness.
18. 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
19. 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: a. Improved neurologic impairment b. Improved motor function c. Improved quality of life 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: a. Baseline polyneuropathy disability (PND) score 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

Becaplermin (Regranex®)

Goal(s):
- Restrict to indications funded by the OHP and supported by 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 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 ICD-10 code.	
2. Is the diagnosis funded by OHP?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP.
3. Does the patient have severe active central nervous system lupus?	**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 diagnosed with lupus nephritis or systemic lupus erythematosus (SLE)?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Is belimumab dosed appropriately and with an approved formulation for patient's age as outlined in Table 1?	**Yes:** Go to # 7	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
7. 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 # 8
8. 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 # 9	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
9. 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: • SLE Index Score (SIS) • British Isles Lupus Assessment Group (BILAG) • Systemic Lupus Activity Measure (SLAM) • Systemic Lupus Erythematosus Disease Activity Score (SLEDAI or modified versions, e.g. SLEDAI-2K, SELENA-SLEDAI) • Physicians Global Assessment (PGA) • Systemic Lupus International Collaborating Clinic (SLICC) Damage Index • Urinary protein to creatinine ratio • Most recent estimated Glomerular Filtration Rate (eGFR)	**Yes:** Go to # 10. Document baseline assessment _____.	**No:** Pass to RPh. Deny; medical appropriateness
10. Is the patient currently taking or have a contraindication to BOTH of the following: • Hydroxychloroquine • Glucocorticoids (e.g. prednisone)	**Yes:** Go to #11	**No:** Pass to RPh. Deny; medical appropriateness. Belimumab has not been studied as monotherapy in patients with SLE.
11. Does the patient have lupus nephritis AND a urine protein: creatinine ratio of >500 mg/g?	**Yes:** Go to #12	**No:** Approve for 6 months

Approval Criteria		
12. 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 ? Note: Belimumab has not been studied in combination with other therapeutic immune modulators.	**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: • SLE Index Score (SIS) • British Isles Lupus Assessment Group (BILAG) • Systemic Lupus Activity Measure (SLAM) • Systemic Lupus Erythematous Disease Activity Score (SLEDAI or modified versions, e.g. SLEDAI-2K, SELENA-SLEDAI) • Physicians Global Assessment (PGA) • Systemic Lupus International Collaborating Clinic (SLICC) Damage Index • Urinary protein to creatinine ratio • eGFR	**Yes:** Approve for 6 months.	**No:** Pass to RPh; Deny; medical appropriateness.

Table 1: FDA approved ages

Indication	Approved formulation	
	Intravenous (IV) powder for solution	**Subcutaneous (SC) Injection**
Systemic Lupus Erythematosus (SLE)	5 years and older	18 years and older
Lupus Nephritis	18 years and older	18 years and older
IV (usual 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 **SC** (usual dosage): **SLE**: 200 mg SC once weekly **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		

Bempedoic Acid

Goal(s):

- Promote use of bempedoic acid that is consistent with medical evidence
- Promote use of high value products

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

Approval Criteria		
2. 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) <u>Major ASCVD events</u> • Recent ACS (within past 12 months) • History of MI (other than recent ACS from above) • History of ischemic stroke • Symptomatic peripheral artery disease <u>High-Risk Conditions:</u> • Age ≥ 65 • Heterozygous familial hypercholesterolemia • History of prior CABG or PCI • Diabetes Mellitus • Hypertension • Chronic Kidney Disease • Current smoking • Persistently elevated LDL-C ≥ 100 despite maximally tolerated statin therapy and ezetimibe • History of congestive heart failure	**Yes:** Go to #3	**No:** Go to #6

Approval Criteria		
3. 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? Prescriber to submit chart documentation of: 1) Doses and dates initiated of statin and ezetimibe; 2) Baseline LDL-C (untreated); 3) Recent LDL-C	**Yes:** Confirm documentation; go to #4 1. Statin: Dose: Date Initiated: 2. Ezetimibe 10 mg daily Date Initiated: Baseline LDL-C _____ Date:_____ Recent LDL-C _____ Date:_____	**No:** Go to #5
4. Is the patient adherent with a high-intensity statin and ezetimibe?	**Yes:** Go to #8 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
5. Does the patient have a history of rhabdomyolysis caused by a statin; or alternatively, a history of creatinine kinase (CK) levels >10-times upper limit of normal with muscle symptoms determined to be caused by a statin? 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 #8 Recent LDL-C _____ mg/dL Date:_____	**No:** Pass to RPh; deny for medical appropriateness
6. Does the patient have a diagnosis of homozygous or heterozygous familial hypercholesterolemia? Note: Prescriber must provide chart documentation of diagnosis and recent LDL-C (within last 12 weeks).	**Yes:** Go to #7	**No:** Pass to RPh; deny for medical appropriateness.

Approval Criteria		
7. Does the patient still have a LDL-C of ≥ 100 mg/dl while taking a maximally tolerated statin and ezetimibe?	**Yes:** Go to #8 Recent LDL-C _____ mg/dL Date:_____	**No:** Pass to RPh; deny for medical appropriateness.
8. Does the patient have a history of gout or hyperuricemia?	**Yes:** Pass to RPh; deny for medical appropriateness.	**No:** Approve for up to 12 months

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 Rosuvastatin 20-40 mg	Atorvastatin 10-20 mg Fluvastatin 80 mg Lovastatin 40-80 mg	Pitavastatin 1-4 mg Pravastatin 40-80 mg Simvastatin 20-40 mg Rosuvastatin 5-10 mg

P&T / DUR Review: *08/21 (MH); 08/20*
Implementation: *9/1/20*

Benign Prostatic Hypertrophy (BPH) Medications

Goal(s):

- BPH with urinary obstruction is an OHP-funded treatment only when post-void residuals are 150 mL or more.
- Restrict use for male pattern baldness and erectile dysfunction, which are not OHP-funded conditions.

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. Will the prescriber consider switching to a preferred product? Message: • 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:** Go to #3
3. Is the request for continuation of therapy previously approved by the FFS program?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #4
4. Is the request for an alpha-1 blocker, and 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 failed 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
6. Does the patient have a diagnosis of benign prostatic hypertrophy (BPH) or enlarged prostate with obstruction?	**Yes:** Approve for up to 12 months	**No:** Go to #7

Approval Criteria		
7. Does the patient have a diagnosis of unspecified urinary obstruction or BPH without obstruction?	**Yes:** Pass to RPh. Deny; not funded by the OHP	**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 (e.g., hair growth, erectile dysfunction) should be denied (not funded 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.		

Renewal Criteria		
1. Is the request for an alpha-1 blocker and does the patient have a diagnosis related to functional and mechanical disorders of the genitourinary system including bladder outlet obstruction?	**Yes:** Go to #2	**No:** Go to #3
2. Has the patient also been taking a 5-alpha reductase inhibitor for the last year?	**Yes:** Recommend against combination therapy exceeding 1 year.	**No:** Approve for the shorter of 12 months or length of the prescription
3. Does the patient have a diagnosis of BPH or enlarged prostate with obstruction?	**Yes:** Approve for up to 12 months	**No:** Go to #4
4. Does the patient have a diagnosis of unspecified urinary obstruction or benign prostatic hyperplasia without obstruction?	**Yes:** Pass to RPh. Deny; not funded by the OHP	**No:** Pass to RPh. Go to #5
5. RPh only: All other indications need to be evaluated as to whether they are a funded condition: • Alpha Blockers and 5-alpha reductase inhibitors may be used concurrently for BPH up to 1 year. Alpha-blockers may be discontinued once prostate is reduced to normal size. • If urine retention, obstructive, ask for more specific diagnosis.	If funded and clinic provides supporting literature, approve for up to 12 months.	If non-funded, deny (not funded by the OHP).

P&T Review: *7/16 (KS); 11/12; 9/10; 3/10; 5/08; 2/06*
Implementation: *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.

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:** Pass to RPh. Deny; not funded by the OHP.
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? 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)? 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 including antidepressants AND psychotherapy (e.g. behavioral therapy, relaxation response training, mindfulness meditation training, eye movement desensitization and reprocessing)? Note: An adequate trial to determine efficacy of an SSRI or SNRI is 4-6 weeks.	**Yes:** Go to #12 Document trial, contraindication, or intolerance to treatment options.	**No:** Pass to RPh; Deny; medical appropriateness. Recommend adequate trial of first-line therapies. 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 including second-generation antipsychotics AND psychotherapy (e.g. counseling, cognitive behavioral therapy, social skills training, or psychoeducation)? 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 Document trial, contraindication, or intolerance to treatment options.	**No:** Pass to RPh; Deny; medical appropriateness. Recommend adequate trial of first-line therapies. 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:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #13
13. RPh only: Is there appropriate rationale to support long-term benzodiazepine use for this indication? For anxiety, panic disorder, or schizophrenia, provider rationale should include information from relevant chart notes. 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

Renewal Criteria		
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. Recommend trial of alternative therapies. 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.
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. 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: *3/19 (SS); 9/18, 3/14*
Implementation: *5/1/19; 11/1/2018; 5/1/16*

Bezlotoxumab (Zinplava™)

Goal(s):

- To optimize appropriate prevention of recurrent *Clostridium difficile*-associated infection.

Length of Authorization:

- One time infusion

Requires PA:

- Bezlotoxumab (physician 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. Does the patient have a diagnosis of **recurrent** *Clostridium difficile*-associated infection (CDI)?	**Yes**: Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Is the patient currently receiving vancomycin or fidaxomicin?	**Yes**: Approve for one dose	**No**: Pass to RPh. Deny; medical appropriateness

P&T / DUR Review: *5/18(DM)*
Implementation: *7/1/18*

Bone Metabolism Agents

Goal(s):

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

Length of Authorization:

- 12 to 24 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 condition?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP
3. Will the prescriber consider a change to a preferred product? Note: • 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:** Go to #4
4. Has the patient tried and failed an oral bisphosphonate (alendronate, risedronate, or ibandronate) or do they have contraindications to these treatments? (document contraindication, if any)	**Yes:** Go to #5	**No:** Pass to RPh; deny and recommend trial of oral bisphosphonate
5. Is the request for denosumab?	**Yes:** Go to # 6	**No:** Go to # 7

Approval Criteria		
6. Is denosumab being prescribed for one of the following reasons: • Treatment of postmenopausal women with osteoporosis at high risk for fracture • Treatment to increase bone mass in men with osteoporosis at high risk for fracture • Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture • Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer • Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer	**Yes:** Go to # 8	**No:** Pass to RPh; Deny; medical appropriateness
7. Is the request for raloxifene?	**Yes:** Go to #8	**No:** Go to #9
8. Is the patient pregnant, or for raloxifene requests, at increased risk for thromboembolism or stroke?	**Yes:** Pass to RPh. Deny; medical appropriateness. Note: inform prescriber of pregnancy category X and for raloxifene: boxed warning for venous thromboembolism and stroke.	**No:** Approve for up to 12 months
9. Is the request for teriparatide and is the patient at high risk for fracture? Examples include: • Postmenopausal women with osteoporosis and T-score ≤ - 2.5 or history of fracture • Men with primary or hypogonadal osteoporosis* • Men or women with osteoporosis associated with sustained systemic glucocorticoid therapy	**Yes:** Go to #12	**No:** Go to #10

Approval Criteria		
10. Is the request for abaloparatide and is the patient a postmenopausal woman aged 49 to 86 years with osteoporosis at high risk for fracture? Inclusion criteria from the ACTIVE[1] trial: • Women with T score between - 2.5 and -5.0 AND radiologic evidence of vertebral fracture or history of nonvertebral fracture within the past 5 years OR • Women aged 65 years or older with T score between -3.0 and -5.0 without history of fracture OR T score between -2.0 and 5.0 with history of fracture.	**Yes:** Go to #11	**No:** Go to #13
11. Has the patient received treatment with anticonvulsants that affect Vitamin D metabolism (phenobarbital, phenytoin, carbamazepine or primidone) or with chronic heparin within the past 6 months OR has the patient received daily treatment with oral, intranasal, or inhaled corticosteroids in the past 12 months?	**Yes:** Pass to RPh. Deny; medical appropriateness. (These patients were excluded from the ACTIVE[1] trial)	**No:** Go to #12.
12. Does the patient meet one of the following conditions: a. Concomitant bisphosphonate; or b. Pediatric or young adult with open epiphyses; or c. History of osteosarcoma or skeletal malignancies; or d. Metabolic bone disease; or e. Underlying hypercalcemic disorders; or 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. Teriparatide and abaloparatide are only FDA approved for a total duration of therapy of 2 years.)
13. Is the request for romosozumab and is the patient a postmenopausal women with osteoporosis and T-score ≤ - 2.5 or history of fracture?	**Yes:** Go to # 14	**No:** Go to # 15

Approval Criteria		
14. 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.* *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, denosumab, or raloxifene).
15. RPh only: All other indications need to be evaluated as to whether they are funded by the OHP or not.	If funded and clinic provides supporting literature, approve for up to 12 months	If non-funded, deny; not funded by the OHP

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

** FDA approved osteoporosis treatments for men include alendronate, risedronate, zoledronic acid, teriparatide, and denosumab.*

1. Miller PD, Hattersley G, Riis BJ, et al. Effect of Abaloparatide vs Placebo on New Vertebral Fractures in Postmenopausal Women With Osteoporosis: A Randomized Clinical Trial. JAMA.316 (7):722-733.

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.

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")?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #2
2. What diagnosis is being treated?	Record ICD10 code	

Approval Criteria		
3. Is botulinum toxin treatment for any of the following? a. Upper or lower limb spasticity (G24.02, G24.1, G35, G36.0, I69.03-I69.06 and categories G71, and G80-G83) b. Strabismus due to a neurological disorder (H50.89) c. Blepharospasm (G24.5) d. Spasmodic torticollis (G24.3) e. Torsion dystonia (G24.9) 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	**No:** Go to #8
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? • Propranolol immediate-release, metoprolol, or atenolol • Topiramate, valproic acid, or divalproex sodium • Amitriptyline, nortriptyline, or venlafaxine	**Yes:** Go to #7 Baseline headaches/month: _____.	**No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of preferred alternatives at www.orpdl.org/drugs/

Approval Criteria		
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. Additional treatment requires documented positive response to therapy from baseline (see Renewal Criteria).
8. Is botulinum toxin treatment detrusor muscle over-activity ("overactive bladder")?	**Yes:** Go to #9	**No:** Pass to RPh. Go to #10
9. Has the patient had an inadequate response to, or is intolerant of, ≥2 of the following drugs? a. Fesoterodine (OHP preferred) b. Oxybutynin (OHP preferred) c. Solifenacin (OHP preferred) d. Darifenacin e. Flavoxate f. Mirabegron g. Tolterodine h. Trospium i. Vibegron	**Yes:** • Baseline urine frequency/day: _____. • Baseline urine incontinence episodes/day: _____. Approve for up to 90 days. Additional treatment requires documented positive response to therapy from baseline (see Renewal Criteria).	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria

10. Review treating condition 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.

Deny for the following conditions; not funded by the OHP

- Axillary hyperhidrosis and palmar hyperhidrosis (L74.52, R61)
- Neurologic conditions with none or minimally effective treatment or treatment not necessary (G244; G2589; G2581; G2589; G259)
- Facial nerve disorders (G510-G519)
- Spastic dysphonia (J387)
- Anal fissure (K602)
- Disorders of sweat glands (e.g., focal hyperhidrosis) (L301; L740-L759; R61)
- Other disorders of cervical region (M436; M4802; M530; M531; M5382; M5402; M5412; M542; M6788)
- 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)
- Disorders of soft tissue (M5410; M609; M790-M792; M797)
- Headaches (G44209; G44009; G44019; G44029; G44039; G44049; G44059; G44099; G44209; G44219; G44221; G44229; G44309; G44319; G44329; G4441; G4451-G4453; G4459; G4481-G4489; G441; R51)
- Gastroparesis (K3184)
- Lateral epicondylitis (tennis elbow)) (M7710-M7712)

Deny for medical appropriateness because evidence of benefit is insufficient

- Dysphagia (R130; R1310-R1319)
- Other extrapyramidal disease and abnormal movement disorders (G10; G230-GG238; G2401; G244; G250-G26)
- Other disorders of binocular eye movements (e.g., esotropia, exotropia, mechanical strabismus, etc.) (H4900-H518)
- Tics (F950-F952; F959)
- Laryngeal spasm (J385)
- Spinal stenosis in cervical region or brachial neuritis or radiculitis NOS (M4802; M5412-M5413)
- Spasm of muscle in absence of neurological diagnoses (M6240-M62838)
- Contracture of tendon (sheath) in absence of neurological diagnoses (M6240; M62838)
- Amyotrophic sclerosis (G1221)
- Clinically significant spinal deformity or disorders of spine with neurological impairment (M4800; M4804; M4806; M4808; M5414-M5417)
- Essential tremor (G25.0)
- Hemifacial spasm (G513)
- Occupational dystonias (e.g., “Writer’s cramp”) (G248, G249)
- Hyperplasia of the prostate (N400-403; N4283)
- 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. Baseline:____ migraine headaches/month 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 Approval Criteria
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 • Baseline:____ urine frequency/day • Current:____ urine frequency/day -or- • Baseline:____ urine incontinence episodes/day • Current:____ urine incontinence episodes/day	**No:** Pass to RPh. Deny; medical appropriateness

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

Brexanolone (Zulresso)

Goal(s):
- To ensure appropriate use of brexanolone in patient with post-partum depression.

Length of Authorization:
- One time use only.

Requires PA:
- Brexanolone requires a prior authorization approval due to safety concerns (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 diagnosis funded by OHP?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP
4. Is the patient an adult with moderate to severe post-partum depression?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Has the patient had an adequate trial (6-8 weeks) of an oral antidepressant?	**Yes:** Approve for a single, continuous, intravenous infusion over 60 hours (titrated per prescribing recommendations)	**No:** Pass to RPh. Deny; recommend trial of oral antidepressant

P&T/DUR Review: 2/21(SS); 7/19 (KS)
Implementation: 8/19/19

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 24 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 diagnosis funded by the OHP?	**Yes:** Go to #2	**No:** Pass to RPh. Deny; not funded by OHP
2. Is the prescription for opioid use disorder (opioid dependence or addiction)?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Is the prescription for a transmucosal formulation of buprenorphine (film, tablet) with an average daily dose of more than 24 mg (e.g., >24 mg/day or >48 mg every other day)?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #4
4. Is the requested medication a preferred agent?	**Yes:** Approve for anticipated length of treatment or 6 months, whichever is less. Note: Notify prescriber concomitant naloxone is recommended if not present in claims history.	**No:** Go to #5
5. Will the prescriber switch to a preferred product? 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 anticipated length of treatment or 6 months, whichever is less. Note: Notify prescriber concomitant naloxone is recommended if not present in claims history.

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:** Pass to RPh. Deny; not funded by the OHP
3. Does the patient meet any of the following criteria: • Pregnancy; • Documented nutrient deficiency; • Diagnosis of osteopenia or osteoporosis; • Infants 0-24 months of age **OR** • 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

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 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)? AND If LFTs are not within normal limits has the cannabidiol dose been adjusted per guidance for moderate to severe hepatic impairment in Table 1? 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 Document results here: Date of lab work_____ AST_____ ALT_____ Total Bilirubin_____	**No**: Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Are recent LFT's documented in patient records? AND 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 Document results here: Date of lab work_____ AST_____ ALT_____ Total Bilirubin_____	**No:** Pass to RPh. Deny; medical appropriateness
2. Has seizure frequency decreased since beginning therapy?	**Yes:** Go to #3 Document baseline and current seizure frequency_____	**No:** Pass to RPh. Deny for lack of treatment response.

Renewal Criteria		
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.

P&T/DUR Review: 10/21 (DM); 10/20 (DM); 6/2020 (DM); 3/19; 1/19 (DM)
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 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

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) antagonists (atogepant, eptinezumab, erenumab, fremanezumab, galcanezumab, rimegepant and ubrogepant) 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 episodic 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

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 the diagnosis funded by OHP?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP.
4. 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 #5

Approval Criteria		
5. Is the medication being prescribed by or in consultation with a neurologist or headache specialist?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Do chart notes indicate headaches are due to medication overuse?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to # 7
7. Is the request for acute (abortive) migraine treatment AND the patient is an adult (18 years or older)?	**Yes:** Go to #13	**No:** Go to #8
8. Is the request for the prevention of cluster headache AND the patient is an adult (18 years or older)?	**Yes:** Go to #16	**No:** Go to #9
9. 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 # 10	**No:** Pass to RPh. Deny; medical appropriateness
10. Has the patient failed an adequate trial (≥6 weeks with a documented adherence of ≥80%) of an FDA-approved migraine prophylaxis medication from each of the following classes: beta-blockers, anticonvulsants, and tricyclic antidepressants? OR Does the patient have a documented intolerance, FDA-labeled contraindication, or hypersensitivity to each of the above migraine prophylaxis classes?	**Yes:** Document agents used and dates _____ _____ Go to # 11	**No:** Pass to RPh. Deny; medical appropriateness
11. Is the request for erenumab and the patient has pre-exisitng hypertension or risk factors for hypertension?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #12
12. 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

Approval Criteria		
13. In a patient with acute migraines, has the patient failed adequate trials of abortive therapy (2 or more different triptans) or have contraindications to triptans?	**Yes:** Go to #14	**No:** Pass to RPh. Deny; medical appropriateness. Recommend triptan trial.
14. Does the patient have chronic migraines?	**Yes**: Go to #15	**No**: Approve for 3 months
15. 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
16. Has the patient failed at least 2 cluster headache preventative treatments (i.e., lithium, verapamil, melatonin, prednisone, subocciptal steroid injection, topiramate)?	**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:** Document response. Approve for up to 6 months	**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:** Document response Approve for up to 6 months	**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. Does the patient have documentation of a positive reponse, indicated by a reduction in the number of cluster headaches per month?	**Yes:** Document response Approve for up to 6 months	**No:** Pass to RPh. Deny; medical Appropriateness

P&T/DUR Review: 10/21 (KS), 8/20 (KS); 5/19; 9/18 (DE)
Implementation: 1/1/2022; 11/1/2018

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 the diagnosis funded by OHP?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP.
4. Is this a request for continuation of therapy?	**Yes:** Go to **Renewal Criteria**	**No:** Go to # 5
5. Is cholic acid prescribed by a hepatologist or pediatric gastroenterologist?	**Yes:** Go to # 6	**No:** Pass to RPh. Deny; not funded by the OHP.

Approval Criteria		
6. Has baseline hepatic function been assessed? *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. 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: a. ALP <1.67-times the ULN; AND b. Decrease of ALP >15% from baseline: AND c. Normal total bilirubin level?	**Yes:** Document ALP and total bilirubin level. Go to # 2 ALP:_____units/L 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

Clobazam

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

Length of Authorization:
- 12 months

Requires PA:
- Clobazam

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. Does the patient have a diagnosis of Lennox-Gastaut syndrome and is the patient 2 years of age or older?	**Yes:** Go to #4	**No:** Go to # 5
4. Is the patient uncontrolled on current baseline therapy with at least one other antiepileptic medication?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness
5. Does the patient have a diagnosis of Dravet Syndrome and is the patient 2 years of age or older?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness.

Renewal Criteria		
1. Has seizure frequency decreased since beginning therapy?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny for lack of treatment response.

Limitations of Use:
- Clobazam is not FDA-approved for epilepsy syndromes other than Lennox-Gastaut.
- National Institute for Health and Care Excellence (NICE) guidance recommends clobazam as a second line agent for management of Dravet Syndrome.[1]

1. National Institute for Health and Care Excellence (NICE). Epilepsies: diagnosis and management. nice.org.uk/guidance/cg137. Accessed July 30, 2018

Codeine

Goal(s):

- Promote safe use of codeine in pediatric patients for analgesia or cough.

Length of Authorization:

- Up to 3 days

Requires PA:

- All codeine products for patients under 19 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/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. What is the age of the patient?	**Ages 0-12 years:** Pass to RPh. Deny; medical appropriateness	**Ages 13-18 years:** Go to #3
3. Is the prescription for an OHP-funded condition?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP
4. Has the patient recently undergone tonsillectomy or adenoidectomy?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #5
5. Does the dose exceed 240 mg per day?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Approve no more than 3-day supply

P&T Review: *5/16; 9/15; 7/15*
Implementation: *7/1/16; 8/25/15*

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.

Initiative:

- Prior Authorization

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? Message: • 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

Approval Criteria		
5. Is the patient being prescribed the medication for the prevention of osteoporosis?	**Yes:** Go to #6	**No:** Go to #7
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

Length of Authorization:

- Up to 6 months

Not Covered by OHP:

- Disorders of function of stomach and other functional digestive disorders which includes constipation and Irritable Bowel Syndrome (ICD-10: K3183-3184, K310, R1110, K30, K3189, K319, K314-315, K312, K589, K591, K594, K5900-5902, K5909, K910-911, K9189, K598-599, R159, R150, R152)

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 covered by the OHP?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; diagnosis not covered by OHP.
3. Will the prescriber consider a change to a preferred product? Message: preferred products do not require a PA.	**Yes:** Inform prescriber of covered alternatives	**No:** Go to #4
4. Has the patient failed a 2-week trial of at least 3 of the following management strategies due to lack of effectiveness, contraindications or adverse effects?	**Yes:** Approve for 6 months.	**No:** Pass to RPh. Go to #5.

A	Dietary modification—increased dietary fiber (25 g/day)
B	Bulk-forming Laxatives: (psyllium [e.g., Metamucil],methylcellulose [e.g., Citrucel], calcium carbophil [e.g., Fibercon])
C	Saline Laxatives: (magnesium hydroxide [e.g., Milk of Magnesia], magnesium citrate, sodium phosphate [Fleet Enema])
D	Stimulant Laxatives: (senna or bisacodyl)
E	Osmotic Laxatives: (lactulose, sorbitol or polyethylene glycol 3350 [e.g., Miralax, Glycolax])

Approval Criteria

5. RPh only:
   Constipation is not covered 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.
   - Alvimopan (ENTEREG): FDA labeling, including a black boxed warning for risk of myocardial infarction, limit use to *in hospital use only* for a maximum of 15 doses. Evidence is primarily for the immediate post-operative period only.
   - Linaclotide (LINZESS): Constipation secondary to irritable bowel syndrome is not approvable. 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.
   - Lubiprostone (AMITIZA): Constipation secondary to irritable bowel syndrome or opioid-induced constipation is not approvable. 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.
   - Methylnaltrexone (RELISTOR): Opioid-induced constipation in patients with non-cancer pain is not approvable. Chronic constipation secondary to continuous opioid use as part of a palliative care regimen is approvable if justification is provided for not meeting criterion #4.
   - Naldemedine (SYMPROIC): Opioid-induced constipation in patients with non-cancer pain is not approvable. Justification must be provided for not meeting criterion #4. Naloxegol (MOVANTIK): Opioid-induced constipation in patients with non-cancer pain is not approvable. Justification must be provided for not meeting criterion #4.
   - Plecanatide (TRULANCE): Chronic idiopathic constipation is not approvable. 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.
   - Prucalopride (MOTEGRITY): Chronic idiopathic constipation is not approvable. 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.
   - Tegaserod (ZELNORM): Constipation secondary to irritable bowel syndrome is not approvable. Justification must be provided for not meeting criterion #4.
   - Tenapanor (ISBRELA): Constipation secondary to irritable bowel syndrome is not approvable. Justification must be provided for not meeting criterion #4.

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

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 #3	**No:** Pass to RPh. Deny; not funded by the OHP.
3. Has the patient tried and failed, or have contraindications to, one of the covered alternatives listed above?	**Yes:** document failure. Approve for up to 1 year.	**No:** Pass to RPh. Deny; cost-effectiveness

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

Emergency Drug Coverage for Citizenship Waived Medical (CWM)

Goal(s):

- Restrict use for conditions when lack of therapy will result in serious jeopardy to the health of the patient or an unborn child, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part

Length of Authorization:

- Up to 12 months (criteria specific)

Requires PA:

- All drugs for the CWM benefit

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 treatment related to any of the diagnoses in Table 1, for which the absence of treatment could result in: • Serious jeopardy to the patient's health • Serious impairment to bodily functions OR • Serious dysfunction of any bodily organ or part?	**Yes**: Go to #3	**No:** Go to #4

Approval Criteria		
3. Is there documentation that the request is for primary or secondary preventative therapy? Note: chemoprophylaxis for primary prevention (to reduce risk of the diagnosis) and secondary prevention (to prevent disease recurrence after complete remission) are not covered.	**Yes:** Pass to RPh. Deny; not covered for CWM benefit Preventative therapy is not covered.	**No:** Adjudicate per clinical criteria (if pertinent). In the absence of specific clinical criteria, therapy can be approved for the length of the prescription or requested duration, whichever is less (not to exceed duration listed below).
4. Is treatment for a covered ancillary diagnosis in Table 2?	**Yes:** Adjudicate per clinical criteria (if pertinent). In the absence of specific clinical criteria, therapy can be approved for the length of the prescription or requested duration, whichever is less (not to exceed 12 months).	**No:** Pass to RPh. Go to #5.
5. RPh only: Provider should include documentation that ancillary diagnoses are 1) related to a covered condition and 2) drug therapy for the ancillary diagnosis is necessary to treat the covered condition. RPh can use clinical judgement to adjudicate requests per clinical criteria or deny based on the documentation provided. If ancillary diagnoses are provided by the prescriber, please forward request to Oregon DMAP for consideration and potential modification of current PA criteria.		

Table 1. Conditions covered for CWM

ICD-10	Condition	Maximum duration per request (months)
C00x-C96x	Malignant neoplasms	12
D00x-D49x	Neoplasms	12
N18.6	End stage renal disease (on dialysis)	12
T86.1-T86.9; Z94.0	Kidney transplant	12
F00x-F99x	Behavioral health conditions only when treatment is prescribed in conjunction with a crisis visit (CPT codes 90839 & 90840)	3

Table 2. Common covered ancillary conditions

Condition (ICD-10 when a specific code is available)
Agranulocytosis secondary to cancer chemotherapy (D70.1) Antineoplastic chemotherapy induced pancytopenia (D61.810) Febrile neutropenia
Blood-clots secondary to cancer or venous access necessary for cancer treatment
Cancer-related pain
Chemotherapy-induced nausea and vomiting
Tumor lysis syndrome (E88.3)

P&T/DUR Review: 4/22 (SS)
Implementation: 1/1/22

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 Is the prescriber experienced in managing metabolic diseases such as nephropathic cystinosis; AND 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*

Oral Cystic Fibrosis Modulators

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
Ivacaftor (Kalydeco)	E56K, G178R, S549R K1060T, G1244E, P67L, E193K, G551D, A1067T, S1251N 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 ≥ 6 months
Lumacaftor/ivacaftor (Orkambi)	Homozygous Phe508del	≥ 2 years
Tezacaftor/Ivacaftor	Homozygous Phe508del, A455E, A1067T, D110E,	≥ 6 years

(Symdeko)	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	
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: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212273	≥ 6 years

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 If unknown, there needs to be a CF mutation test to detect the presence of the CFTR mutation prior to use.

Approval Criteria		
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. 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 If unknown, there needs to be a CF mutation test to detect the presence of the CFTR mutation prior to use. CF due to other CFTR gene mutations are not approved indications (including the F508del mutation).
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? • Dornase alfa; AND • Hypertonic saline; AND • 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 1)?	**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 If unknown, these labs need to be collected prior to approval.	

Approval Criteria		
11. Is medication dosed appropriately based on age, weight, and co-administered drugs (see dosing and administration below)?	**Yes:** Approve for 6 months. 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)
2. Does the patient have documented response to therapy as defined as below : For patients age ≥6 years: • An improvement or lack of decline in lung function as measured by the FEV1 when the patient is clinically stable; OR • A reduction in the incidence of pulmonary exacerbations; OR • A significant improvement in BMI by 10% from baseline? For patients age 2-5 years (cannot complete lung function tests) • Significant improvement in BMI by 10% from baseline; OR • Improvement in exacerbation frequency or severity	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
3. Have liver function tests been appropriately monitored? What are the most recent liver function tests (AST, ALT, and bilirubin)? Note: Monitoring LFTs is recommended every 3 months for the first year, followed by once a year.	Document. Go to #4 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:

Ivacaftor:

- 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 1. Examples of CYP3A4 inhibitors and inducers.

Drug co-	Co-administered drug category	Recommended dosage adjustment

administered with IVA		for IVA
Ketoconazole Itraconazole Posaconazole Voriconazole Clarithromycin 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 Erythromycin Clofazimine	CYP3A4 moderate inhibitors	Reduce IVA dose to 1 tablet or 1 packet of oral granules **once daily** (half of normal dose)
Rifampin Rifabutin Phenobarbital Phenytoin Carbamazepine 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.

<u>Elexacaftor/tezacaftor/ivacaftor:</u>

- 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): <u>Use not recommended</u>
- 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.

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. Does the patient have moderate or severe renal impairment (est. GFR <50 mL/min)?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #7
7. Is the patient ambulatory with a walking disability requiring use of a walking aid **OR;** 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

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:** Go to #2	**No:** Pass to RPh. Deny; medical appropriateness
2. Is the medication being prescribed by or in consultation with a neurologist?	**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.

P&T Review: *6/21(DM); 8/20 (DM); 6/20; 11/17; 5/16; 3/12*
Implementation: *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:** Pass to RPH; Deny (Not Covered by the OHP). Offer alternative of using generic or pharmacy accepting generic price (no DAW-1)
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)*

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 drug being used to treat an OHP funded condition?	**Yes**: Go to #3	**No**: Pass to RPh. Deny; not funded by the OHP.
3. Is the request for continuation of dichlorphenamide treatment previously approved by Fee-For-Service?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #4
4. Is the requested treatment for Andersen-Tawil Syndrome or Paramytonia congenita?	**Yes:** Pass to RPh. Deny; medical appropriateness. Note: Dichlorphenamide is only approved for Hyperkalemic and Hypokalemic Periodic Paralyses.	**No:** Go to #5
5. Is the request for treatment of Hyperkalemic or Hypokalemic Periodic Paralysis based on genetic testing or clinical presentation?	**Yes:** Go to #6	**No**: Pass to RPh. Deny; medical appropriateness. Note: Dichlorphenamide is not indicated for other forms of periodic paralysis.

Approval Criteria		
6. Does the patient have an average baseline attack rate of ≥1 attack per week?	**Yes:** Go to #7 Document baseline attack rate.	**No:** Pass to RPh. Deny; medical appropriateness.
7. Has the patient previously tried and failed acetazolamide?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness.
8. Has the patient previously experienced disease worsening upon treatment with acetazolamide?	**Yes:** Pass to RPh. Deny; medical appropriateness. Note: Dichlorphenamide was not studied in this population due to potential for similar disease worsening effects.	**No:** Go to #9
9. 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? Note: Medications which affect potassium levels include, but are not limited to, oral potassium, steroids, insulin, and diuretics.	**Yes:** Go to #10	**No:** Pass to RPh. Deny; medical appropriateness. Note: Lifestyle and medication changes are generally regarded as first line therapy.
10. Is the patient currently taking ≥1000mg of aspirin daily?	**Yes:** Pass to RPh. Deny; medical appropriateness. Note: Concurrent use of ≥1000mg aspirin daily with dichlorphenamide is contraindicated.	**No:** Go to #11
11. Is the patient ≥18 years old?	**Yes:** Go to #12	**No:** Pass to RPh. Deny; medical appropriateness. Note: There is insufficient evidence of safety and efficacy in the pediatric population.

Approval Criteria		
12. 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 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

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? (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? Message: • 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.

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. Is the treated diagnosis on OHP funded condition?	**Yes:** Go to #3.	**No:** Pass to RPH. Deny for medical appropriateness.
3. 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 #4.	**No:** Pass to RPH. Deny for medical appropriateness.
4. Is the patient currently receiving antihypertensive medication?	**Yes:** Pass to RPH. Deny for medical appropriateness.	**No:** Go to #5.

Approval Criteria		
5. Does the patient have a documented trial of appropriate therapy with both fludrocortisone and midodrine? Message: 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. 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.

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:** Go to #3
3. Is the patient 21 years of age or younger AND is there documentation that the therapy is expected to improve the patient's ability to grow, develop or participate in school?	**Yes:** Approve for 6 months, or for length of the prescription, whichever is less	**No:** Deny; not funded by the OHP.
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: *4/22 (SS); 11/15 (AG)*
Implementation *TBD; 1/1/16*

Drugs for Duchenne Muscular Dystrophy

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

Length of Authorization:
- 6 months

Requires PA:
- Targeted therapies for exon skipping (see Table 1; pharmacy or physician administered claims)
- Deflazacort

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)
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
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
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
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

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. Note: Therapies are not indicated for other forms of muscular dystrophy or other diagnoses.
3. Is the request for deflazacort?	**Yes:** Go to #4	**No:** Go to #7

Approval Criteria		
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? 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 2 doses of measles, mumps, rubella, and varicella.	**Yes:** Go to #6 Document physician attestation of immunization history.	**No:** Pass to RPh. Deny; medical appropriateness.
6. Does the patient have a documented contraindication or intolerance to oral prednisone that is not expected to crossover to deflazacort? Note: deflazacort may be an option for patients with clinically significant weight gain associated with prednisone use.	**Yes:** Approve for up to 12 months. Document contraindication or intolerance reaction.	**No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of prednisone.
7. Is the request for continuation of treatment previously approved by FFS?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #8
8. Is the request for an FDA-approved indication (Table 1)?	**Yes:** Go to #9 Document genetic testing.	**No:** Pass to RPh, Deny; medical appropriateness.
9. Is the request for golodirsen or viltolarsen?	**Yes:** Go to #10	**No:** Go to #12
10. Is the request for combination treatment with 2 or more targeted therapies (e.g., golodirsen and viltolarsen)?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #11
11. Has the provider assessed baseline renal function as recommended in the FDA label? Recommended monitoring includes serum cystatin C, urine dipstick, and urine protein-to-creatinine within the past 3 months	**Yes:** Go to #12	**No:** Pass to RPh. Deny; medical appropriateness.
12. Has the patient been on a stable dose of corticosteroid for at least 6 months or have documented contraindication to steroids?	**Yes:** Go to #13	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
13. 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. Is the request for golodirsen or viltolarsen?	**Yes:** Go to #2	**No:** Go to #3
2. Has the provider assessed renal function? Recommended monitoring includes urine dipstick monthly, serum cystatin C every 3 months, and protein-to-creatine ratio every 3 months.	**Yes:** Go to #3	**No:** Pass to RPh, Deny; medical appropriateness.
3. 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 #4 Document functional status and provider attestation.	**No:** Pass to RPh, Deny; medical appropriateness.
4. Is there documentation based on chart notes of any serious adverse events related to treatment (e.g., acute kidney injury, infections, etc.)?	**Yes:** Go to #5	**No:** Approve for up to 6 months
5. Has the adverse event been reported to the FDA Adverse Event Reporting System (FAERS)?	**Yes:** Approve for up to 6 months Document provider attestation	**No:** Pass to RPh, Deny; medical appropriateness.

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

Eculizumab (Soliris®)

Goal(s):

- Restrict use to OHP-funded conditions and according to OHP guidelines for use.
- Promote use that is consistent with national clinical practice guidelines and medical evidence.
- Eculizumab is approved by the FDA for the following indications:
  - Neuromyelitis Optica Spectrum Disorder (NMOSD) in adult patients who are anti-AQP4-IgG-antibody positive
  - Reducing hemolysis in patients with paroxysmal nocturnal hemoglobinuria (PNH)
  - Inhibiting complement-mediated thrombotic microangiopathy in patients with atypical hemolytic uremic syndrome (aHUS)
  - Treatment of generalized myasthenia gravis (MG) in adult patients who are anti-acetylcholine receptor (AchR) antibody positive

Length of Authorization:

- Up to 12 months

Requires PA:

- Soliris® (eculizumab) 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 the diagnosis funded by OHP?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP.
3. Is this request for continuation of therapy?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #4

Approval Criteria		
4. Has the patient been vaccinated against *Streptococcus pneumoniae, Haemophilus influenzae* type B, and *Neisseria meningitidis serogroups A, C, W, and Y and serogroup B* according to current Advisory Committee on Immunization Practice (ACIP) recommendations for vaccination in patients with complement deficiencies*?* Note: Prescribing information recommends vaccination at least 2 weeks prior to starting therapy. If the risk of delaying therapy outweighs the risk of developing a serious infection, a 2 week course of antibiotic prophylaxis must be immediately initiated if vaccines are administered less than 2 weeks before starting complement therapy.	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Is the diagnosis one of the following: • Neuromyelitis Optica Spectrum Disorder (NMOSD) in an adult who is anti-aquaporin-4 (AQP4) antibody positive, • Paroxysmal Nocturnal Hemoglobinuria (PNH), OR • atypical Hemolytic Uremic Syndrome (aHUS)? (Note: Eculizumab is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).	**Yes:** Go to #6	**No:** Go to #7
6. Does the requested dosing align with the FDA- approved dosing (**Table 1**)?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness
7. Is the request for a diagnosis of myasthenia gravis in an adult patient who is ACh Receptor (AChR) antibody-positive?	**Yes:** Go to # 8	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
8. Has the patient tried: • at least 2 or more immunosuppressant therapies (e.g., glucocorticoids in combination with azathioprine or mycophenolate mofetil or cyclosporine or tacrolimus or methotrexate or rituximab) for 12 months without symptom control OR • at least 1 or more nonsteroidal immunosuppressant with maintenance intravenous immunoglobulin once monthly or plasma exchange therapy (PLEX) over 12 months without symptom control?	**Yes:** Go to #9	**No:** Pass to RPh. Deny; medical appropriateness
9. Is the Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score ≥ 6?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Is there objective documentation of treatment benefit from baseline? Appropriate measures will vary by indication (e.g., hemoglobin stabilization, decreased transfusions, symptom control or improvement, functional improvement, etc.).	**Yes:** Approve for 12 months Document baseline assessment and physician attestation received.	**No:** Pass to RPh. Deny; medical appropriateness

Table 1. FDA-Approved Indications and Dosing for Eculizumab[1]

	Eculizumab (Soliris®)		
FDA-approved Indications	• Neuromyelitis Optica Spectrum Disorder (NMOSD) in adult patients who are anti-AQP4-IgG-antibody • Reducing hemolysis in patients with paroxysmal nocturnal hemoglobinuria (PNH) • Inhibiting complement-mediated thrombotic microangiopathy in patients with atypical hemolytic uremic syndrome (aHUS) • Treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor antibody positive		
Recommended NMOSD dose in patients 18 yo and older	900 mg IV every week x 4 weeks, followed by 1200 mg IV for the fifth dose 1 week later, then 1200 mg IV every 2 weeks thereafter		
Recommended PNH dose in patients 18 yo and older	600 mg IV every week x 4 weeks, followed by 900 mg IV for the fifth dose 1 week later, then 900 mg IV every 2 weeks thereafter		
Recommended aHUS dose in	**Body Weight**	**Induction Dose**	**Maintenance Dose**

patients less than 18 yo	5 kg to 9 kg 10 kg to 19 kg 20 kg to 29 kg 30 kg to 39 kg ≥ 40 kg	300 mg weekly x 1 dose 600 mg weekly x 1 dose 600 mg weekly x 2 doses 600 mg weekly x 2 doses 900 mg weekly x 4 doses	300 mg at week 2; then 300mg every 3 weeks 300 mg at week 2; then 300mg every 2 weeks 600 mg at week 3; then 600mg every 2 weeks 900 mg at week 3; then 900 mg every 2 weeks 1200 mg at week 5; then 1200 mg every 2 weeks
Recommended aHUS dose in patients 18 yo and older	900 mg IV every week x 4 weeks, followed by 1200 mg IV for the fifth dose 1 week later, then 1200 mg IV every 2 weeks thereafter		
Recommended generalized MG dose	900 mg IV every week x 4 weeks, followed by 1200 mg IV for the fifth dose 1 week later, then 1200 mg IV every 2 weeks thereafter		
Dose Adjustment in Case of Plasmapheresis, Plasma Exchange, or Fresh Frozen Plasma Infusion	Dependent on most recent eculizumab dose: refer to prescribing information for appropriate dosing (300 mg to 600 mg)		

1. Soliris (eculizumab) Solution for Injection Prescribing Information. Boston, MA: Alexion Pharmaceuticals, Inc. 11/2020.

P&T/DUR Review:12/21; 4/21 (DM)
Implementation: 5/1/21

Edaravone (Radicava™)

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 amytrophic lateral sclerosis
- To monitor for clinical response for appropriate continuation of therapy

Length of Authorization:
- Up to 12 months

Requires PA:
- Edavarone (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 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 treatment for amyotrophic lateral sclerosis (ALS)?	**Yes**: Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Is the diagnosis funded by OHP?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; not funded by the OHP.
5. Is the patient currently on riluzole therapy, OR have a documented contraindication or intolerance to riluzole?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Is the medication being prescribed by or in consultation with a neurologist?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness
7. Does the patient have documented percent-predicted forced vital capacity (%FVC) ≥ 80%?	**Yes:** Record lab result. Go to #8	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
8. 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. (0 [worst] to 48 [best]) Approve for 6 months based on FDA-approved dosing.*	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Is the medication being prescribed by or in consultation with a neurologist?	**Yes**: Go to #2	**No:** Pass to RPh. Deny; medical appropriateness
2. Has the prescriber provided documentation that the use of Radicava (edarvone) 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 #3	**No:** Pass to RPh. 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."
3. Does the patient have documented percent-predicted forced vital capacity (%FVC) ≥ 80%?	**Yes:** Record lab result. Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. 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. (0 [worst] to 48 [best]) Approve for 12 months.	**No:** Pass to RPh. Deny; medical appropriateness

* = see below for summary of FDA-approved dosage and administration. Consult FDA website for prescribing information details at www.fda.gov

P&T/DUR Review: 7/18 (DE)
Implementation: 8/15/18

***Dosage and Administration:**

60 mg (two consecutive 30 mg infusion bags) IV infusion over 60 minutes
- Initial treatment cycle: daily dosing for 14 days followed by a 14-day drug-free period
- Subsequent treatment cycles: daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free period

Efgartigimod (Vyvgart™)

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:
- Vyvgart™ (efgartigimod) 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 this a request for continuation of therapy?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #4
4. Is the diagnosis funded by OHP?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; not funded by the OHP.
5. Is the request for efgartigimod made by, or in consultation with, a neurologist or rheumatologist?	**Yes**: Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Does the patient have an active infection?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #7
7. Has the patient received, or have contraindications to, all routine immunizations recommended for their age? 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-attenuated or live vaccines is not recommended during efgartigimod treatment.	**Yes:** Go to #8. Document physician attestation of immunization history	**No:** Pass to RPh. Deny; medical appropriateness. Administer vaccines before initiation of a new treatment cycle of efgartigimod

Approval Criteria		
8. Does the patient have a positive serological test for anti-AChR antibodies?	**Yes:** Go to #9	**No:** Pass to RPh. Deny; medical appropriateness
9. Does the patient have a Myasthenia Gravis Foundation of America (MGFA) 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 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? Example immunosuppressant therapies: - Azathioprine - Cyclosporine - Mycophenolate mofetil - Tacrolimus - Methotrexate - Cyclophosphamide	**Yes:** Go to #12	**No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of immunosuppressant therapy
12. Is the request for efgartigimod dosing that corresponds to FDA labeling? • 10 mg/kg once weekly for 4 weeks • 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

Renewal Criteria		
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. 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. Record MG-ADL score	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 4/22 (KS)
Implementation: 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): - Hemoglobin <9 g/dL (infants <4 weeks: <10 g/dL) - Platelets <100 x 109/L - 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*) 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.	
3. Is the diagnosis funded by OHP?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP.

Approval Criteria		
4. 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? *Conventional therapy should have included an etoposide and dexamethasone-based regimen*	**Yes:** Document prior therapies or reasons for failure. Go to #5	**No:** Pass to RPh. Deny; medical appropriateness.
5. Has the diagnosis of pHLH been confirmed by genetic testing or by diagnostic criteria listed in **Table 1**?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness.
6. Is the agent prescribed by or in consultation with a specialist (e.g. hematologist) with experience in treating HLH patients?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness.
7. Is the agent being prescribed concurrently with dexamethasone?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness.
8. Is there documentation that the prescriber has assessed the patient and found no evidence of active infection?	**Yes:** Go to #9	**No:** Pass to RPh. Deny; medical appropriateness.
9. Has the patient received prophylaxis for Herpes Zoster, *Pneumocystis Jirovecii*, and fungal infections?	**Yes:** Go to #10	**No:** Pass to RPh. Deny; medical appropriateness.
10. 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 #11	**No:** Pass to RPh. Deny; medical appropriateness.
11. Is the agent dosed appropriately based on documentation of a recent patient weight (see **Table 2** above)?	**Yes:** Document patient weight and go to #12 Weight:_____	**No:** Pass to RPh. Deny; medical appropriateness.
12. 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

Erythropoiesis Stimulating Agents (ESAs)

Goal(s):

- Cover ESAs according to OHP guidelines and current medical literature.
- Cover preferred products when feasible.

Length of Authorization:

- 12 weeks initially, then up to 12 months
- Quantity limit of 30 day per dispense

Requires PA:

- All ESAs require PA for clinical appropriateness.

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 covered diagnosis?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP
3. Is this continuation of therapy previously approved by the FFS program?	**Yes:** Go to #12	**No:** Go to #4
4. Is the requested product preferred?	**Yes:** Go to #6	**No:** Go to #5
5. Will the prescriber change to a preferred product? Message: • Preferred products do not require PA. • 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 #6
6. Is the diagnosis anemia due to chronic renal failure[1] or chemotherapy[2,3]?	**Yes:** Go to #7	**No:** Go to #8
7. Is Hgb <10 g/dL or Hct <30% **AND** Transferrin saturation >20% and/or ferritin >100 ng/mL?	**Yes:** Approve for 12 weeks with additional approval based upon adequate response.	**No:** Pass to RPh. Deny; medical appropriateness
8. Is the diagnosis anemia due to HIV[4]?	**Yes:** Go to #9	**No:** Go to #10

Approval Criteria		
9. Is the Hgb <10 g/dL or Hct <30% **AND** Transferrin saturation >20% **AND** Endogenous erythropoietin <500 IU/L **AND** If on zidovudine, is dose <4200 mg/week?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness
10. Is the diagnosis anemia due to ribavirin treatment[5]?	**Yes:** Go to #11	**No:** Pass to RPh. Deny; medical appropriateness
11. Is the Hgb <10 g/dL or Hct <30% **AND** Is the transferrin saturation >20% and/or ferritin >100 ng/mL **AND** Has the dose of ribavirin been reduced by 200 mg/day and anemia persisted >2 weeks?	**Yes:** Approve up to the length of ribavirin treatment.	**No:** Pass to RPh. Deny; medical appropriateness
12. Has the patient responded to initial therapy?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness

- References:

1. National Kidney Foundation. NKF KDOQI Guidelines. *NKF KDOQI Guidelines* 2006. Available at: http://www.kidney.org/professionals/KDOQI/guidelines_anemia/index.htm . Accessed May 25, 2012.
2. Rizzo JD, Brouwers M, Hurley P, et al. American Society of Clinical Oncology/American Society of Hematology Clinical Practice Guideline Update on the Use of Epoetin and Darbepoetin in Adult Patients With Cancer. *JCO* 2010:28(33):4996-5010. Available at: www.asco.org/institute-quality/asco-ash-clinical-practice-guideline-update-use-epoetin-and-darbepoetin-adult. Accessed May 1, 2012.
3. Rizzo JD, Brouwers M, Hurley P, et al. American Society of Hematology/American Society of Clinical Oncology clinical practice guideline update on the use of epoetin and darbepoetin in adult patients with cancer. *Blood*. 2010:116(20):4045-4059.
4. Volberding PA, Levine AM, Dieterich D, et al. Anemia in HIV infection: Clinical Impact and Evidence-Based Management Strategies. *Clin Infect Dis*. 2004:38(10):1454-1463. Available at: http://cid.oxfordjournals.org/content/38/10/1454. Accessed May 8, 2012.
5. Recombinant Erythropoietin Criteria for Use for Hepatitis C Treatment-Related Anemia. VHA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel. April 2007

P&T Review: *1/19 (JP); 7/16; 5/14; 11/12; 6/12; 2/12, 9/10*
Implementation: *10/13/16; 1/1/13; 9/24/12; 5/14/12*

Esketamine (Spravato)

Goal(s):

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

Length of Authorization:

- Up to 6 months

Requires PA:

- Esketamine requires a prior authorization approval due to safety concerns (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 diagnosis funded by OHP?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP.
4. 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 #5
5. Is the patient 65 years or older?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #6
6. Does the patient have treatment resistant depression (failure of two separate antidepressant trials which were each given for at least 6 weeks at target doses)?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness. Recommend an adequate trial (minimum of 6-8 weeks) of 2 or more antidepressants.

Approval Criteria		
7. Is the patient currently on an FDA approved dose of an oral antidepressant?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness. Esketamine is indicated for use with an oral antidepressant.
8. Does the patient have documentation of any of the following: • Current Aneurysmal vascular disease or arterial venous malformation OR • History of Intracerebral hemorrhage OR • Current Pregnancy OR • Current Uncontrolled hypertension (e.g., >140/90 mmHg)	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Approve for induction phase only: 28 days of treatment with a maximum of 23 nasal spray devices (each device contains 28 mg of esketamine)

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 #4
2. Is the request for administration of esketamine once weekly?	**Yes:** Go to #3	**No**: Pass to RPh. Deny; medical appropriateness. Esketamine is administered once weekly after 4 weeks. Other dosing frequencies have not been adequately studied.
3. Has the patient been adherent to oral antidepressant therapy?	**Yes:** Approve for up to 6 months (maximum of 12 per 28 days)	**No:** Pass to RPh. Deny; medical appropriateness.

Renewal Criteria		
4. 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 23 nasal spray devices (each device contains 28 mg of esketamine)

P&T/DUR Review: 10/21 (SS); 2/21(SS); 7/19 (KS)
Implementation: 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
- All estrogen derivatives for patients <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/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the estrogen requested for a patient ≥18 years old?	**Yes:** Go to #3	**No**: Go to #4
3. Will the prescriber consider a change to a preferred product? Message: • 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 and approve for up to 12 months.	**No:** Approve for up to 12 months.
4. Is the medication requested for gender dysphoria (ICD10 F642, F641)?	**Yes:** Go to #5	**No:** Go to #6
5. Have **all** of the following criteria been met? • Patient has the capacity to make fully informed decisions and to give consent for treatment; and • If patient <18 years of age, the prescriber is a pediatric endocrinologist; and • The prescriber agrees criteria in Guideline Notes on the OHP List of Prioritized Services have been met. See: https://www.oregon.gov/oha/HPA/DSI-HERC/SearchablePLdocuments//Prioritized-List-GN-127.docx	**Yes:** Approve for up to 6 months	**No**: Pass to RPh. Deny; medical appropriateness

Approval Criteria		
6. Is the medication requested for hypogonadism?	**Yes:** Approve for up to 6 months	**No**: Go to #7
7. RPh only: All other indications need to be evaluated to see if funded under the OHP.	If funded and prescriber provides supporting literature: Approve for up to 12 months.	If non-funded: Deny; not funded by the OHP

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

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™)

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? • 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: • Statin, and • Ezetimibe, and • PCSK9 inhibitor (alirocumab or evolocumab)	**Yes:** Go to #4 LDL-C ____mg/dL 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 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 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 drug claims for drugs that are only FDA-approved for indications that are not covered by the Oregon Health Plan (OHP).
- 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): • Expired drug products; • Drug products from non-rebatable manufacturers, with the exception of selected oral nutritionals, vitamins, and vaccines; • Active Pharmaceutical Ingredients (APIs) and Excipients as described by Centers for Medicare and Medicaid (CMS); • Drug products that are not assigned a National Drug Code (NDC) number; • Drug products that are not approved by the Food and Drug Administration (FDA); • Non-emergency drug products dispensed for Citizenship Waived Medical client benefit type; • Drug Efficacy Study Implementation (DESI) drugs; • 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 #2B
4. "70" NDC Not Covered (Transaction line states "Bill Medicare or Bill Medicare D"	**Yes:** Informational Pa to bill specific agency	**No:** Go to #2C
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 #2D
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 #2E

Approval Criteria		
7. "70" NDC Not Covered (Transaction line states "Non-Rebatable Drugs")	**Yes:** 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"	**No:** Go to #2F
8. "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:** Pass to RPh. Go to #3
9. RPh only: "70" NDC Not Covered (Drugs on the Exclusion List) All indications need to be evaluated to see if 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. 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:** Deny. Not funded by the OHP. Message: "The treatment for your condition is not a covered service on the Oregon Health Plan."

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

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
DCC = D	Diagnostics	DME Billing Required

DCC= F	Weight Loss Drugs	Weight Loss Not Covered on OHP List.
DCC= Y	Ostomy Supplies	DME Billing Required
HIC3= B0P	Inert Gases	DME Billing Required
HIC3= L1C	Hypertrichotic Agents, Systemic/Including Combinations	Cosmetic Indications Not Covered on OHP List
HIC3= Q6F	Contact Lens Preparations	Cosmetic Indications Not Covered on OHP List
HIC3=X1C	IUDs	DME Billing Required
HIC3=D6C	Alosetron Hcl	IBS Not Covered on OHP List
HIC3=D6E	Tegaserod	IBS Not Covered on OHP List
HIC3=L1D	Hyperpigmentation Agents	
Drug Code	**Description**	**DMAP Policy**
HIC3=L3P	Astringents	
HIC3=L4A	Topical Antipruritic Agents	
HIC3=L5A; Except HSN= 002466, 002557 006081 (Podophyllin Resin), 002470 (benzoyl peroxide)	Keratolytics	Warts, Corns/Calluses; Seborrhea Are Not Covered on OHP List
HIC3=L5B	Sunscreens	Cosmetic Indications, Acne, Warts, Corns/Callouses; Diaper Rash, Seborrhea Are Not Covered on OHP List
HIC3=L5C	Abrasives	Cosmetic Indications, Acne, Warts, Corns/Callouses; Diaper Rash, Seborrhea Are Not Covered on OHP List
HIC3=L5E	Anti Seborrheic Agents	Seborrhea Not Covered on OHP List
HIC3=L5G	Rosacea Agents, Topical	Rosacea Not Covered on OHP list, some acne severities are covered
HIC3=L6A; Except HSN = 002577 002576 002574 036916 002572 (Capsaicin)	Irritants	Seborrhea, Sprains Not Covered on OHP List
HIC3=L7A	Shampoos	Cosmetic Indications, Seborrhea, Not Covered on OHP List
HIC3=L8A	Deodorants	Cosmetic Indications Not Covered on OHP List
HIC3=L8B	Antiperspirants	Cosmetic Indications Not Covered on OHP List
HIC3=L9A	Topical Agents, Misc	Cosmetic Indications Warts, Corns/Callouses; Diaper Rash, Seborrhea, are Not Covered on

		OHP List
HIC3=L9C	Antimelanin Agents	Pigmentation Disorders Not Covered on OHP List
HIC3=L9D	Topical Hyperpigmentation Agent	Pigmentation Disorders Not Covered on OHP List
HIC3=L9F	Topical Skin Coloring Dye Agent	Cosmetic Indications Not Covered on OHP List
HIC3=L9I	Topical Cosmetic Agent; Vit A	Cosmetic Indications Not Covered on OHP List
HIC3=L9J	Hair Growth Reduction Agents	Cosmetic Indications Not Covered on OHP List
Drug Code	**Description**	**DMAP Policy**
HIC3=Q5C	Topical Hypertrichotic Agents	Cosmetic Indications Not Covered on OHP List
HIC3=Q6R, Q6U, Q6D	Antihistamine-Decongestant, Vasoconstrictor and Mast Cell Eye Drops	Allergic Conjunctivitis Not Covered on OHP List
HIC3= U5A, U5B, U5F & S2H plus HSN= 014173	Herbal Supplements " Natural Anti-Inflammatory Supplements" - Not Including Nutritional Supplements such as: Ensure, Boost, Etc.	
HSN=003344	Sulfacetamide Sodium/Sulfur Topical	Seborrhea Not Covered on OHP list
HSN=025510	Rosacea	Rosacea Not Covered on OHP List, some acne severities are covered
TC=93; Except HSN = 002363 (dextranomer) 002361 (zno)	Emollients/Protectants	Cosmetic Indications, Warts, Corns/Callouses; Diaper Rash, Seborrhea Are Not Covered on OHP List

P&T Review: *3/18; 2/23/06*
Implementation: *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 physician 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 the diagnosis funded by OHP?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP.
4. Is this a request for continuation of therapy?	**Yes:** Go to **Renewal Criteria**	**No:** Go to # 5
5. Is the provider a specialist in managing Fabry disease?	**Yes**: Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Is the request for migalastat?	**Yes:** Go to # 7	**No:** Go to # 10
7. Does the patient have a mutation that is amenable to migalastat therapy as confirmed by a genetic specialist?	**Yes**: Got to # 8	**No:** Pass to RPh. Deny; medical appropriateness
8. Is the patient currently receiving agalsidase beta?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to # 9
9. 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		
10. 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 # 11	**No:** Go to # 12
11. Does the patient have end stage renal disease requiring dialysis?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Approve for 12 months
12. 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: • Uncontrolled pain that interferes with quality of life • Gastrointestinal symptoms that are significantly reducing quality of life and not attributable to other pathology • Mild to moderate renal impairment (GFR > 30 mL/min) • Cardiac disease (left ventricular hypertrophy, conduction abnormalities, ejection fraction< 50%, arrhythmias) • 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: • Renal function • Pain Scores • Quality of Life measurement • Cardiac function • Neurologic status • Growth and development in children	**Yes:** Approve for 12 months. 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 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

Approval Criteria		
6. Is baseline echocardiogram on file that was performed within past 6 months?	**Yes:** Approve for 12 months Document results here: Date of echocardiogram_____ 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 Document results here: Date of echocardiogram____	**No:** Pass to RPh. Deny; medical appropriateness
2. Has seizure frequency decreased since beginning therapy?	**Yes:** Go to #3 Document baseline and current seizure frequency_____	**No:** Pass to RPh. Deny for lack of treatment response.
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: *10/21 (DM); 10/2020 (DM)*
Implementation: *11/1/20*

Fidaxomicin (Dificid®)

Goal(s):

- To optimize appropriate treatment of *Clostridium difficile*-associated infection.

Length of Authorization:

- 10 days

Requires PA:

- Fidaxomicin

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 *Clostridium 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: *5/18 (DM); 5/15 (AG); 4/12*
Implementation: *7/1/18; 10/15; 7/12*

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 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/

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 diagnosis funded by OHP?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP.
3. Is the request for continuation of therapy previously approved by FFS?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #4
4. Is the request from a provider experienced in the treatment of Gaucher disease?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Is the request for treatment of Type 1 Gaucher Disease? Note: Type 1 disease is characterized predominately by bone involvement without CNS symptoms.	**Yes**: Go to #7	**No:** Go to #6

Approval Criteria		
6. Is the request for treatment of Type 3 Gaucher Disease? 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
7. Is the request for an FDA-approved age in Table 1?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Does the patient have current symptoms characteristic of bone involvement such as: a. Low platelet count b. Low hemoglobin and hematocrit levels c. Radiologic bone disease, T-score less than -2.5 or bone pain d. Delayed growth in children (<10th percentile for age) OR e. Splenomegaly or hepatomegaly?	**Yes:** Go to #9 Document baseline labs and symptoms	**No:** Pass to RPh. Deny; medical appropriateness
9. 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 #10
10. Is the request for enzyme replacement therapy?	**Yes:** Go to #11	**No:** Go to #12
11. Is the request for a non-preferred product and will the prescriber consider a change to a preferred product? Message: 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		
12. Does the patient have a documented contraindication, intolerance, inadequate response, or inability to access or adhere to enzyme replacement therapy?	**Yes:** Go to #13	**No:** Pass to RPh. Deny; medical appropriateness
13. Is the request for eliglustat?	**Yes:** Go to #14	**No:** Approve for up to 6 months
14. 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 #15
15. Does the patient have moderate to severe hepatic impairment?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #16
16. Does testing for CYP2D6 metabolizer status indicate extensive, intermediate or poor CYP2D6 metabolism?	**Yes:** Go to #17	**No:** Pass to RPh. Deny; medical appropriateness
17. 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 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 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

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. 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. Will the prescriber consider a change to a preferred product? Message: • 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
4. Has the patient tried and failed metformin or have contraindications to metformin? (document contraindication, if any)	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of metformin. See below for metformin titration schedule.
5. Is the request for semaglutide or dulaglutide?	**Yes:** Approve for up to 12 months	**No:** Go to #6

Approval Criteria		
6. Is the patient currently taking prandial insulin?	**Yes:** Pass to RPh. Deny; medical appropriateness The safety and efficacy of other insulin formations with GLP-1 agonists have not been studied.	**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 Review: *8/20 (KS), 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: *9/1/20; 5/1/19; 8/15/18; 4/1/17; 2/15; 1/14*

Gonadotropin-Releasing Hormone Agonists

Goal(s):

- Restrict pediatric use of gonadotropin-releasing hormone (GnRH) agonists to medically appropriate conditions funded under the Oregon Health Plan (e.g., central precocious puberty or gender dysphoria)
- Promote use that is consistent with medical evidence and product labeling

Length of Authorization:

- Up to 6 months

Requires PA:

- GnRH agonists prescribed for pediatric patients less than 18 years of age
- Non-preferred 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 diagnosis funded by OHP?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP.
3. Is the prescriber a pediatric endocrinologist?	**Yes:** Go to #4	**No:** Go to #8
4. What diagnosis is being treated and what is the age and gender of the patient assigned at birth?	Record ICD10 code. Record age and gender assigned at birth	
5. Is the diagnosis central precocious puberty (ICD10 E30.1, E30.8) or other endocrine disorder (E34.9)?	**Yes:** Approve for up to 6 months	**No:** Go to #6
6. Is the diagnosis gender dysphoria (ICD10 F64.2, F64.1)?	**Yes:** Go to #7	**No:** Go to #12

Approval Criteria		
7. Does the request meet **all** of the following criteria? • Diagnosis of gender dysphoria made by a mental health professional with experience in gender dysphoria. • Onset of puberty confirmed by physical changes and hormone levels, but no earlier than Tanner Stages 2. • The prescriber agrees criteria in the Guideline Notes on the OHP List of Prioritized Services have been met.* *From Guideline Note 127: To qualify for cross-sex hormone therapy, the patient must: A) have persistent, well-documented gender dysphoria B) have the capacity to make a fully informed decision and to give consent for treatment C) have any significant medical or mental health concerns reasonably well controlled D) have a comprehensive mental health evaluation provided in accordance with Version 7 of the World Professional Association for Transgender Health (WPATH) Standards of Care (www.wpath.org).	**Yes:** Approve for up to 6 months.	**No:** Pass to RPh; deny for medical appropriateness
8. Is this request for treatment of breast cancer or prostate cancer?	**Yes:** Approve up to 1 year	**No:** Go to #9
9. 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 # 10
10. Is this request for management of moderate to severe pain associated with endometriosis in a woman ≥18 years of age?	**Yes**: Go to #11	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
11. 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? -or- Does the patient have a documented intolerance, FDA-labeled contraindication, or hypersensitivity the first-line therapy options?	**Yes:** Approve for 6 months. *Note maximum recommended duration of therapy for nafarelin, leuprolide, and goserelin is 6 months. If requesting continuation of therapy beyond 6 months, pass to RPh. Deny; medical appropriateness.	**No:** Pass to RPh. Deny; medical appropriateness *First-line therapy options such as hormonal contraceptives or progestins do not require PA
12. RPh only: 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: *12/21 (DM); 3/19 (DM); 5/15*
Implementation: *1/1/22; 5/1/19*

Gonadotropin-Releasing Hormone Antagonists

Goal(s):
- Promote safe use of elagolix in women 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.

Length of Authorization:
- Initial: Up to 6 months
- Elagolix renewal: Up to 6 months for 150 mg daily dose with total cumulative treatment period not to exceed 24 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
- Elagolix/estradiol/norethindrone
- Relugolix/estradiol/norethindrone

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 #3	**No:** Pass to RPh. Deny; not funded by the OHP.
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 patient pregnant or actively trying to conceive?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #5
5. Is this request for management of moderate to severe pain associated with endometriosis in a patient ≥18 years of age?	**Yes**: Go to #6	**No:** Go to #11

Approval Criteria		
6. 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? -or- • Does the patient have a documented intolerance, FDA- labeled contraindication, or hypersensitivity the first-line therapy options?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness First-line therapy options such as combined hormonal contraceptives or progestins do not require PA
7. Is the patient taking any concomitant medications that are strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (e.g. cyclosporine, gemfibrozil, etc.)?	**Yes:** Deny; medical appropriateness	**No:** Go to #8
8. Does the patient have severe hepatic impairment as documented by Child-Pugh class C?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #9
9. Does the patient have moderate hepatic impairment as documented by Child-Pugh class B?	**Yes:** Go to #10	**No:** Approve for 6 months * FDA approved 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
10. Is the dose for elagolix 150 mg once daily?	**Yes:** Approve for 6 months * FDA approved dosing for moderate hepatic impairment: 150 mg once daily for up to 6 months	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
11. 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 #12	**No:** Pass to RPh. Deny; medical appropriateness
12. Has the patient tried and failed a trial of first line therapy options including 1 of the following: a) levonorgestrel-releasing IUD OR b) continuous administration of combined hormonal contraceptives OR c) cyclic progestins OR d) tranexamic acid ? OR Does the patient have a documented intolerance, FDA-labeled contraindication, or hypersensitivity to the first-line therapy options?	**Yes**: Go to #13	**No:** Pass to RPh. Deny; medical appropriateness First-line therapy options such as hormonal contraceptives, progestins, or tranexamic acid do not require PA
13. Does the patient have a diagnosis of osteoporosis or related bone-loss condition? 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

Renewal Criteria		
1. Has the patient been receiving elagolix/estradiol/norethindrone or relugolix/estradiol/norethindrone for management of uterine fibroids?	**Yes:** Go to #4	**No:** Go to #2

Renewal Criteria		
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. (Elagolix 200 mg twice daily is limited to 6-month maximum treatment duration per FDA labeling)
3. Does the patient have moderate hepatic impairment as documented by Child-Pugh Class B?	**Yes:** Pass to RPh; Deny; medical appropriateness. (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? *For endometriosis: has pain associated with endometriosis improved? For uterine fibroids: has patient experienced at least a 50% reduction in menstrual blood loss from baseline?	**Yes:** Approve for up to 18 months Document physician attestation received. Total cumulative treatment period not to exceed 24 months.	**No:** Pass to RPh; Deny; medical appropriateness.

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

19. Does the patient have moderate hepatic impairment as documented by Child-Pugh class B?	**Yes:** Go to #20	**No:** Approve for 6 months *Note maximum recommended duration of therapy for nafarelin, leuprolide, and goserelin is 6 months. If requesting continuation of therapy beyond 6 months, pass to RPh. Deny; medical appropriateness.
20. Is the dose for elagolix 150 mg once daily?	**Yes:** Approve for 6 months	**No:** Pass to RPh. Deny; medical appropriateness
21. RPh only: All other indications need to be evaluated as to whether it is funded under the OHP. Refer unique situations to Medical Director of DMAP.		

Renewal Criteria		
1. Has the patient been receiving therapy with elagolix 150 mg once daily?	**Yes:** Go to #2	**No:** Pass to RPh; Deny; medical appropriateness. (Elagolix 200 mg twice daily is limited to 6-month maximum treatment duration per FDA labeling)
2. Does the patient have moderate hepatic impairment as documented by Child-Pugh Class B?	**Yes:** Pass to RPh; Deny; medical appropriateness. (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 #3

Renewal Criteria		
3. Has the patient's condition improved as assessed and documented by the prescriber?	**Yes:** Approve for up to 6 months. Total cumulative treatment period not to exceed 24 months. Document baseline assessment and physician attestation received.	**No:** Pass to RPh; Deny; medical appropriateness.

P&T / DUR Review: *3/19 (DM); 1/19*
Implementation: *5/1/19*

Agents for Gout

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? 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 up12 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) for funded diagnoses where there is medical evidence of effectiveness and safety.

NOTE: Treatment with GH in children should continue only until adult height, as determined by bone age, is achieved. Treatment is not included for isolated deficiency of human growth hormone in adults.

Length of Authorization:

- Up to 12 months

Requires PA:

- All GH products require prior authorization for OHP coverage. Treatment of human growth hormone deficiency for adults is not funded by the OHP.

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/

Initial Approval Criteria		
1. What is the diagnosis 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 this a request for initiation of growth hormone?	**Yes:** Go to #4	**No:** Go to **Renewal Criteria**
4. Is the agent being prescribed by, or in consultation with, a pediatric endocrinologist or pediatric nephrologist?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Is the patient an adult (>18 years of age)?	**Yes:** Go to #10	**No:** Go to #6
6. Is the diagnosis funded?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness
7. 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 #8

Initial Approval Criteria		
8. If male, is bone age <16 years? If female, is bone age <14 years?	**Yes:** Go to #9	**No:** Pass to RPh. Deny; medical appropriateness
9. Is there evidence of non-closure of epiphyseal plate?	**Yes:** Go to #11	**No:** Pass to RPh. Deny; medical appropriateness
10. Is the request for the treatment of isolated human growth hormone deficiency in an adult (E23.0) or short stature due to an endocrine disorder (E34.3), or another unfunded condition? Per Guideline Note 74, treatment with GH for children with conditions such as panhypopituitarism, iatrogenic and other pituitary disorders, as well as gonadal dysfunction, should only continue until adult height, as determined by bone age, is achieved.	**Yes:** Pass to RPh. Deny; not funded by the OHP.	**No:** Go to #11
11. Is the request for a pediatric patient with Prader-Willi syndrome who has: • Severe obesity OR • A history of upper airway obstruction or sleep apnea OR • Severe respiratory impairment? 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 # 12
12. Is the requested product preferred?	**Yes:** Approve for up to 12 months	**No:** Go to #13
13. Will the prescriber consider a change to a preferred product that is FDA-approved for the condition? Message: • 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 #14

Initial Approval Criteria		
14. Is the request for lonapegsomatropin?	**Yes:** Go to #15	**No:** Approve for up to 12 months
15. Is the request for a pediatric patient 1 year or older with a body weight >11.5 kg?	**Yes:** Approve for up to 12 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 patient prior to reaching adulthood (<18 years of age)?	**Yes:** Go to #3	**No:** Go to #5
3. Is growth velocity greater than 2.5 cm per year?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Is male bone age <16 years or female bone age <14 years?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
5. Is the request for isolated human growth hormone deficiency in an adult (E23.0), short stature due to an endocrine disorder (E34.3), or another unfunded condition?	**Yes:** Pass to RPh. Deny; not funded by the OHP.	**No:** Go to #6
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? Message: • 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 12 months

P&T Review: *12/21 (DE); 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: *1/1/22; 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 all hepatitis C treatments.
- Ensure appropriate patient regimen based on disease severity, genotype, and patient comorbidities.

Length of Authorization:
- 8-16 weeks

Requires PA:
- All direct-acting antivirals for treatment of Hepatitis C

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for treatment of chronic Hepatitis C infection (B18.2)? Note: Accurate diagnosis of chronic hepatitis C infection typically includes positive detection of a viral load. Diagnosis should not rely solely on HCV antibody testing.	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness.
3. Is expected survival from non-HCV-associated morbidities more than 1 year?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
4. Has <u>all</u> the following pre-treatment testing been documented: 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 b. Current HBV status of patient c. History of previous HCV treatment and outcome d. Presence or absence of cirrhosis as clinically determined (e.g., clinical, laboratory, or radiologic evidence) Note: Direct-acting antiviral agents can re-activate hepatitis B in some patients. Patients with history of HBV should be monitored carefully during and after treatment for flare-up of hepatitis. Prior to treatment with a DAA, all patients should be tested for HBsAG, HBsAb, and HBcAB status. HIV testing is also recommended, and modification of HIV or HCV treatment regimens may be needed if there are drug-drug interactions. Treatment-experienced: Patients who received more than 4 weeks of HCV DAA therapy.	**Yes:** Record results of each test and go to #5 Note: If the patient has HIV or HBV co-infection, it is highly recommended that a specialist be consulted prior to treatment. Currently treatment is not recommended during pregnancy due to lack of safety and efficacy data	**No**: Pass to RPh. Request updated testing.
5. Which regimen is requested?	Document and go to #6	
6. Does the patient have complications of cirrhosis (ascites, portal hypertension, hepatic encephalopathy, hepatocellular carcinoma, esophageal varices)?	**Yes:** Go to #7	**No:** Go to #8
7. Is the regimen prescribed by, OR is the patient in the process of establishing care with or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness. Recommend prescriber document referral to a specialist.

Approval Criteria		
8. 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, including measuring and reporting of a post-treatment viral load OR Is there attestation from the patient and provider that they have opted out of OHA case management? Case management includes assessment of treatment barriers and offer of patient support to mitigate potential barriers to regimen adherence as well as facilitation of SVR12 evaluation to assess treatment success. Patients may opt out of OHA case management with attestation that they understand goals and benefits of the program and responsibilities associated with treatment including adherence to treatment and lab tests. Members may rejoin the program at any time.	**Yes**: Go to #9	**No:** Pass to RPh. Deny; medical appropriateness.
9. Is the prescribed drug: a) Elbasvir/grazoprevir for GT 1a infection; or b) Daclatasvir + sofosbuvir for GT 3 infection?	**Yes**: Go to #10	**No:** Go to #11
10. Has the patient had a baseline NS5a resistance test that documents a resistant variant to one of the agents in #16? Note: Baseline NS5A resistance testing is required.	**Yes:** Pass to RPh; deny for appropriateness	**No:** Go to #11 Document test and result.
11. Does the prescribed regimen include a NS3/4a protease inhibitor (elbasvir, glecaprevir, simeprevir, paritaprevir, voxilaprevir)?	**Yes:** Go to #12	**No:** Go to #13
12. Does the patient have moderate-severe hepatic impairment (Child-Pugh B or Child-Pugh C)?	**Yes:** Pass to RPh; deny for appropriateness	**No:** Go to #13
13. Is the prescribed regimen for the retreatment after failure of a DAA due to noncompliance or loss of follow-up?	**Yes:** Pass to RPh; Deny and refer to medical director for review	**No:** Go to #14

Approval Criteria		
14. 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**)? Note: Safety and efficacy of DAAs for children < 3 years of age have not been established Pediatric dosing available in **Table 3** and **Table 4**	**Yes:** Approve for 8-16 weeks based on duration of treatment indicated for approved regimen	**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 PEG/RBV	Non-cirrhotic or compensated cirrhosis	SOF/VEL x 12 weeks G/P x 8 weeks
	Compensated cirrhosis	G/P x 8 weeks SOF/VEL x 12 weeks (baseline resistance testing recommended for GT3)
	Decompensated Cirrhosis	SOF/VEL + RBV x 12 weeks SOF/VEL x 24 weeks (if ribavirin ineligible*)
Treatment Experienced (Genotype 1-6)		
Sofosbuvir based regimen treatment failures, including: **Sofosbuvir + ribavirin** **Ledipasvir/sofosbuvir** **Velpatasvir/sofosbuvir**	Non-cirrhotic or compensated cirrhosis	SOF/VEL/VOX x12 weeks 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 SOF/VEL/VOX x 12 weeks (plus RBV if compensated cirrhosis)
Multiple DAA Treatment Failures, including: **sofosbuvir/velpatasvir/voxilaprevir** **glecaprevir/pibrentasvir + sofosbuvir**	Non-cirrhotic or compensated cirrhosis	G/P + SOF + RBV x 16-24 weeks SOF/VEL/VOX x 24 weeks

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

*** Ribavirin ineligible/intolerance may include : 1) neutrophils < 750 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 PEG/RBV	Non-cirrhotic or compensated cirrhosis	SOF/VEL x 12 weeks G/P x 8 weeks
	Decompensated Cirrhosis	SOF/VEL + RBV x 12 week
Treatment Experienced with DAA regimen		
Note: Efficacy and safety extremely limited in treatment experienced to other DAAs in this population. Can consider recommended treatment regimens in adults if FDA approved for pediatric use. Recommend consulting with hepatologist.		
Abbreviations: DAA = direct acting antiviral; G/P = glecaprevir and pibrentasvir; RBV = ribavirin; SOF = sofosbuvir; SOF/VEL = sofosbuvir/velpatasvir • **All regimens containing a protease inhibitor (elbasvir, glecaprevir, simeprevir, paritaprevir, voxilaprevir) should not be used in patients with moderate to severe hepatic impairment (CTP B and C).** • **There is limited data supporting DAA regimens in treatment- experienced patients with decompensated cirrhosis. These patients should be handled on a case by case basis with the patient, prescriber, and CCO or FFS medical director.**		

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

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

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

Body weight	Dosing of sofosbuvir/velpatasvir
Less than 20 kg	Three 50mg/20 mg pellet packets once daily
20 kg to less than 30 kg	Four 50 mg/20 mg pellet packets once daily
30 kg to less than 45 kg	Five 50 mg/20 mg pellet packets once daily
45 kg and greater OR 12 years of age and older	Three 100mg/40 mg tablets once daily

P&T Review: *10/21 (MH); 6/20; 9/19 (MH); 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: *1/1/2022; 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 Hepatitis B antivirals

Covered Alternatives:

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

Pediatric Age Restrictions:

- lamivudine (Epivir HBV) – 2-17 years
- adefovir dipivoxil (Hepsera) – 12 years and up
- entecavir (Baraclude) – 2 years and up
- telbivudine (Tyzeka) –16 years and up
- tenofovir disoproxil fumarate (Viread) – 12 years and up
- tenofovir alafenamide (Vemlidy) – safety and effectiveness not established in pediatrics

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code	
2. Is the diagnosis an OHP-funded diagnosis?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP
3. Is the request for an antiviral for the treatment of HIV/AIDS?	**Yes:** Approve for up to 12 months	**No:** Go to #4
4. Is the request for treatment of chronic Hepatitis B?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
5. 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. ***If request is for Pegasys, refer to PA criteria "Pegylated Interferon and Ribavirin."***	**Yes:** Go to Renewal Criteria	**No:** Go to #6
6. Has the client tried and is intolerant to, resistant to, or has a contraindication to the preferred products?	**Yes:** Document intolerance or contraindication. Approve requested treatment for 6 months with monthly quantity limit of 30-day supply.	**No:** Go to #7
7. 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? 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: *3/17(MH); 3/12*
Implementation: *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 physician 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 ≥12 years of age	300 mg subcutaneous injection every 2 weeks; may consider dosing every 4 weeks for patients who are well-controlled for > 6 months

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 Document labs	**No:** Pass to RPh. Deny; medical appropriateness
4. Is the diagnosis funded by OHP?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; not funded by the OHP.
5. Has the provider documented discussion with the patient of risks (including thrombotic events and/or anaphylaxis) versus benefits of therapy?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness. Notify provider of potential serious adverse effects of therapy. See notes below.
6. Is the request for a C1 esterase inhibitor or ecallantide?	**Yes:** Go to #7	**No:** Go to #8
7. Is the patient prescribed concurrent epinephrine or do they have epinephrine on hand?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness.
8. Is the medication intended to be administered by a non-healthcare professional (e.g., self-administered)?	**Yes:** Go to #9	**No:** Go to #10
9. Has the member received training on identification of an acute attack?	**Yes:** Go to #10	**No:** Pass to RPh. Deny; medical appropriateness.
10. Is the request for treatment of an acute hereditary angioedema attack?	**Yes:** Go to #13 Document attack severity if available	**No:** Go to #11

Approval Criteria		
11. Is the request for prophylactic use in a patient with a history of hereditary angioedema attacks?	**Yes:** Go to #12 Document baseline number of attacks in the last 6 months	**No:** Pass to RPh. Deny; medical appropriateness.
12. 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 #13	**No:** Pass to RPh. Deny; medical appropriateness.
13. Will the prescriber consider a change to a preferred product? Message: 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: Acute treatment: Approve based on standard FDA dosing for treatment of a single acute attack (see **Table 1**) 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**). 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**). 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 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.

Notes on adverse effects of treatment:

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.

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

Hydroxyprogesterone caproate

Goal(s):

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

Length of Authorization:

- 20 weeks to 6 months (criteria-specific)

Requires PA:

- Hydroxyprogesterone caproate injection(physician 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 diagnosis funded by OHP?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP
3. Is the drug formulation to be used for an FDA-approved indication? Message: Only Makena and its generics are approved for prevention of preterm birth	**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? 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.	**No**: Go to #5

Approval Criteria		
5. Is the request for Delalutin® or its generic products?	**Yes:** Approve for 6 month	**No:** Go to #6
6. Is the request for Makena or its generics and is the patient between 16 weeks and 36 weeks 6 days gestation with a singleton pregnancy?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness
7. Has the patient had a prior history of preterm delivery before 37 weeks gestation (spontaneous preterm singleton birth)?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Is treatment being initiated at 16 weeks, 0 days and to 20 weeks, 6 days of gestation?	**Yes:** Approve up to but no more than20 doses Start date: Between 16 weeks, 0 days and 20 weeks, 6 days of gestation End date: week 37 of gestation or delivery, whichever occurs first	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: *3/19 (SS); 1/17 (SS); 5/13*
Implementation: *5/1/19; 4/1/17, 1/1/14*

Inebilizumab-cdon (Uplizna™)

Goal(s):

- Restrict use to OHP funded conditions and according to OHP guidelines for use.
- Promote use that is consistent with national clinical practice guidelines and medical evidence.

Length of Authorization:

- Up to 12 months

Requires PA:

- Uplizna™ (Inebilizumab-cdon)(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 the diagnosis funded by OHP?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; not funded by the OHP.
3. Is this request for continuation of therapy?	**Yes:** Go to **Renewal Criteria**	**No:** Go to # 4
4. Is the request for Neuromyelitis Optica Spectrum Disorder (NMOSD) in an adult who is anti-aquaporin-4 (AQP4) antibody positive?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Has the patient been screened for Hepatitis B and tuberculosis infection?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Does the patient have active Hepatitis B or untreated latent tuberculosis?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Approve for 12 months

Renewal Criteria		
1. Is there objective documentation of treatment benefit from baseline? Appropriate measures will vary by indication (e.g., hemoglobin stabilization, decreased transfusions, symptom improvement, functional improvement, etc.).	**Yes:** Approve for 12 months Document baseline assessment and physician attestation received.	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 4/21 (DM) Implementation: 5/1/2

Inhaled Corticosteroids (ICS)

Goals:
- To optimize the safe and effective use of ICS therapy in patients with asthma and COPD.
- Step-therapy required prior to coverage for non-preferred ICS products:
  - Asthma: inhaled short-acting beta-agonist.
  - COPD: short-acting and long-acting bronchodilators (inhaled anticholinergics and beta-agonists). Preferred short-acting and long-acting bronchodilators do NOT require prior authorization. See preferred drug list options at http://www.orpdl.org/drugs/.

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? Message: 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 #7	**No:** Go to #4

Approval Criteria		
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. Need a supporting diagnosis. If prescriber believes diagnosis is appropriate, inform prescriber of the appeals process for Medical Director Review. Chronic bronchitis is unfunded.
5. Does the patient have an active prescription for an on-demand short-acting bronchodilator (anticholinergic or beta-agonist)?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness.
6. 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.
7. 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: *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. Is this an OHP-funded diagnosis?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP
3. Will the prescriber consider a change to a preferred product? Message: Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee	**Yes:** Inform prescriber of covered alternatives	**No:** Go to #4
4. Is the request for an insulin pen or cartridge?	**Yes:** Go to #5	**No:** Approve for up to 12 months
5. Has the patient tried and failed or have contraindications to any of the preferred pens or cartridges listed above?	**Yes:** Go to #6	**No:** Pass to RPh; deny and recommend a trial of one of the preferred insulin products

Approval Criteria		
6. Will the insulin be administered by the patient or a non-professional caregiver **AND** do any of the following criteria apply: • The patient has physical dexterity problems/vision impairment • The patient is unable to comprehend basic administration instructions • The patient has a history of dosing errors with use of vials • 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: *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. 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.

Length of Authorization:
- 30 days to 6 months

Requires PA:
- Preferred intranasal corticosteroids without prior claims evidence of asthma
- Non-preferred intranasal corticosteroids
- Intranasal antihistamines
- Intranasal 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 second generation antihistamines, and first generation antihistamines DO NOT require prior authorization.

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code	
2. Is the prescribed drug an intranasal corticosteroid?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP
3. Is the prescribed drug a preferred product?	**Yes:** Go to #5	**No:** Go to #4
4. Will the prescriber consider switching to a preferred product? Note: Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee.	**Yes:** Inform prescriber of preferred alternatives. Go to #5	**No:** Go to #5

Approval Criteria		
5. Does patient have co-morbid conditions funded by the OHP? • Chronic Sinusitis (J320-J329) • Acute Sinusitis (J0100; J0110; J0120; J0130; J0140; J0190) • Sleep Apnea (G4730; G4731; G4733; G4739)	**Yes:** Document ICD10 code(s) and approve for up to 6 months for chronic sinusitis or sleep apnea and approve for no more than 30 days for acute sinusitis	**No:** Go to #6
6. Is there a diagnosis of asthma or reactive airway disease in the past 1 year (J4520-J4522; J45901-45998)?	**Yes:** Go to #7	**No:** Go to #8
7. Is there a claim for an *orally* inhaled corticosteroid in the past 90 days? 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
8. RPh only: Is the diagnosis funded by the OHP?	**Funded:** Deny; medical appropriateness. (eg, COPD; Obstructive Chronic Bronchitis; or other Chronic Bronchitis [J449; J40; J410-418; J42; J440-449] Use clinical judgment to APPROVE for 1 month starting today to allow time for appeal. 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. (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: *11/15 (AG); 7/15; 9/08; 2/06; 9/04; 5/04; 5/02*
Implementation: *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? *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)? *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.
- Step-therapy required prior to coverage of non-preferred LABA products:
  - Asthma: inhaled corticosteroid and short-acting beta-agonist.
  - COPD: inhaled short-acting bronchodilator.

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? Message: • 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 #6	**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. Need a supporting diagnosis. If prescriber believes diagnosis is appropriate, inform prescriber of the appeals process for Medical Director Review. Chronic bronchitis is unfunded

Approval Criteria		
5. Does the patient have an active prescription for an on-demand short-acting bronchodilator (anticholinergic or beta-agonist)?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness.
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:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness
7. 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

P&T/DUR Review: *10/20 (KS), 5/19 (KS); 1/18; 9/16; 9/15); 5/12; 9/09; 5/09*
Implementation: *3/1/18; 10/9/15; 8/12; 1/10*

Long-acting Beta-agonist/Corticosteroid Combination (LABA/ICS)

Goals:
- To optimize the safe and effective use of LABA/ICS therapy in patients with asthma and COPD.
- Step-therapy required prior to coverage:
  - Asthma: short-acting beta-agonist and inhaled corticosteroid or moderate to severe persistent asthma.
  - COPD: short-acting bronchodilator and previous trial of a long-acting bronchodilator (inhaled anticholinergic or beta-agonist). Preferred LABA/ICS products do NOT require prior authorization.

Length of Authorization:
- Up to 12 months

Requires PA:
- Non-preferred 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 provider consider a change to a preferred product? Message: • Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics (P&T) Committee.	**Yes:** Inform provider 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 #7	**No:** Go to #4

Approval Criteria		
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. Need a supporting diagnosis. If prescriber believes diagnosis is appropriate, inform prescriber of the appeals process for Medical Director Review. Chronic bronchitis is unfunded.
5. Does the patient have an active prescription for an on-demand short-acting bronchodilator (anticholinergic or beta-agonist)?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness.
6. Is there a documented trial of an inhaled long-acting bronchodilator (anticholinergic or beta-agonist)?	**Yes:** Approve for up to 12 months. Stop coverage of all other LABA and ICS inhalers.	**No:** Pass to RPh. Deny; medical appropriateness.
7. 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:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Is there a documented trial of an inhaled corticosteroid (ICS) or does the patient have moderate or severe persistent asthma?	**Yes:** Approve for up to 12 months. Stop coverage of all other ICS and LABA inhalers.	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: *10/20 (KS), 5/19 (KS); 1/18; 9/16; 11/15; 9/15; 11/14; 11/13; 5/12; 9/09; 2/06*

Implementation: *3/1/18; 10/13/16; 1/1/16; 1/15; 1/14; 9/12; 1/10*

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 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? Message: • 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 #9	**No:** Go to #4

Approval Criteria		
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. Need a supporting diagnosis. If prescriber believes diagnosis is appropriate, inform prescriber of the appeals process for Medical Director Review. Chronic bronchitis is unfunded.
5. Does the patient have an active prescription for an on-demand short-acting bronchodilator (anticholinergic or beta-agonist)?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness.
6. Is the request for a LAMA/LABA combination product?	**Yes:** Go to #7	**No:** Go to #8
7. Is there a documented trial of a LAMA or LABA, or alternatively a trial of a fixed dose combination short-acting anticholinergic with beta-agonist (SAMA/SABA) (i.e., ipratropium/albuterol), or ≥ 2 moderate exacerbations or ≥ 1 leading to a hospitalization?	**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:** Pass to RPh. Deny; medical appropriateness.
8. 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:** Approve for up to 12 months. Stop coverage of all other LAMA, LABA and ICS inhalers.	**No:** Pass to RPh. Deny; medical appropriateness.
9. 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 #10	**No:** Pass to RPh. Deny; medical appropriateness.
10. 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.	**No:** Pass to RPh. Deny; medical appropriateness.

Lidocaine Patch

Goal(s):
- Provide coverage only for funded diagnoses that are supported by the medical literature.

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 an OHP-funded diagnosis with evidence supporting its use in that condition (refer to Table 1 for examples).	**Yes:** Go to # 3	**No:** Pass to RPh. Deny; not funded by the OHP
3. Is this a request for renewal of a previously approved prior authorization for lidocaine patch?	**Yes**: Go to **Renewal Criteria**	**No**: Go to # 4
4. 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	

Lofexidine

Goal(s):
- Encourage use of substance use disorder medications on the Preferred Drug List.
- Restrict use of lofexidine under this PA to ensure medically appropriate use of lofexidine based on FDA-approved indications.

Length of Authorization:
- Up to 14 days

Requires PA:
- Lofexidine 0.18mg 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 this an FDA approved indication? (Mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults)	**Yes**: Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Will the prescriber consider a change to a preferred product? Message: • 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 14 days of total therapy. Note: FDA approved indication is for up to 14 days of therapy AND Notify prescriber concomitant naloxone is recommended if not present in claims history.

P&T/DUR Review: 12/20 (DM); 11/19; 1/19
Implementation: 3/1/19

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 (Seroquel® and Seroquel XR®)

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

Requires PA:
- Quetiapine (HSN = 14015) doses ≤50 mg/day
- Auto PA approvals for :
  - 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

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

Table 1. Adult (age ≥18 years) FDA-approved Indications for Quetiapine

Bipolar Disorder	
Major Depressive Disorder (MDD)	Adjunctive therapy with antidepressants for MDD
Schizophrenia	
Bipolar Mania	
Bipolar Depression	

Table 2. Pediatric FDA-approved indications

Schizophrenia	Adolescents (13-17 years)	
Bipolar Mania	Children and Adolescents (10 to 17 years)	Monotherapy

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code. Do not proceed and deny if diagnosis is not listed in Table 1 or Table 2 above (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 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: • low dose needed due to debilitation from a medical condition or age; • unable to tolerate higher doses; • stable on current dose; or • impaired drug clearance? • any diagnosis in table 1 or 2 above?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny for medical appropriateness. Note: may approve up to 6 months to allow taper.

P&T/DUR Review: *4/21 (SF); 8/20; 3/19; 9/18; 11/17; 9/15; 9/10; 5/10*
Implementation: *1/1/18; 10/15; 1/1/11*

Milnacipran

Goal(s):

- Provide coverage only for funded diagnoses that are supported by the medical literature.

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. 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.		

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

Monoclonal Antibodies for Severe Asthma

Goal(s):

- Restrict use of monoclonal antibodies to patients with severe asthma requiring chronic systemic corticosteroid use or with history of asthma exacerbations in the past year that required an Emergency Department visit or hospitalization.
- Restrict use for conditions not funded by the OHP (e.g., chronic urticaria).

Length of Authorization:

- Up to 12 months

Requires PA:

- Biologic drugs with indications for asthma (see **Table 2** below) (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. 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
Aerospan (flunisolide)	320 mcg BID
Arnuity Ellipta (fluticasone furoate)	200 mcg daily
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 RespiClick (fluticasone/salmeterol)	464/28 mcg BID
Breo Ellipta (fluticasone/vilanterol)	200/25 mcg daily
Dulera (mometasone/formoterol)	400/10 mcg BID

Table 2. FDA-approved indications and ages

Drug	**Eosinophilic Asthma**	**Moderate to Severe Persistent Asthma**	**Hypereosinophilic Syndrome (HES)**	**Eosinophilic Granulomatosis with Polyangiitis (EGPA)**	**Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)**	**Atopic Dermatitis (AD)**
Dupilumab	≥6 years (or with oral corticosteroid dependent asthma)				≥18 years	≥6 years
Benralizumab	≥12 years					
Reslizumab	≥18 years					
Mepolizumab	≥6 years		≥ 12 years	≥18 years	≥18 years	
Omalizumab		≥6 years			≥18 years	

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the diagnosis an OHP-funded diagnosis? Note: chronic idiopathic urticaria is not an OHP-funded condition	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP.
3. Is the request for an FDA-approved indication and age (**Table 2**)?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness.
4. Is the request for continuation of therapy?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #5
5. 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 #6	**No:** Pass to RPh. Deny; medical appropriateness.
6. Is the diagnosis Severe Atopic Dermatitis (AD)?	**Yes:** Go to #7	**No:** Go to #9
7. Is the medication being prescribed by or in consultation with a dermatologist or a provider who specializes in care of atopic dermatitis?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
8. Does the patient have a documented contraindication or failed trial of the following treatments: • Moderate to high potency topical corticosteroid (e.g., clobetasol, desoximetasone, desonide, mometasone, betamethasone, halobetasol, fluticasone, or fluocinonide) AND • Topical calcineurin inhibitor (tacrolimus, pimecrolimus) or topical phosphodiesterase (PDE)-4 inhibitor (crisaborole) AND • Oral immunomodulator therapy (cyclosporine, methotrexate, azathioprine, mycophenolate mofetil, or oral corticosteroids)?	**Yes**: Document drug and dates trialed and intolerances (if applicable): 1._____(dates) 2._____(dates) 3._____(dates) Approve for length of treatment; maximum 6 months.	**No**: Pass to RPh. Deny; medical appropriateness
9. Is the request for eosinophilic granulomatosis with polyangiitis (EGPA, formerly known as Churg-Strauss Syndrome) for at least 6 months that is refractory to at least 4 weeks of oral corticosteroid therapy (equivalent to oral prednisone or prednisolone 7.5 to 50 mg per day)?	**Yes:** Approve for 12 months. Mepolizumab dose: 300 mg (3 x 100mg syringes) every 4 weeks	**No:** Go to #10
10. Is the request for the treatment of a patient with hypereosinophilic syndrome (HES) with a duration of 6 months or greater without an identifiable non-hematologic secondary cause?	**Yes:** Approve for 12 months. Mepolizumab dose: 300 mg (3 x 100mg syringes) every 4 weeks	**No:** Go to #11
11. Is the request for treatment of nasal polyps?	**Yes:** Go to # 12	**No:** Go to #14
12. Is the prescriber an otolaryngologist, or allergist who specializes in treatment of chronic rhinosinusitis with nasal polyps?	**Yes:** Go to # 13	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
13. Has the patient failed medical therapy with intranasal corticosteroids (2 or more courses administered for 12 to 26 weeks[1])?	**Yes:** Approve for 6 months	**No:** Pass to RPh. Deny; medical appropriateness
14. Is the prescriber a pulmonologist or an allergist who specializes in management of severe asthma?	**Yes:** Go to #15	**No:** Pass to RPh. Deny; medical appropriateness.
15. Has the patient required at least 1 hospitalization or ≥ 2 ED visits in the past 12 months while receiving a maximally-dosed inhaled corticosteroid (Table 1) AND 2 additional controller drugs (i.e., long-acting inhaled beta-agonist, montelukast, zafirlukast, tiotropium)?	**Yes:** Go to #16 Document number of hospitalizations or ED visits in past 12 months: _____. This is the baseline value to compare to in renewal criteria.	**No:** Pass to RPh. Deny; medical appropriateness.
16. Has the patient been adherent to current asthma therapy in the past 12 months?	**Yes:** Go to #17	**No:** Pass to RPh. Deny; medical appropriateness.
17. Is the patient currently receiving another monoclonal antibody for asthma (e.g., dupilumab, omalizumab, mepolizumab, benralizumab or reslizumab)?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #18
18. If the claim is for omalizumab, can the prescriber provide documentation of allergic IgE-mediated asthma diagnosis, confirmed by a positive skin test or in vitro reactivity to perennial allergen?	**Yes:** Approve once every 2-4 weeks for up to 12 months. Document test and result:_____	**No:** Go to #19
19. If the request is for asthma with an eosinophilic phenotype, can the prescriber provide documentation of severe eosinophilic asthma, confirmed by blood eosinophil count ≥300 cells/μL in the past 12 months?	**Yes:** Approve once every 4 to 8 weeks for up to 12 months. Note: Initial benralizumab dose is 30 mg every 4 weeks x 3 doses followed by 30 mg every 8 weeks Document eosinophil count (date):_____	**No:** Pass to RPh. Deny; medical appropriateness.

Renewal Criteria		
1. Is the request to renew therapy for EGPA, nasal polyps, or HES?	**Yes:** Go to #2	**No:** Go to #3
2. Have the patient's symptoms improved with therapy?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness.
3. Is the request to renew therapy for atopic dermatitis?	**Yes:** Go to #4	**No:** Go to #5
4. Have the patient's symptoms improved with dupilumab therapy? • at least a 50% reduction in the Eczema Area and Severity Index score (EASI 50) from when treatment started OR • at least a 4-point reduction in the Dermatology Life Quality Index (DLQI) from when treatment started OR • 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.
5. Is the patient currently taking an inhaled corticosteroid and 2 additional controller drugs (i.e., long-acting inhaled beta-agonist, montelukast, zafirlukast, theophylline)?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness.
6. Has the number of 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?	**Yes:** Approve for up to 12 months.	**No:** Pass to RPh. Deny; medical appropriateness.

1. Chong LY, Head K, Hopkins C, Philpott C, Burton MJ, Schilder AG. Different types of intranasal steroids for chronic rhinosinusitis. *Cochrane Database Syst Rev.* 2016; 4:Cd011993.

P&T Review: *8/21 (DM); 10/20 (KS),7/19; 7/18; 7/16*
Implementation: *1/1/22; 9/1/21; 8/19/19, 8/15/18, 8/16*

Oral Multiple Sclerosis 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 6 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: • Mercaptopurine, azathioprine, or budesonide; or • Have a documented intolerance or contraindication these conventional therapies? AND • 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? Message: • 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 #11	**No:** Go to #14
11. Is the patient of childbearing potential?	**Yes:** Go to #12	**No:** Approve for up to 6 months.
12. Is the patient pregnant or actively trying to conceive?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #13
13. 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 #14	**No:** Pass to RPh. Deny; medical appropriateness.
14. Is the prescription for a sphingosine 1-phosphate receptor modulator (Table 1)?	**Yes:** Go to #15	**No:** Go to #18
15. Does the patient have evidence of macular edema?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #16

Approval Criteria		
16. 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 #17	**No:** Go to #21
17. Has the patient had a cardiology consultation before initiation (see clinical notes)?	**Yes:** Go to #21	**No:** Pass to RPh. Deny; medical appropriateness.
18. Is the prescription for a fumarate product?	**Yes:** Go to # 19	**No:** Go to #20
19. Does patient have a baseline CBC with lymphocyte count greater than 500/µL?	**Yes:** Approve for up to 6 months.	**No:** Pass to RPh. Deny; medical appropriateness.
20. Is the request for cladribine?	**Yes:** Go to #21	**No:** Go to #24
21. Is the patient of child bearing potential?	**Yes:** Go to #22	**No:** Go to #24
22. Is the patient pregnant or actively trying to conceive?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #23
23. 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 #24	**No:** Pass to RPh. Deny; medical appropriateness.
24. Has the patient had an inadequate response to or they are unable to tolerate alternative MS (or alternative UC treatment if the request is for ozanimod) treatment?	**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 physician and physician attests to patient's improvement?	**Yes:** Approve for 12 months. 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		
Ozanimod*	X	X	X	X	X		
Ponesimod*	X	X	X	X	X		
Siponimod*	X	X	X	X	X	X	
Teriflunomide	X (box warning)	X (box warning)	X				
Cladribine	X (box warning)	X	X (WNL)		X		TB; HBV; HIV; HCV; MRI for PML
Abbreviations: HBV = hepatitis B; HCV = hepatitis C; HIV = human immunodeficiency 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).

P&T/DUR Review: *10/21 (DM); 8/21 (DM); 6/21 (DM); 8/20 (DM); 6/20; 11/17; 11/16; 9/15; 9/13; 5/13; 3/12*
Implementation: *1/1/2022, 9/1/20; 1/1/18; 1/1/17; 1/1/14; 6/21/2012*

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.

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 #3	**No:** Pass to RPh. Deny; not funded by the OHP

Approval Criteria		
3. Does the patient have a documented nutrient deficiency **OR** Does the patient have an increased nutritional need resulting from severe trauma (e.g., severe burn, major bone fracture, etc.) **OR** 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.) **OR** 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 (Tysabri®)

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®)

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 for medical appropriateness
3. Does the patient have a diagnosis of relapsing multiple sclerosis (CIS, RRMS, or SPMS)?	**Yes:** Go to #4	**No:** Go to #6
4. Has the patient failed trials for at least 2 drugs indicated for the treatment of RRMS?	**Yes:** Document drug and dates trialed: 1._____(dates) 2._____(dates) Go to #5	**No:** Pass to RPh. Deny; medical appropriateness.
5. Is the medication being prescribed by or in consultation with a neurologist?	**Yes:** Approve for 12 months	**No:** Pass to RPH; Deny for medical appropriateness.
6. Does the patient have Crohn's Disease?	**Yes:** Go to #7	No: Pass to RPH; Deny for medical appropriateness.
7. Has the patient been screened for latent or active tuberculosis and if positive, started tuberculosis treatment?	**Yes:** Go to #8	**No:** Pass to RPH; Deny for medical appropriateness.

Approval Criteria		
8. Has the patient failed to respond to at least one of the following conventional immunosuppressive therapies for ≥6 months: • Mercaptopurine, azathioprine, or budesonide; or • Have a documented intolerance or contraindication to conventional therapy? • AND • Has the patient tried and failed a 3 month trial of Humira?	**Yes:** Approve for up to 12 months. Document each therapy with dates. If applicable, document intolerance or contraindication(s).	**No:** Pass to RPh. Deny; medical appropriateness.

P&T / DUR Action: *10/21 (DM); 10/20; 11/17*
Implementation: *1/1/18*

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.

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 #4	**No:** Pass to RPh. Deny; not funded by the OHP.
4. Is baseline monitoring recommended for efficacy or safety and has the provider submitted documentation of recommended monitoring parameters?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness.
5. 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 #6

Approval Criteria

6. Pass to RPh. 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.

P&T / DUR Review: *7/18 (SS); 11/17; 11/15; 12/09*
Implementation: *8/15/18; 1/1/18; 1/1/16; 1/1/10*

Nusinersen

Goal(s):
- Approve nusinersen for funded OHP conditions supported by evidence of benefit (e.g. Spinal Muscular Atrophy)

Length of Authorization:
- Up to 8 months for initial approval and up to 12 months for renewal.

Requires PA:
- Nusinersen (billed as a pharmacy or physician 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 ICD-10 code. Go to #2	
2. Is this a request for continuation of therapy?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #3
3. Does the patient have type 1, 2 or 3 Spinal Muscular Atrophy documented by genetic testing and at least 2 copies of the SMN2 gene?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness.
4. Is the patient ventilator dependent (using at least 16 hours per day on at least 21 of the last 30 days)? Note: This assessment does not apply to patients who require ventilator assistance	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #5

Approval Criteria		
5. Is a baseline motor assessment available such as one of the following functional assessment tools: • Hammersmith Infant Neurological Examination (HINE-2) • Hammersmith Functional Motor Scale (HFSME) • Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) • Upper Limb Module (ULM) • 6-Minute Walk Test	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness.
6. Has the patient received onasemnogene abeparvovec (Zolgensma®)?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #7
7. Is the drug being prescribed by a pediatric neurologist or a provider with experience treating spinal muscular atrophy?	**Yes:** For initial approval, approve 5 doses over 8 months.	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Has the patient's motor function improved or stabilized in a meaningful manner from the baseline functional assessment?	**Yes:** Approve for 12 months	**No:** Pass to RPh; Deny; medical appropriateness.

P&T Review: *9/19 (DM); 7/17; 3/17*
Implementation: *11/1/19: 9/1/17; 5/17*

Nutritional Supplements (Oral Administration Only)

Goals:

- Restrict use to patients unable to take food orally in sufficient quantity to maintain adequate weight.
- Requires ANNUAL nutritional assessment for continued use.
  - Use restriction consistent with DMAP EP/IV rules at: www.oregon.gov/OHA/HSD/OHP/Pages/Policy-Home-EPIV.aspx

These products are NOT federally rebate-able; Oregon waives the rebate requirement for this class.

Note:

- Nutritional formulas, when administered enterally (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). However, the equipment do require a PA (i.e., pump).
- Providers can be referred to 800-642-8635 or 503-945-6821 for enteral equipment PAs
- 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

Note:

- Criteria is divided into: 1) Patients age 6 years or older
  2) Patients under 6 years of age

Not Covered:

- Supplements such as *acidophilis*, Chlorophyll, Coenzyme Q10 are not covered and should not be approved.

Requires PA:

- All supplemental nutrition products in HIC3 = C5C, C5F, C5G, C5U, C5B
  (nutritional bars, liquids, packets, powders, wafers such as Ensure, Ensure Plus, Nepro, Pediasure, Promod).

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/

Patients 6 years and older:
Document:

- Name of product being requested
- Physician name
- Quantity/Length of therapy being requested

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is product requested a supplement or herbal product without an FDA indication?	**Yes:** Pass to RPh. Deny; medical appropriateness)	**No:** Go to #3
3. Is the product to be administered by enteral tube feeding (e.g., G-tube)?	**Yes:** Go to #10	**No:** Go to #4
4. All indications need to be evaluated as to whether they are funded conditions under the OHP.	**Funded:** Go to #5	**Not Funded:** Pass to RPh. Deny; not funded by the OHP.
5. Is this request for continuation of therapy previously approved by the FFS program?	**Yes:** Go to #6	**No:** Go to #7
6. Has there been an annual assessment by a physician for continued use of nutritional supplementation? Document assessment date.	**Yes:** Approve up to 1 year	**No:** Request documentation of assessment. Without documentation, pass to RPh. Deny; medical appropriateness.
7. Patient must have a nutritional deficiency identified by one of the following: • Recent (within 1 year) Registered Dietician assessment indicating adequate intake is not obtainable through regular/liquefied or pureed foods (supplement cannot be approved for convenience of patient or caregiver); **OR** • Recent serum protein level <6 g/dL?	**Yes:** Go to #9	**No:** Go to #8

Approval Criteria		
8. Does the patient have a prolonged history (>1 year) of malnutrition and cachexia OR reside in a long-term care facility or nursing home? Document: • Residence • Current body weight • Ideal body weight	**Yes:** Go to #9	**No:** Request documentation. Without documentation, pass to RPh. Deny; medical appropriateness.
9. Does the patient have a recent unplanned weight loss of at least 10%, plus one of the following: • increased metabolic need resulting from severe trauma (e.g., severe burn, major bone fracture, etc.); **OR** • malabsorption (e.g., Crohn's Disease, Cystic Fibrosis, bowel resection/removal, Short Gut Syndrome, gastric bypass, hemodialysis, dysphagia, achalasia, etc.); **OR** • diagnosis that requires additional calories and/or protein intake (e.g., malignancy, AIDS, pulmonary insufficiency, MS, ALS, Parkinson's, Cerebral Palsy, Alzheimer's, etc.)?	**Yes:** Approve for up to 1 year	**No:** Request documentation. Without documentation, pass to RPh. Deny; medical appropriateness.
10. Is this request for continuation of therapy previously approved by the FFS program? • **Yes:** Approve for 1 month and reply: Nutritional formulas, when administered by enteral tube, are no longer available through the point-of-sale (POS) system. For future use, service providers should use the CMS form 1500 or the 837P electronic claim form and not bill through POS. A 1-month approval has been given to accommodate the transition. Go to: www.oregon.gov/OHA/HSD/OHP/Pages/Policy-Home-EPIV.aspx • **No:** Enter an Informational PA and reply: Nutritional formulas, when administered by enteral tube, are no longer available through the point-of-sale (POS) system. For future use, service providers should use the CMS form 1500 or the 837P electronic claim form and not bill through POS. When billed using a HCPCS code, enterally administered nutritional formulas do not require a prior authorization (PA). However, the equipment does require a PA. Providers can be referred to 800-642-8635 or 503-945-6821 for enteral equipment PAs. For complete information of how to file a claim, go to: www.oregon.gov/OHA/HSD/OHP/Pages/Policy-Home-EPIV.aspx		

Patients under 6 years of age

Document:

- Name of product requested
- Physician name
- Quantity/Length of therapy requested

Approval Criteria		
1. What diagnosis is being treated?	Record the ICD10 code	
2. Is the product to be administered by enteral tube feeding (e.g., G-tube)?	**Yes:** Go to #9	**No:** Go to #3
3. All indications need to be evaluated as to whether they are funded conditions under the OHP.	**Funded:** Go to #4	**Not Funded:** Pass to RPh. Deny; not funded by the OHP.
4. Is this request for continuation of therapy previously approved by the FFS program?	**Yes:** Go to #5	**No:** Go to #6
5. Has there been an annual assessment by a physician for continued use of nutritional supplementation? Document assessment date.	**Yes:** Approve up to 1 year	**No:** Request documentation. Without documentation, pass to RPh. Deny; medical appropriateness.
6. Is the diagnosis failure-to-thrive (FTT)?	**Yes:** Approve for up to 1 year	**No:** Go to #7
7. Does the patient have one of the following: • increased metabolic need resulting from severe trauma (e.g., severe burn, major bone fracture, etc.); **OR** • malabsorption (e.g., Crohn's Disease, Cystic Fibrosis, bowel resection/removal, Short Gut Syndrome, hemodialysis, dysphagia, achalasia, etc.); **OR** • diagnosis that requires additional calories and/or protein intake (e.g., malignancy, AIDS, pulmonary insufficiency, Cerebral Palsy, etc.)?	**Yes:** Approve for up to 1 year	**No:** Go to #8

8. Patient must have a nutritional deficiency identified by one of the following: • Recent (within 1 year) Registered Dietician assessment indicating adequate intake is not obtainable through regular/liquefied or pureed foods (supplement cannot be approved for convenience of patient or caregiver); **OR** • Recent serum protein level <6 g/dL?	**Yes:** Approve for up to 1 year	**No:** Request documentation. Without documentation, pass to RPh. Deny; medical appropriateness.

9. Is this request for continuation of therapy previously approved by the FFS program?

- **Yes:** Approve for 1 month and reply:
  Nutritional formulas, when administered by enteral tube, are no longer available through the point-of-sale (POS) system. For future use, service providers should use the CMS form 1500 or the 837P electronic claim form and not bill through POS. A 1-month approval has been given to accommodate the transition.

  Go to: www.oregon.gov/OHA/HSD/OHP/Pages/Policy-Home-EPIV.aspx

- **No:** Enter an Informational PA and reply: Nutritional formulas, when administered by enteral tube, are no longer available through the point-of-sale (POS) system. For future use, service providers should use the CMS form 1500 or the 837P electronic claim form and not bill through POS. When billed using a HCPCS code, enterally administered nutritional formulas do not require a prior authorization (PA). However, the equipment does require a PA. Providers can be referred to 800-642-8635 or 503-945-6821 for enteral equipment PAs.

  For complete information of how to file a claim, go to:
  www.oregon.gov/OHA/HSD/OHP/Pages/Policy-Home-EPIV.aspx

Note: ***Normal Serum Protein 6-8 g/dL***
Normal albumin range 3.5-5.5 g/dL

P&T Review: *11/14*
Implementation: *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: • without cirrhosis OR • 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 ALP:____ units/L 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: a. ALP <1.67-times the ULN; AND b. Decrease of ALP >15% from baseline: AND c. Normal total bilirubin level?	**Yes**: Document ALP and total bilirubin level go to # 2 ALP:_____ units/L 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 5 mg once daily for patients intolerant to 10 mg once daily 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*

Ocrelizumab (Ocrevus™)

Goal(s):

- Restrict use of ocrelizumab in patients with relapsing-remitting multiple sclerosis (RRMS) to those who have failed multiple drugs for the treatment of RRMS.
- Ensure appropriate baseline monitoring to minimize patient harm.

Length of Authorization:

- 6 to 12 months

Requires PA:

- Ocrevus™ (ocrelizumab) pharmacy or 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 the medication FDA-approved or compendia-supported for the requested indication?	**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 #4	**No:** Pass to RPh. Deny; not funded by the OHP.
4. Is this a request for continuation of therapy?	**Yes**: Go to **Renewal Criteria**	**No:** Go to #5
5. Is the patient an adult (age ≥18 years) diagnosed with relapsing multiple sclerosis?	**Yes:** Go to #6	**No:** Go to #7
6. Has the patient failed trials for at least 2 drugs indicated for the treatment of relapsing multiple sclerosis?	**Yes:** Document drug and dates trialed: 1._____(dates) 2._____(dates) Go to #7	**No:** Pass to RPh. Deny; medical appropriateness
7. Has the patient been screened for an active Hepatitis B infection?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
8. Is the drug prescribed by or in consultation with a neurologist who regularly treats multiple sclerosis?	**Yes**: Approve ocrelizumab 300 mg every 2 weeks x 2 doses followed by 600mg IV every 6 months for 12 months	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1.Has the patient's condition improved as assessed by the prescribing physician and physician attests to patient's improvement.	**Yes:** Approve for 12 months. Document baseline assessment and physician attestation received.	**No:** Pass to RPh; Deny; medical appropriateness.

P&T/DUR Review: *6/21(DM); 6/20; 11/17 (DM); 1/17*
Implementation: *7/1/20; 1/1/18; 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

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? Message: 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. • If funded and clinic provides supporting literature: Approve for 12 months, or for length of the prescription, whichever is less. • If not funded: Deny; not funded by the OHP.		

P&T / DUR Review: *8/20 (SS); 3/17*
Implementation: *TBD*

Ofatumumab (Kesimpta™)

Goal(s):

- Restrict drug use to patient populations in which the drug has been shown to be effective and safe.
- Ensure appropriate baseline monitoring to minimize patient harm.

Length of Authorization:

- 6 to 12 months

Requires PA:

- Kesimpta™ (ofatumumab) pharmacy or physician administered claims
- Requests for Arzerra™ 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 medication FDA-approved or compendia-supported for the requested indication?	**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 #4	**No:** Pass to RPh. Deny; not funded by the OHP.
4. Is this a request for continuation of therapy?	**Yes**: Go to **Renewal Criteria**	**No:** Go to #5
5. Is the patient an adult (age ≥18 years) diagnosed with relapsing multiple sclerosis?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Is the patient of childbearing potential?	**Yes:** Go to #7	**No:** Go to #9
7. Is the patient pregnant or actively trying to conceive?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #8
8. 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 # 9	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
9. Has the patient failed trials for at least 2 drugs indicated for the treatment of relapsing multiple sclerosis?	**Yes:** Document drug and dates trialed: 1._____(dates) 2._____(dates) Go to #10	**No:** Pass to RPh. Deny; medical appropriateness
10. Has the patient been screened for an active Hepatitis B infection?	**Yes:** Go to #11	**No:** Pass to RPh. Deny; medical appropriateness
11. Is the drug prescribed by or in consultation with a neurologist?	**Yes**: Approve ofatumumab 20 mg SC at week 0, 1 and 2 followed by 20 mg once monthly starting at week 4 for 6 months.	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Has the patient's condition improved as assessed by the prescribing physician and physician attests to patient's improvement?	**Yes:** Approve for 12 months. Document baseline assessment and physician attestation received.	**No:** Pass to RPh; Deny; medical appropriateness.

P&T/DUR Review: *6/21 (DM)*
Implementation: *7/1/2021*

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 #3	**No:** Pass to RPh. Deny; not funded by the OHP
3. Will the prescriber consider a change to a preferred product? Message: • Preferred products do not require PA. • 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 #4
4. Does the patient have clinically diagnosed hypertriglyceridemia with triglyceride levels ≥ 500 mg/dL?	**Yes:** Go to #5	**No:** Go to #6

Approval Criteria		
5. 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** 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).
6. Is the prescription for icosapent ethyl?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness.
7. 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 #8	**No:** Pass to RPh. Deny; medical appropriateness.
8. 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

Onasemnogene abeparvovec (Zolgensma®)

Goal(s):
- Ensure utilization of onasemnogene abeparvovec in appropriate SMA (spinal muscular atrophy) populations with demonstrated efficacy.

Length of Authorization:
- Once in a lifetime dose

Requires PA:
- Onasemnogene abeparvovec (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 diagnosis funded by OHP?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP.
4. Is the medication prescribed by or in consultation with a physician who specializes in treatment of spinal muscular atrophy such as pediatric neurologist?	**Yes:** Go to # 5	**No:** Pass to RPh. Deny; medical appropriateness
5. Is the patient less than 2 years of age?	**Yes:** Go to # 6	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
6. Has the Spinal Muscular Neuropathy (SMA) diagnosis been confirmed to document the Spinal Motor Neuron (SMN)1 gene is missing or not functional by genetic documentation of fewer than 4 copies of SMN2 AND at least one of the following: • Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13); OR • Compound heterozygous mutation of SMN1 gene (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 (allele 2)	**Yes:** Go to # 7	**No:** Pass to RPh. Deny; medical appropriateness
7. Does the patient have advanced SMA* (complete paralysis of the limbs, permanent ventilator dependence)? *Note FDA label states efficacy has not been established in these patients	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to # 8
8. Has baseline motor ability been documented via: • Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) OR • Assessment of motor function developmental milestones by physical therapist OR • Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score • Gross Motor Function Measure OR • Hammersmith Functional Motor Scale (HFMS) OR • Modified/Expanded Hammersmith Functional Motor Scale	**Yes:** Go to # 9	**No:** Pass to RPh. Deny; medical appropriateness
9. Has the child been screened for viral infection?	**Yes:** Go to # 10	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
10. Is the baseline adeno-associate virus vector (AAV) 9 antibody titer < 1:50? Note: Efficacy has not been established in this population and high anti-AAV9 antibody titers are expected to limit efficacy of therapy.	**Yes:** Go to # 11	**No:** Pass to RPh. Deny; medical appropriateness
11. Have the following labs been obtained: a.) a baseline platelet count AND b.) baseline liver function tests (AST, ALT, total bilirubin, and PT) AND c.) baseline troponin-I	**Yes:** Go to # 12	**No:** Pass to RPh. Deny; medical appropriateness
12. 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:** Go to # 13	**No:** Pass to RPh. Deny; medical appropriateness
13. Is the patient currently receiving nusinersen?	**Yes:** Go to # 14	**No:** Go to # 15
14. Are there plans to discontinue nusinersen?	**Yes:** Go to #15	**No:** Pass to RPh. Deny; medical appropriateness
15. Is there attestation that the patient and provider will comply with case management required by the Oregon Health Authority? Case management includes follow-up assessment to assess treatment success, monitoring, and adverse events.	**Yes:** Approve for one time infusion	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 9/19 (DM)
Implementation: 11/1/19

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 physician 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/

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 or 12 months, whichever is less.	**No:** Go to #3
3. Is the request for any continuation of therapy?	**Yes:** Approve for length of therapy or 12 months, whichever is less.	**No**: Go to #4
4. Is the diagnosis funded by OHP?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; not funded by the OHP.
5. Is the indication FDA-approved for the requested drug? 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**: Pass to RPh. Approve for length of therapy or 12 months, whichever is less.	**No:** Go to #6

Approval Criteria		
6. Is the indication recommended by National Comprehensive Cancer Network (NCCN) Guidelines® for the requested drug? 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:** Pass to RPh. Approve for length of therapy or 12 months, whichever is less.	**No:** Go to #7
7. Is there documentation based on chart notes that the patient is enrolled in a clinical trial to evaluate efficacy or safety of the requested drug?	**Yes:** Pass to RPh. Deny; medical appropriateness. Note: The Oregon Health Authority is statutorily unable to cover experimental or investigational therapies.	**No:** Go to #8
8. 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 #9	**No:** Pass to RPh. Deny; medical appropriateness.
9. All other diagnoses must be evaluated for evidence of clinical benefit. The prescriber must provide the following documentation: • medical literature or guidelines supporting use for the condition, • clinical chart notes documenting medical necessity, and • documented discussion with the patient about treatment goals, treatment prognosis and the side effects, and knowledge of the realistic expectations of treatment efficacy. 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 3/9/2022)
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
acalabrutinib	CALQUENCE
ado-trastuzumab emtansine	KADCYLA
afatinib dimaleate	GILOTRIF
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
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
capmatinib	TABRECTA
carfilzomib	KYPROLIS
cemiplimab-rwlc	LIBTAYO
ceritinib	ZYKADIA
cobimetinib fumarate	COTELLIC
copanlisib di-HCl	ALIQOPA

Generic Name	Brand Name
crizotinib	XALKORI
dabrafenib mesylate	TAFINLAR
dacomitinib	VIZIMPRO
daratumumab	DARZALEX
daratumumab/hyaluronidase-fihj	DARZALEX FASPRO
darolutamide	NUBEQA
decitabine and cedazuridine	INQOVI
degarelix acetate	FIRMAGON
dostarlimab-gxly	JEMPERLI
dinutuximab	UNITUXIN
durvalumab	IMFINZI
duvelisib	COPIKTRA
elotuzumab	EMPLICITI
enasidenib mesylate	IDHIFA
encorafenib	BRAFTOVI
enfortumab vedotin-ejfv	PADCEV
entrectinib	ROZLYTREK
enzalutamide	XTANDI
erdafitinib	BALVERSA
eribulin mesylate	HALAVEN
everolimus	AFINITOR
everolimus	AFINITOR DISPERZ
fam-trastuzumab deruxtecan-nxki	ENHERTU
fedratinib	INREBIC
gilteritinib	XOSPATA
glasdegib	DAURISMO
ibrutinib	IMBRUVICA
idecabtagene vicleucel	ABECMA
idelalisib	ZYDELIG
infigratinib	TRUSELTIQ
ingenol mebutate	PICATO
inotuzumab ozogamicin	BESPONSA
ipilimumab	YERVOY
Isatuximab	SARCLISA
ivosidenib	TIBSOVO
ixazomib citrate	NINLARO
larotrectinib	VITRAKVI
lenvatinib mesylate	LENVIMA
lisocabtagene maraleucel	BREYANZI
loncastuximab tesirine-lpyl	ZYNLONTA
lorlatinib	LORBRENA
lurbinectedin	ZEPZELCA

Generic Name	Brand Name
lutetium Lu 177 dotate	LUTATHERA
margetuximab-cmkb	MARGENZA
melphalan flufenamide	PEPAXTO
midostaurin	RYDAPT
mobecertinib	EXKIVITY
moxetumomab pasudotox-tdfk	LUMOXITI
naxitamab-gqgk	DANYELZA
necitumumab	PORTRAZZA
neratinib maleate	NERLYNX
niraparib tosylate	ZEJULA
nivolumab	OPDIVO
obinutuzumab	GAZYVA
ofatumumab	ARZERRA
olaparib	LYNPARZA
olaratumab	LARTRUVO
olatuzumab vedotin-piiq	POLIVY
omacetaxine mepesuccinate	SYNRIBO
osimertinib mesylate	TAGRISSO
palbociclib	IBRANCE
panobinostat lactate	FARYDAK
pazopanib HCl	VOTRIENT
pembrolizumab	KEYTRUDA
pemigatinib	PEMAZYRE
pertuzumab	PERJETA
pertuzumab/trastuzumab/hyaluronidase-zzxf	PHESGO
pexidartinib	TURALIO
polatuzumab vedotin-piiq	POLIVY
pomalidomide	POMALYST
ponatinib	ICLUSIG
pralatrexate	FOLOTYN
pralsetinib	GAVRETO
ramucirumab	CYRAMZA
regorafenib	STIVARGA
relugolix	ORGOVYZ
ribociclib succinate	KISQALI
ribociclib succinate/letrozole	KISQALI FEMARA CO-PACK
ripretinib	QINLOCK
romidepsin	ISTODAX
romidepsin	ROMIDEPSIN
ropeginterferon alfa-2b-njft	BESREMI
rucaparib camsylate	RUBRACA

Generic Name	Brand Name
ruxolitinib phosphate	JAKAFI
sacitizumab govitecan-hziy	TRODELVY
selinexor	XPOVIO
selpercatinib	RETEVMO
siltuximab	SYLVANT
sipuleucel-T/lactated ringers	PROVENGE
sirolimus albumin-bound nanoparticles	FYARRO
sonidegib phosphate	ODOMZO
sotorasib	LUMAKRAS
tafasitamab-cxix	MONJUVI
tagraxofusp-erzs	ELZONRIS
talazoparib	TALZENNA
talimogene laherparepvec	IMLYGIC
tazemetostat	TAZVERIK
tebentafusp-tebn	KIMMTRAK
tepotinib	TEPMETKO
tisagenlecleucel	KYMRIAH
tisotumab vedotin-tftv	TIVDAK
tivozanib	FOTIVDA
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
trifluridine/tipiracil HCl	LONSURF
trilaciclib	COSELA
tucatinib	TUKYSA
umbralisib	UKONIQ
vandetanib	VANDETANIB
vandetanib	CAPRELSA
vemurafenib	ZELBORAF
venetoclax	VENCLEXTA
venetoclax	VENCLEXTA STARTING PACK
vismodegib	ERIVEDGE
zanubrutinib	BRUKINSA
ziv-aflibercept	ZALTRAP

P&T/DUR Review: 6/2020 (JP)
Implementation: 10/1/20

Long-acting Opioid Analgesics

Goals:

- Restrict use of long-acting opioid analgesics to OHP-funded conditions with documented sustained improvement in pain and function and with routine monitoring for opioid misuse and abuse.
- Restrict use of long-acting opioid analgesics for conditions of the back and/or spine due to evidence of increased risk vs. benefit.
- 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 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:

- 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 ***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 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	2 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 request for a patient already established on any opioid treatment for >6 weeks (long-term, chronic treatment)?	**Yes**: Go to **Renewal Criteria**	**No**: Go to #3
3. Is the diagnosis funded by the OHP? 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 #4	**No:** Pass to RPh. Deny; not funded by the OHP. Note: Management of opioid dependence is funded by the OHP.
4. Is the requested medication a preferred agent?	**Yes:** Go to #6	**No:** Go to #5
5. Will the prescriber change to a preferred product? 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 #6
6. 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 #7
7. Is the prescription for pain associated with migraine or other type of headache? 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 #8

8. Does the total daily opioid dose exceed 90 MME (see Table 1)?	**Yes:** Pass to RPh. Deny; medical appropriateness. Note: Management of opioid dependence is funded by the OHP.	**No:** Go to #9
9. 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 #10	**No:** Pass to RPh. Deny; medical appropriateness
10. Is the patient concurrently on other short- or long-acting opioids (patients may receive a maximum of one opioid product regardless of formulation)? 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 Note: Management of opioid dependence is funded by the OHP.	**No:** Go to #11
11. Is the patient currently taking a benzodiazepine or other central nervous system (CNS) depressant? 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 #12
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. 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? Note: Pain control, quality of life, and function can be quickly assessed using the 3-item PEG scale. **	**Yes:** Go to #14 Document tool used and score vs. baseline: _____	**No:** Pass to RPh. Deny; medical appropriateness. Note: Management of opioid dependence is funded by the OHP.

14. 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. 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 there documentation indicating it is **unsafe** to initiate a taper at this time?	**Yes:** Go to #5 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? Note: Pain control, quality of life, and function can be quickly assessed using the 3-item PEG scale. **	**Yes:** Go to #9 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 dose compared to previously approved therapy or average dose in the past 6 weeks?	**Yes:** Go to #10	**No:** Go to #13
10. Does the prescription exceed quantity limits applied in Table 2 (if applicable)?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #11
11. Does the total cumulative daily opioid dose exceed 90 MME (see Table 1)?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #12
12. Is there documented rationale (e.g., new acute injury) to support the increase in dose?	**Yes:** Go to #13	**No:** Pass to RPh; deny; medical appropriateness
13. Does the patient have any of the following risk factors for overdose? a. Concomitant CNS depressants (benzodiazepines, muscle relaxants, sedating antipsychotics, etc) b. Total daily opioid dose > 90 MME or exceeding quantity limits in Table 2 c. Recent urine drug screen indicating illicit or non-prescribed opioids d. Concurrent short- and long-acting opioid use e. Diagnosis of opioid use disorder	**Yes:** Go to #14 Document number of risk factors	**No:** Go to #15
14. Has the member been prescribed or have access to naloxone?	**Yes:** Go to #15	**No:** Pass to RPh. Deny. Medical appropriateness
15. 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): Risk factors: >=3: 2 month 1-2: 4 months 0: 6 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.

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), 3/17; 11/16; 05/16*
Implementation: *5/1/21; 3/1/20; 10/1/19*

Short-acting Opioid Analgesics

Goals:
- Restrict use of short-acting opioid analgesics for acute conditions funded by the OHP.
- Promote use of preferred short-acting opioid analgesics.

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? Note: Currently, conditions such as fibromyalgia, TMJ, pelvic pain syndrome, neuropathy, and tension headache are not funded by the OHP.	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP. Note: Management of opioid dependence is funded by the OHP.
4. Is the requested medication a preferred agent?	**Yes:** Go to #6	**No:** Go to #5
5. Will the prescriber change to a preferred product? 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 #6
6. 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 #7
7. Is the prescription for a product containing codeine or tramadol in a patient less than 19 years of age? Note: Cold symptoms are not funded on the prioritized list	**Yes:** Deny for medical appropriateness	**No:** Go to #8
8. Is the prescription for a short-acting fentanyl product? 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 Note: Management of opioid dependence is funded by the OHP.	**No:** Go to #9

9. Is the opioid prescribed for pain related to migraine or other type of headache? 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. 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 #11	**No:** Pass to RPh. Deny; medical appropriateness.
11. Is the patient currently taking a benzodiazepine or other central nervous system (CNS) depressant? 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 #12
12. 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 #13	**No:** Pass to RPh. Deny; medical appropriateness
13. Is the opioid prescription for pain associated with a back or spine condition?	**Yes:** Go to #14	**No:** Approve for up to 30 days not to exceed 90 MME
14. 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 #15	**No:** Pass to RPh. Deny; medical appropriateness
15. 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 #16

16. 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 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? Note: Pain control, quality of life, and function can be quickly assessed using the 3-item PEG scale. *	**Yes:** Go to #9 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? a. Concomitant CNS depressants (benzodiazepines, muscle relaxants, sedating antipsychotics, etc) b. Total daily opioid dose > 90 MME c. Recent urine drug screen indicating illicit or non-prescribed opioids d. Concurrent short- and long-acting opioid use e. Diagnosis of opioid use disorder	**Yes:** Go to #13 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): Risk factors: >=3: 2 month 1-2: 4 months 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.
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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:

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Symptoms and Treatment of Opioid Withdrawal.
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 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/

Table 1. Indications for orphan drugs based on FDA labeling

Drug	Indication	Age	Dose	Recommended Monitoring
Avacopan (TAVNEOS)	Severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with glucocorticoids.	≥18 yrs	30 mg (three 10 mg capsules) twice daily, with food	Baseline Monitoring • Liver function tests ALT, AST, ALP, and total bilirubin • Hepatitis B (HBsAg and anti-HBc) Ongoing Monitoring • Liver function tests every 4 wks for 6 months, then as clinically indicated
Burosumab-twza (CRYSVITA)	X-linked hypophosphatemia (XLH) FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO)	XLH ≥ 6 mo TIO ≥ 2 yrs	Pediatric <18 yrs: Initial (administered SC every 2 wks): XLH • <10 kg: 1mg/kg • ≥10 mg: 0.8 mg/kg TIO • 0.4 mg/kg Max dose of 2 mg/kg (not to exceed 90 mg for XLH or 180 mg for TIO) Adult: XLH 1 mg/kg monthly (rounded to nearest 10 mg; max 90 mg) TIO: 0.5 mg/kg monthly initially (Max dose 2 mg/kg or 180mg every	Baseline and Ongoing Monitoring • Use of active vitamin D **analogues** or oral phosphate within prior week; concurrent use is contraindicated • Fasting serum phosphorous: do not administer if serum phosphorous is within or above normal range • Renal function: use is contraindicated in ESRD or with severe renal impairment (CrCl <30 mL/min for adults or eGFR <30 mL/min/1.73m^2 for pediatric patients) • 25-hydroxy vitamin D levels: supplementation with vitamin D (cholecalciferol or ergocalciferol)

			2 wks)	is recommended as needed. <u>Additional baseline monitoring for TIO only:</u> • Documentation that tumor cannot be located or is unresectable • Elevated FGF-23 levels • Documentation indicating concurrent treatment for the underlying tumor is not planned (i.e., surgical or radiation)
Belumosudil (REZUROCK)	Treatment of chronic graft-versus-host disease after failure of at least two prior lines of systemic therapy	≥ 12 yrs	200 mg orally once daily with food 200 mg twice daily when coadministered with strong CYP3A inducers or proton pump inhibitors	<u>Baseline & Ongoing Monitoring</u> • Total bilirubin, AST, ALT at least monthly • Pregnancy test (if childbearing potential)
Cerliponase alfa (BRINEURA)	To slow the loss of ambulation in symptomatic Batten Disease (late infantile neuronal ceroid lipofuscinosis type 2 or TPP1 deficiency)	3-17 yrs	300 mg every other week via intraventricular route	<u>Baseline Monitoring</u> • Enzymatic or genetic testing to confirm tripeptidyl peptidase 1 deficiency or CLN2 gene mutation • Baseline motor symptoms (e.g., ataxia, motor function, etc) • ECG in patients with a history of bradycardia, conduction disorders or structural heart disease <u>Ongoing Monitoring</u> • Disease stabilization or lack of decline in motor symptoms compared to natural history
Elapegademase-lvlr (REVCOVI)	adenosine deaminase severe combined immune deficiency (ADA-SCID)	N/A	Initial: 0.2mg/kg twice weekly; No max dose	<u>Baseline Monitoring</u> • CBC or platelet count <u>Ongoing Monitoring</u> • trough plasma ADA activity • trough erythrocyte dAXP levels (twice yearly) • total lymphocyte counts
Fosdenopterin (NULIBRY)	To reduce risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A	N/A	Dosed once daily; Preterm Neonate (Gestational Age <37 wks) Initial: 0.4mg/kg Month 1: 0.7 mg/kg Month 3: 0.9 mg/kg	Initiation of therapy is recommended with known or presumed MoCD Type A. Discontinue therapy if diagnosis is not confirmed with genetic testing.

			Term Neonate (Gestational Age ≥ 37 wks) Initial: 0.55 mg/kg Month 1: 0.75 mg/kg Month 3: 0.9 mg/kg Age ≥1 yr: 0.9 mg/kg	
Givosiran (GIVLAARI)	acute hepatic porphyria	≥ 18 yrs	2.5 mg/kg monthly	Baseline and ongoing monitoring • Liver function tests • Blood homocysteine levels-If homocysteine elevated, assess folate, vitamin B12, and vitamin B6
Lonafarnib (ZOKINVY)	To reduce risk of mortality in Hutchinson-Gilford Progeria Syndrome For treatment of processing-deficient Progeroid Laminopathies with either: ○ Heterozygous LMNA mutation with progerin-like protein accumulation ○ Homozygous or compound heterozygous ZMPSTE24 mutations	≥12 mo AND ≥0.39 m^2 BSA	• Initial 115 mg/m^2 twice daily • Increase to 150 mg/m^2 twice daily after 4 months Round all doses to nearest 25 mg	Baseline and ongoing monitoring • Contraindicated with strong or moderate CYP3A inducers, midazolam, lovastatin, simvastatin, or atorvastatin • Comprehensive metabolic panel • CBC • Ophthalmological evaluation • Blood pressure • Pregnancy test (if childbearing potential)
Lumasiran (OXLUMO)	Treatment of primary hyperoxaluria type 1 to lower urinary oxalate levels	N/A	**<10 kg** Loading: 6 mg/kg once/month for 3 doses Maintenance: 3 mg/kg once/month **10 kg to <20 kg** Loading: 6 mg/kg once/month for 3 doses Maintenance: 6 mg/kg once every 3 months **≥ 20 kg** Loading: 3 mg/kg once/month for 3 doses Maintenance: 3 mg/kg once every 3 months All maintenance dosing begins 1 month after	N/A

			last loading dose.	
Luspatercept (REBLOZYL)	Anemia (Hgb <11 g/dL) due to beta thalassemia in patients requiring regular red blood cell transfusions Anemia (Hgb <11 g/dL) due to myelodysplastic syndromes with ring sideroblasts or myelodysplastic/ myeloproliferative neoplasm with ring sideroblasts and thrombocytosis	≥ 18 yr	Initial: 1 mg/kg SC Max dose of 1.25 mg/kg every 3 wks for beta thalassemia Max dose of 1.75 mg/kg every 3 wks for myelodysplastic syndromes	<u>Baseline Monitoring/Documentation</u> • Number of red blood cell transfusions in the prior 2 months; minimum of 2 RBC units over the prior 8 wks in patients with myelodysplastic syndromes • Trial and failure of an erythropoiesis stimulating agent in patients with myelodysplastic syndromes • Hemoglobin level • Blood pressure <u>Ongoing Monitoring</u> • Discontinue if there is not a decrease in transfusion burden after 3 maximal doses (about 9-15 wks) • Hemoglobin level • Blood pressure
Maralixibat (LIVMARLI)	Cholestatic pruritis in patients with Alagille syndrome	≥ 1 yr	Initial: 190 mcg/kg once daily, 30 min before first meal of day Goal: 390 mcg/kg once daily after 1 week on initial dose, as tolerated	<u>Baseline/Ongoing Monitoring</u> • Liver function tests (ALT, AST, total bilirubin and direct bilirubin) • Fat soluble vitamins (A, D, E, K); INR used as surrogate for Vitamin K
Odevixibat (BYLVAY)	Pruritus in patients with progressive familial intrahepatic cholestasis (PFIC) Limitation of Use: may not be effective in PFIC type 2 in patients with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3)	≥ 3 mo	Initial: 40 mcg/kg once daily with morning meal Titration: After 3 months of initial dose, 40 mcg/kg increments Max dose: 120 mcg/kg once daily; not to exceed 6 mg	<u>Baseline/Ongoing Monitoring</u> • Liver function tests (ALT, AST, total bilirubin and direct bilirubin) • Fat soluble vitamins (A, D, E, K); INR used as surrogate for Vitamin K
Plasminogen, human-tvmh (RYPLAZIM)	Treatment of patients with plasminogen deficiency type 1 (hypoplasmino-genemia)	N/A	6.6 mg/kg body weight given IV every 2 to 4 days	<u>Baseline Monitoring</u> • Plasminogen activity level (allow 7 day washout if receiving with fresh frozen plasma) • CBC (bleeding)

				Ongoing Monitoring • Trough Plasminogen activity level 72 hours after initial dose and every 12 wks with ongoing therapy • CBC (bleeding)
Sutimlimab-jome (ENJAYMO)	Decrease need for RBC transfusion due to hemolysis in cold agglutinin disease (CAD)	≥ 18 yr	Dosed IV infusion weekly for two weeks, then every two weeks thereafter. **39 to <75 kg** 6500 mg **≥75 kg** 7500 mg	Baseline Monitoring • Vaccination against encapsulated bacteria (*Neisseria meningititides* (any serogroup), *Streptococcus pneumonia,* and *Haemophilus influenza*) at least prior to treatment or as soon as possible if urgent therapy needed

Abbreviations: ALP = alkaline phosphatase; ALT = alanine aminotransferase, AST = aspartate aminotransferase; BSA = body surface area; CBC = complete blood count; CrCL = creatinine clearance; ECG = electrocardiogram; eGFR = estimated glomerular filtration rate; ESRD = end stage renal disease; Hgb = hemoglobin; INR = international normalized ratio; IV = intravenously; mo = months; RBC = red blood cells; SC = subcutaneously; wks = weeks; yrs = years

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the diagnosis funded by OHP?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP.
3. Is the request for a drug FDA-approved for the indication, age, and dose as defined 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 baseline monitoring recommended for efficacy or safety (e.g., labs, baseline symptoms, etc) AND has the provider submitted documentation of recommended monitoring parameters?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness.
6. Is this medication therapy being prescribed by, or in consultation with, an appropriate medical specialist?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
7. Have other therapies been tried and failed?	**Yes:** Approve for up to 3 months (or length of treatment) whichever is less Document therapies which have been previously tried	**No:** Approve for up to 3 months (or length of treatment) whichever is less 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 Document provider attestation	**No:** Pass to RPh. Deny; medical appropriateness
3. Is baseline efficacy monitoring available?	**Yes:** Go to #4	**No:** Go to #5
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 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 Document benefit and provider attestation	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 4/22 (SF); 12/21 ; 10/21; 6/21; 2/21; 8/20; 6/20; 2/20
Implementation: 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 physician-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 for RSV prophylaxis to be administered during the typical high viral activity season from November through March?	**Yes:** Go to #5	**No:** Go to #4
4. Is the request for prophylaxis starting in October due to interseasonal increase in RSV activity with season onset designated by the OHA*? * 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 #5	**No:** Pass to RPh. Deny; medical appropriateness. Prophylaxis is indicated only during high viral activity.
5. Is the current age of the patient < 24 months at start of RSV season?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness. Not recommended for patients ≥24 months old.

Approval Criteria		
6. GROUP A 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: a. diuretics b. chronic corticosteroid therapy c. supplemental oxygen therapy	**Yes:** Go to #18	**No:** Go to #7
7. GROUP B Has the patient received a cardiac transplant during the RSV season?	**Yes:** Go to #18	**No:** Go to #8
8. GROUP C Is the child profoundly immunocompromised during the RSV season (i.e. solid organ transplant or hematopoietic stem cell transplantation)?	**Yes:** Go to #18	**No:** Go to #9
9. GROUP D Does the infant have cystic fibrosis and manifestations of severe lung disease or weight or length less than the 10th percentile?	**Yes:** Go to #18	**No:** Go to #10
10. GROUP E 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 #18	**No:** Go to #11
11. Will the patient be <12 months at start of RSV season?	**Yes:** Go to #12	**No:** Pass to RPh. Deny; medical appropriateness.
12. GROUP F Was the infant born before 29 weeks, 0 days gestation?	**Yes:** Go to #18	**No:** Go to #13

Approval Criteria		
13. GROUP G Does the infant have pulmonary abnormalities of the airway or neuromuscular disease compromising handling of secretions?	**Yes:** Go to #18	**No:** Go to #14
14. GROUP H 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: a. Acyanotic heart disease who are receiving treatment to control congestive heart failure and will require cardiac surgical procedures; OR b. Have moderate to severe pulmonary hypertension; OR c. History of lesions adequately corrected by surgery AND still requiring medication for congestive heart failure?	**Yes:** Go to #18	**No:** Go to #15
15. GROUP I 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 #18	**No:** Go to #16
16. GROUP J Does the patient have cyanotic heart defects and immunoprophylaxis is recommended?	**Yes:** Go to #18	**No:** Go to #17
17. GROUP K Does the patient have cystic fibrosis with clinical evidence of CLD and/or nutritional compromise?	**Yes:** Go to #18	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
18. 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. May approve for the following on a case-by-case basis: a. >5 doses; b. Prophylaxis for a second / subsequent RSV season	**No:** Go to #19
19. Has the patient had a weight taken within the last 30 days?	**Yes:** Document weight and date and go to #20 Weight:_____ Date:_____	**No:** Pass to RPh. Obtain recent weight so accurate dose can be calculated.
20. 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): Total number of doses approved for RSV season:_____ Number of doses received in the hospital:_____ 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 RSV Prophylaxis

MONTH OF BIRTH	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.

P&T/DUR Review: *2/22 (KS); 11/16 (DE); 9/14; 5/11; 5/12*
Implementation: *4/1/22; 1/1/17; 3/30/12*

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 Inhibitors

Goal(s):

- Promote use of PCSK9 inhibitors that is consistent with medical evidence
- Promote use of high value products

Length of Authorization:

- Up to 12 months

Requires PA:

- All PCSK9 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. 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) <u>Major ASCVD events</u> • Recent ACS (within past 12 months) • History of MI (other than recent ACS from above) • History of ischemic stroke • Symptomatic peripheral artery disease <u>High-Risk Conditions:</u> • Age ≥ 65 • Heterozygous familial hypercholesterolemia • History of prior CABG or PCI • Diabetes Mellitus • Hypertension • Chronic Kidney Disease • Current smoking • Persistently elevated LDL-C ≥ 100 despite maximally tolerated statin therapy and ezetimibe • History of congestive heart failure	**Yes:** Go to #4	**No:** Go to #7

Approval Criteria		
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? Prescriber to submit chart documentation of: 1) Doses and dates initiated of statin and ezetimibe; 2) Baseline LDL-C (untreated); 3) Recent LDL-C	**Yes:** Confirm documentation; go to #5 1. Statin: Dose: Date Initiated: 2. Ezetimibe 10 mg daily Date Initiated: Baseline LDL-C _____ mg/dL Date:_____ Recent LDL-C _____ mg/dL Date:_____	**No:** Go to #6
5. Is the patient adherent with a high-intensity statin and ezetimibe?	**Yes:** Approve for up to 12 months 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

Approval Criteria		
6. Does the patient have: • A history of rhabdomyolysis caused by a statin; or alternatively, • a history of creatinine kinase (CK) levels >10-times upper limit of normal with muscle symptoms determined to be caused by a statin; or • Intolerable statin-associated side effects that have been re-challenged with ≥ 2 statins 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 Recent LDL-C _____ mg/dL Date:_____	**No:** Pass to RPh; deny for medical appropriateness
7. Does the patient have a diagnosis of homozygous or heterozygous familial hypercholesterolemia? 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:** Approve for up to 12 months Recent LDL-C _____ mg/dL Date:_____	**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 Date:_____ ; go to #2

Renewal Criteria		
2. Is the patient adherent with PCSK9 inhibitor therapy?	**Yes:** Approve for up to 12 months Note: pharmacy profile may be reviewed to verify >80% adherence (PCSK9 inhibitor prescription refilled 10 months' supply in last 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 Rosuvastatin 20-40 mg	Atorvastatin 10-20 mg Fluvastatin 80 mg Lovastatin 40-80 mg	Pitavastatin 1-4 mg Pravastatin 40-80 mg Simvastatin 20-40 mg Rosuvastatin 5-10 mg

P&T / DUR Review: *8/21 (MH); 8/20; 5/19; 1/18; 11/16; 11/15*
Implementation: *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.

Initiative:
- PDL: Preferred Drug List

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/

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 an OHP-funded diagnosis?	**Yes**: Go to #4	**No**: Go to #5
4. Will the prescriber consider a change to a preferred product? 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.
5. RPh only: All other indications need to be evaluated as to whether they are a funded diagnosis on the OHP prioritized list. • If funded and clinic provides supporting literature: Approve until anticipated formal review by the P&T committee, for 6 months, or for length of the prescription, whichever is less. • If not funded: Deny; not funded by the OHP.		

P&T / DUR Review: *7/15 (RC), 9/10; 9/09; 5/09*
Implementation: *10/13/16; 8/25/15; 8/15; 1/1/11, 9/16/10*

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.

Initiative:

- PDL: Preferred Drug List

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/

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 an OHP-funded diagnosis?	**Yes**: Go to #4	**No**: Go to #5
4. Will the prescriber consider a change to a preferred product? 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.

Approval Criteria

5. RPh only: All other indications need to be evaluated for funding status on the OHP prioritized list
    - If funded and clinic provides supporting literature: Approve until anticipated formal review by the P&T committee, for 6 months, or for length of the prescription, whichever is less.
    - If not funded and patient is over 21 years of age: Deny; not funded by the OHP.
    - If not funded and patient is 21 year of age or less: Approve for 6 months, or for length of the prescription, whichever is less if treatment has or is expected to improve the patient's ability to grow, develop or participate in school.[1] If no documentation is provided: Deny; not funded by the OHP.

1. *Statement of intent 4:* https://www.oregon.gov/oha/HPA/DSI-HERC/SearchablePLdocuments//Prioritized-List-SOI-004.docx

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P&T / DUR Review: *4/22 (SS); 7/15 (RC), 9/10; 9/09; 5/09*
Implementation: *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:
- Initial: 12 months
- Renewal: Up to 12 months

Requires PA:
- Peanut (arachis hypogaea) allergen powder-dnfp (Palforzia) (both 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 the diagnosis funded by OHP? Line 123, Guideline note 203	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP.
3. Is the request by, or in consultation with, an allergist or immunologist?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP.
4. Is the request for continuation of current therapy?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #5
5. Is the request for an FDA-approved indication and age?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Does the patient have a history of serious peanut allergy or anaphylaxis?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; not funded by the OHP
7. 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 #8 Epi administrations:_____ Hospital/ED visits:_____	**No:** Pass to RPh. Deny; medical appropriateness
8. 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 #9

Approval Criteria		
9. 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 #10	**No:** Pass to RPh. Deny; not funded by the OHP
10. Does the patient have a peanut allergy confirmed with a double-blind, placebo-controlled food challenge?	**Yes:** Go to #11	**No:** Pass to RPh. Deny; not funded by the OHP
11. 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 #12
12. 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; 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: • Absence of, or reduction in the number of needed epinephrine administrations due to presumed peanut exposure OR • Absence of, or reduction in the number of hospital/emergency department visits due to presumed peanut exposure	**Yes**: Approval for 12 months	**No:** Pass to RPh. Deny; medical appropriateness

Pegcetacoplan (Empaveli™)

Goal(s):

- Restrict use to OHP-funded conditions and according to OHP guidelines for use.
- Promote use that is consistent with national clinical practice guidelines and medical evidence.
- Pegcetacoplan is approved by the FDA for the following indication:
  - Treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH)

Length of Authorization:

- Up to 12 months

Requires PA:

- Empaveli™ (pegcetacoplan) 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 the diagnosis funded by OHP?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Is this request for continuation of therapy?	**Yes:** Go to **Renewal Criteria**	**No:** Go to # 4
4. Has the patient been vaccinated against *Streptococcus pneumoniae, Haemophilus influenzae* type B, and *Neisseria meningitidis serogroups A, C, W, and Y and serogroup B* according to current Advisory Committee on Immunization Practice (ACIP) recommendations for vaccination in patients with complement deficiencies? Note: Prescribing information recommends vaccination at least 2 weeks prior to starting therapy. If the risk of delaying therapy outweighs the risk of developing a serious infection, a 2 week course of antibiotic prophylaxis must be immediately initiated if vaccines are administered less than 2 weeks before starting complement therapy.	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
5. Is the diagnosis for an adult (age 18 years or older) with Paroxysmal Nocturnal Hemoglobinuria (PNH)?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Is there objective documentation of treatment benefit from baseline? Appropriate measures will vary by indication (e.g., hemoglobin stabilization, decreased transfusions, symptom improvement, functional improvement, etc.).	**Yes:** Approve for 12 months Document baseline assessment and physician attestation received.	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 12/21 (DM)
Implementation: 1/1/22

Peginterferon Beta-1a (Plegridy®)

Goal(s):

- Approve therapy for covered diagnosis that are supported by the medical literature.

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 request for an FDA-approved form of multiple sclerosis?	**Yes:** Go to #3.	**No:** Pass to RPH; Deny for medical appropriateness.
3. Will the prescriber consider a change to a Preferred MS product?	**Yes:** Inform provider of covered alternatives in the class.	**No:** Go to #4.
4. Is the medication being prescribed by or in consultation with a neurologist?	**Yes:** Go to #5.	**No:** Pass to RPH; Deny for medical appropriateness.
5. Does the patient have any of the following: • Adherence issues necessitating less frequent administration • Dexterity issues limiting ability to administer subcutaneous injections	**Yes:** Approve for up to one year.	**No:** Pass to RPH; Deny for medical appropriateness.

P&T / DUR Action: *6/21(DM); 8/20 (DM); 6/20; 11/17; 9/23/14*
Implementation: *10/15*

Pegylated Interferons and Ribavirins

Goal(s):

- Cover drugs only for those clients where there is medical evidence of effectiveness and safety

Length of Authorization:

- 16 weeks plus 12-36 additional weeks or 12 months

Requires PA:

- All drugs in HIC3 = W5G

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 peginterferon requested preferred?	**Yes:** Go to #4	**No:** Go to #2
2. Will the prescriber consider a change to a preferred product? Message: Preferred products are evidence-based reviewed for comparative effectiveness & safety Oregon Pharmacy and Therapeutics (P&T) Committee	**Yes:** Inform provider of covered alternatives in class.	**No:** Go to #3
3. If the request is for interferon alfacon-1, does the patient have a documented trial of a pegylated interferon?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Is the request for treatment of Chronic Hepatitis C? Document appropriate ICD10 code: (K739; K730; K732 or K738)	**Yes:** Go to #5	**No:** Go to #11
5. Is the request for continuation of therapy previously approved by the FFS program? (Patient has been on HCV treatment in the preceding 12 weeks according to the Rx profile)	**Yes:** Go to "Continuation of Therapy"	**No:** Go to #6

Approval Criteria		
6. Does the patient have a history of treatment with previous pegylated interferon-ribavirin combination treatment? Verify by reviewing member's Rx profile for PEG-Intron or Pegasys, PLUS ribavirin history. Does not include prior treatment with interferon monotherapy or non-pegylated interferon.	**Yes:** Forward to DMAP Medical Director	**No:** Go to #7
7. Does the patient have any of the following contraindications to the use of interferon-ribavirin therapy? • severe or uncontrolled psychiatric disorder • decompensated cirrhosis or hepatic • encephalopathy • hemoglobinopathy • untreated hyperthyroidism • severe renal impairment or transplant • autoimmune disease • pregnancy • unstable CVD	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #8
8. If applicable, has the patient been abstinent from IV drug use or alcohol abuse for ≥ 6 months?	**Yes:** Go to #9	**No:** Pass to RPh. Deny; medical appropriateness
9. Does the patient have a detectable HCV RNA (viral load) > 50IU/mL? Record HCV RNA and date.	**Yes:** Go to #10	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
10. Does the patient have a documented HCV Genotype? Record Genotype.	**Yes:** Approve for 16 weeks with the following response: Your request for has been approved for an initial 16 weeks. Subsequent approval is dependent on documentation of response via a repeat viral load demonstrating undetectable or 2-log reduction in HCV viral load. Please order a repeat viral load after 12 weeks submit lab results and relevant medical records with a new PA request for continuation therapy. Note: For ribavirin approve the generic only.	**No:** Pass to RPh. Deny; medical appropriateness
11. Is the request for Pegasys and the treatment for confirmed, compensated Chronic Hepatitis B?	**Yes:** Go to #11	**No:** Pass to RPh. Deny; medical appropriateness
12. Is the patient currently on LAMIVUDINE (EPIVIR HBV), ADEFOVIR (HEPSERA), ENTECAVIR (BARACLUDE), TELBIVUDINE (TYZEKA) and the request is for combination Pegasys-oral agent therapy?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #12
13. Has the member received previous treatment with pegylated interferon?	**Yes:** Pass to RPh. Deny; medical appropriateness Recommend: LAMIVUDINE (EPIVIR HBV) ADEFOVIR (HEPSERA)	**No:** Approve Pegasys #4 x 1mL vials or #4 x 0.5 mL syringes per month for 12 months (maximum per lifetime).

<table>
<tr><th colspan="4">Continuation of Therapy- HCV</th></tr>
<tr>
<td>1. Does the client have undetectable HCV RNA or at least a 2-log reduction (+/- one standard deviation) in HCV RNA measured at 12 weeks?</td>
<td colspan="2">Yes: Approve as follows:

Approval for beyond quantity and duration limits requires approval from the medical director.

<table>
<tr><th>Geno-type</th><th>Approve for:</th><th>Apply</th></tr>
<tr><td>1 or 4</td><td>An additional 36 weeks or for up to a total of 48 weeks of therapy (whichever is the lesser of the two).</td><td>Ribavirin quantity limit of 200 mg tablets QS# 180 / 25 days (for max daily dose =1200 mg).</td></tr>
<tr><td>2 or 3</td><td>An additional 12 weeks or for up to a total of 24 weeks of therapy (whichever is the lesser of the two).</td><td>Ribavirin quantity limit of 200 mg tab QS# 120 / 25 days (for max daily dose = 800 mg).</td></tr>
<tr><td>For all genotypes and HIV co-infection</td><td>An additional 36 weeks or for up to a total of 48 weeks of therapy (whichever is the lesser of the two)</td><td>Ribavirin quantity limit of 200 mg tablets QS# 180 / 25 days (for max daily dose = 1200 mg).</td></tr>
</table>
</td>
<td>No: Pass to RPh. Deny; medical appropriateness

Treatment with pegylated interferon-ribarvirin does not meet medical necessity criteria because there is poor chance of achieving an SVR.</td>
</tr>
</table>

Clinical Notes:

- Serum transaminases: Up to 40% of clients with chronic hepatitis C have normal serum alanine aminotransferase (ALT) levels, even when tested on multiple occasions.

- RNA: Most clients with chronic hepatitis C have levels of HCV RNA (viral load) between 100,000 (105) and 10,000,000 (107) copies per ml. Expressed as IU, these averages are 50,000 to 5 million IU. Rates of response to a course of peginterferon-ribavirin are higher in clients with low levels of HCV RNA. There are several definitions of a “low level” of HCV RNA, but the usual definition is below 800,000 IU (~ 2 million copies) per ml (5).

- Liver biopsy: Not necessary for diagnosis but helpful for grading the severity of disease and staging the degree of fibrosis and permanent architectural damage and for ruling out other causes of liver disease, such as alcoholic liver injury, nonalcoholic fatty liver disease, or iron overload.

Stage is indicative of fibrosis:			Grade is indicative of necrosis:	

Stage 0	No fibrosis			
Stage 1	Enlargement of the portal areas by fibrosis		Stage 1	None
Stage 2	Fibrosis extending out from the portal areas with rare bridges between portal areas		Stage 2	Mild
Stage 3	Fibrosis that link up portal and central areas of the liver		Stage 3	Moderate
Stage 4	Cirrhosis		Stage 4	Marked

The following are considered investigational and/or do not meet medical necessity criteria:

- Treatment of HBV or HCV in clinically decompensated cirrhosis
- Treatment of HCV or HBV in liver transplant recipients
- Treatment of HCV or HBV > 48 weeks
- Treatment of advanced renal cell carcinoma
- Treatment of thrombocytopenia
- Treatment of human papilloma virus
- Treatment of multiple myeloma

P&T Review: *2/12; 9/09; 9/05; 11/04; 5/04*
Implementation: *8/16, 5/14/12, 1/1/10, 5/22/08*

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 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. Is the diagnosis funded by OHP?	**Yes:** Go to #2	**No:** Pass to RPh. Deny; not funded by OHP
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
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

Approval Criteria		
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 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
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

Goal(s):
- Promote use of preferred drugs

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 #5
3. Has the patient tried or contraindicated to calcium acetate?	**Yes:** Document trial dates and/or intolerance. Go to #4	**No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of preferred calcium acetate product.
4. Will the prescriber consider a change to a preferred non-calcium-based phosphate binder?	**Yes:** Approve for 1 year and inform prescriber of preferred alternatives in class.	**No:** Approve for 1 year or length of prescription, whichever is less.
5. 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 non-funded, deny; not funded by the OHP.		

P&T Review: *8/21 (DM); 1/16 (AG); 11/12; 9/12; 9/10*
Implementation: *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 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: *8/20(SF); 3/19 (DM); 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. Is the diagnosis an OHP funded diagnosis?	**Yes:** Go to #3	**No:** Pass to RPh. Deny, not funded by the OHP.
3. Will the prescriber consider a change to a preferred product?	**Yes:** Inform provider of preferred alternatives.	**No:** Go to #4
4. 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 #5
5. 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 #6
6. Is the request for ticagrelor?	**Yes:** Go to #7	**No:** Got to #8
7. 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		
8. 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. 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° = prevention, 2° = 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

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 physician administered claims)
- Avalglucosidase alfa (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/

Table 1: FDA-approved Dosage and Administration

Agent	Indication	Age Minimum	Dosing Regimen
Alglucosidase alfa	Early Onset Pompe Disease (EOPD) Late Onset Pompe Disease (LOPD)	None	20 mg/kg IV once every 2 weeks
Avalglucosidase alfa	Late Onset Pompe Disease (LOPD)	≥ 1 year	< 30 kg: 40 mg/kg IV once every 2 weeks
			≥ 30 kg: 20 mg/kg IV once every 2 weeks

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the diagnosis funded by OHP?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP.
3. 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 #4. Weight: _____	**No:** Pass to RPh. Deny; medical appropriateness.
4. Is there documentation that the patient is switching enzyme replacement therapy (ERT) agents due to lack of benefit with prior therapy?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #5

Approval Criteria		
5. Is there documentation that the provider has assessed the patient for signs or susceptibility to the following? • Fluid volume overload • Acute underlying respiratory illness • Compromised cardiac or respiratory function necessitating fluid restriction	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Is the request for continuation of therapy previously approved by FFS?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #7
7. 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 #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Is this request from a metabolic specialist, biochemical geneticist, or has provider documented experience in the treatment of Pompe disease?	**Yes:** Go to #9	**No:** Pass to RPh. Deny; medical appropriateness
9. Is the request for treatment of late-onset Pompe disease (LOPD)?	**Yes:** Go to #13	**No:** Go to #10
10. Has the provider documented a baseline value for ALL the following assessments? • Muscle weakness/Motor function? (e.g. AIMS, PDMS-2, Pompe PEDI, etc) • Respiratory status (e.g. FEV, FVC, or other age-appropriate test of pulmonary function)? • Cardiac imaging (e.g. chest x-ray, echocardiography)? • CRIM status?	**Yes:** Document baseline results and go to #11	**No:** Pass to RPh. Deny; medical appropriateness
11. Is the patient CRIM-negative?	**Yes:** Go to #12	**No:** Approve for 3 months If approved, a referral will be made to case management by the OHA.

Approval Criteria		
12. 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
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? • Pulmonary function test (PFT) with spirometry including baseline percent predicted forced vital capacity (FVC) • Demonstration of completed 6-minute walk test (6MWT) -OR- Muscle weakness in the lower extremities?	**Yes:** Approve for 6 months Document baseline results. 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: • Muscle weakness/Motor function? (e.g. AIMS, PDMS-2, Pompe PEDI, etc) • Respiratory status (e.g. FEV, FVC, or other age-appropriate test of pulmonary function)?	**Yes:** Approve for 3 months Document baseline results. 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
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

Renewal Criteria		
4. Is there documentation that the patient has recently been tested* for IgG antibody formation? ** 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?	**Yes:** Approve for 3 months	**No:** Go to #7
7. Has the patient received the requested therapy for at least 6 months?	**Yes:** Approve for 12 months	**No:** Approve for 3 months

P&T/DUR Review: 2/22 (DE); 4/21 (DE)
Implementation: 4/1/22; 5/1/21

Pregabalin

Goal(s):
- Provide coverage only for funded 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 diagnosis an OHP-funded diagnosis with evidence supporting its use in that condition (see Table 1 below for examples)?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; not funded by the OHP.
6. Has the patient tried and failed gabapentin therapy for 90 days or have contradictions or intolerance to gabapentin?	**Yes**: Approve for 90 days	**No:** Pass to RPh. Deny and recommend trial of gabapentin for 90 days

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

Table 1. Pregabalin formulations for specific indications based on available evidence

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	
Non-funded		
Fibromyalgia	X	

P&T Review: *10/21 (DM); 10/20 (DM); 1/19 (DM); 7/18; 3/18; 3/17*
Implementation: *10/1/18; 8/15/18; 4/1/17*

Proton Pump Inhibitors (PPIs)

Goals:

- Promote PDL options
- Restrict PPI use to patients with OHP-funded conditions

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 #5	**No:** Go to #3
3. Is the treating diagnosis an OHP-funded condition (see **Table**)?	**Yes:** Go to #4	**No:** Pass to RPh; deny, not funded by OHP.
4. Will the prescriber consider changing to a preferred PPI product? 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 #5
5. Has the patient already received 68 days of PPI therapy in past year for either of the following diagnoses: • Esophagitis or gastro-esophageal reflux disease with or without esophagitis (K20.0-K21.9); or • Current *H. pylori* infection?	**Yes:** Go to #8	**No:** Go to #6
6. 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 #7

7. Does the patient have a history of gastrointestinal ulcer or bleed and have one or more of the following risk factors? a. Age 65 years or older b. Requires at least 3 months of continuous daily: i. Anticoagulant; ii. Aspirin (all doses) or non-selective NSAID; or iii. Oral corticosteroid	**Yes:** Approve for 1 year	**No:** Go to #8
8. Are the indication, daily dose and duration of therapy consistent with criteria outlined in the **Table**? Message: OHP-funded conditions are listed in the **Table**.	**Yes:** Approve for recommended duration.	**No:** Pass to RPh. Deny; medical appropriateness or not funded by OHP 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. Dosing and Duration of PPI Therapy for OHP Funded Conditions.

Funded OHP Conditions*	Maximum Duration	Maximum Daily Dose
GERD: Esophageal reflux (K219) Esophagitis (K200-K210)	8 weeks* *Treatment beyond 8 weeks is not funded by OHP.	Dexlansoprazole 30 mg Dexlansoprazole Solu Tab 30 mg Esomeprazole 20 mg Lansoprazole 15 mg Omeprazole 20 mg Pantoprazole 40 mg Rabeprazole 20 mg
H. pylori Infection (B9681)	2 weeks	Dexlansoprazole 60 mg Dexlansoprazole 30 mg† Esomeprazole 40 mg Lansoprazole 60 mg Omeprazole 40 mg Pantoprazole 80 mg 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) Barrett's esophagus (K22.70; K22.71x) Dyskinesia of esophagus (K224) Esophageal hemorrhage (K228) Gastritis and duodenitis (K2900-K2901; K5281) Gastroesophageal laceration-hemorrhage syndrome (K226) Gastrojejunal ulcer (K280-K289) Malignant mast cell tumors (C962) Multiple endocrine neoplasia [MEN] type I (E3121) Neoplasm of uncertain behavior of other and unspecified endocrine glands (D440; D442; D449) Perforation of Esophagus (K223) Stricture & Stenosis of Esophagus (K222) Zollinger-Ellison (E164)	1 year	

*A current list of funded conditions is available at: https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx

† Dexlansoprazole SoluTab 30 mg (given as 2 SoluTabs at once) are not recommended for healing of erosive esophagitis.

P&T / DUR Review: *10/20 (KS), 5/17(KS); 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: *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*

Injectable Pulmonary Arterial Hypertension Agents (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

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 condition?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP.
3. Will the prescriber consider a change to a preferred product? Note: preferred products do not require PA.	**Yes:** Inform prescriber of preferred alternatives in class.	**No:** Go to #4
4. Is there a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1; ICD 10 I27.0)? Note: injectable PAH medications are not FDA-approved for other forms of pulmonary hypertension.	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness.
5. Is the patient classified as having World Health Organization (WHO) Functional Class III-IV symptoms?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness.
6. Is the drug being prescribed by a pulmonologist or a cardiologist?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness.

P&T Review: *10/21(SS); 9/18; 3/16; 9/12*
Implementation: *10/13/16; 1/1/13*

Oral/Inhaled Pulmonary Hypertension Agents

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 funded by the Oregon Health Plan (OHP). Note: erectile dysfunction is not funded by the OHP.

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:** Pass to RPh. Deny; not funded by the OHP.
3. Is the drug being prescribed by a pulmonologist or cardiologist?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness.
4. Is the request for riociguat (Adempas®) or ambrisentan (Letairis®)?	**Yes:** Go to #5	**No:** Go to #6
5. 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 #6
6. Is the patient classified as having World Health Organization (WHO) Functional Class II-IV symptoms?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness.
7. Is there a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1; ICD10 I27.0)?	**Yes:** Go to #8	**No:** Go to #9

Approval Criteria		
8. Will the prescriber consider a change to a preferred product? Note: preferred products do not require PA.	**Yes:** Inform prescriber of preferred alternatives in class.	**No:** Approve for 12 months
9. 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 #10
10. Is the request for nebulized treprostinil (Tyvaso®) in a patient with a diagnosis of interstitial lung disease (WHO Group 3; ICD10 I27.23)? Note: treprostinil has not been studied and is not recommended in patients with pulmonary hypertension due to chronic obstructive pulmonary disease.	**Yes:** Approve for 12 months	**No:** Go to #11
11. RPh Only: Prescriber must provide supporting literature for use.	**Yes:** Approve for length of treatment.	**No:** Deny; not funded by the OHP

P&T Review: *10/21 (SS); 9/18; 3/16; 7/14; 3/14; 2/12; 9/10*
Implementation: *1/1/2022; 11/1/2018; 10/13/16; 5/1/16; 5/14/12; 1/24/12; 1/1/11*

Ravulizumab (Ultomiris®)

Goal(s):

- Restrict use to OHP-funded conditions and according to OHP guidelines for use.
- Promote use that is consistent with national clinical practice guidelines and medical evidence.
- Ravulizumab is approved by the FDA for the following indications:
  - The treatment of adults and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH)
  - Inhibiting complement-mediated thrombotic microangiopathy in adult and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS)

Length of Authorization:

- Up to 12 months

Requires PA:

- Ultomiris® (Ravulizumab) 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 the diagnosis funded by OHP?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Is this request for continuation of therapy?	**Yes:** Go to **Renewal Criteria**	**No:** Go to # 4
4. Has the patient been vaccinated against *Streptococcus pneumoniae, Haemophilus influenzae* type B, and *Neisseria meningitidis serogroups A, C, W, and Y and serogroup B* according to current Advisory Committee on Immunization Practice (ACIP) recommendations for vaccination in patients with complement deficiencies? Note: Prescribing information recommends vaccination at least 2 weeks prior to starting therapy. If the risk of delaying therapy outweighs the risk of developing a serious infection, a 2 week course of antibiotic prophylaxis must be immediately initiated if vaccines are administered less than 2 weeks before starting complement therapy.	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
5. Is the diagnosis for a patient at least 1 month of age or older and weighs at least 5 kg with atypical Hemolytic Uremic Syndrome (aHUS) or Paroxysmal Nocturnal Hemoglobinuria (PNH) ? Note: Ravulizumab is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Does the requested dosing align with the FDA- approved dosing (**Table 1**)?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Is there objective documentation of treatment benefit from baseline? Appropriate measures will vary by indication (e.g., hemoglobin stabilization, decreased transfusions, symptom improvement, functional improvement, etc.).	**Yes:** Approve for 12 months Document baseline assessment and physician attestation received.	**No:** Pass to RPh. Deny; medical appropriateness

Table 1. FDA-Approved Intravenous Infusion Dosing for Ravulizumab[1]

Body Weight	Loading Dose	Maintenance Dose (begins 2 weeks after loading dose)
5 to 9 kg	600 mg	300 mg every 4 weeks
10 to 19 kg	600 mg	600 mg every 4 weeks
20 to 29 kg	900 mg	2,100 mg every 8 weeks
30 to 39 kg	1,200 mg	2,700 mg every 8 weeks
40 to 59 kg	2,400 mg	3,000 mg every 8 weeks
60 to 99 kg	2,700 mg	3,300 mg every 8 weeks
100 kg or greater	3,000 mg	3,600 mg every 8 weeks

1. Ultomiris™ (Ravulizumab-cwvz) Solution for Intravenous Infusion Prescribing Information. Boston, MA: Alexion Pharmaceuticals Inc. 6/2021.

P&T/DUR Review: 12/21 (DM); 4/21 (DM)
Implementation: 1/1/22; 5/1/21

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: • The following rheumatic disorders: psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis or ankylosing spondylitis; **OR** • The following collagen diseases: systemic lupus erythematosus or systemic dermatomyositis; **OR** • Dermatologic diseases such as erythema multiforme or Stevens-Johnson syndrome; **OR** • Ophthalmic diseases such as keratitis, iritis, uveitis, optic neuritis, or chorioretinitis; **OR** • 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*

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.

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 and is the indication funded by OHP?	**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? Message: • Preferred products do not require a PA. • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. • 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 for 3 days	**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**: Pass to RPh. Deny; not funded by OHP or for medical appropriateness
7. Is the patient currently managed with a regularly scheduled daily regimen of lactulose?	**Yes**: Go to #9	**No**: Go to #8
8. Does the patient have a contraindication to lactulose?	**Yes**: Go to #9	**No**: Pass to RPh Deny; medical appropriateness Note: studies demonstrate effectiveness of rifaximin as add-on therapy to lactulose.
9. Is the patient currently prescribed a benzodiazepine drug?	**Yes**: Go to #10	**No**: Approve for up to 12 months
10. Is the patient tapering off the benzodiazepine? Note: tapering process may be several months	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness Note: studies explicitly excluded use of benzodiazepines and benzodiazepine-like drugs because of their risk for precipitating an episode of hepatic encephalopathy**.**

Table 1. Acute diarrhea treatment recommendations for adults[1]

Antibiotic	Dose	Treatment Duration
Levofloxacin	500 mg orally	Single dose - If symptoms not resolved after 24 hours, complete a 3 day course
Ciprofloxacin	750 mg orally **OR** 500 mg orally once a day	Single dose - If symptoms not resolved after 24 hours, complete a 3 day course 3-day course
Ofloxacin	400 mg orally	Single dose - If symptoms not resolved after 24 hours, complete a 3 day course
Azithromycin[a,b]	1000 mg orally **OR** 500 mg once a day	Single dose - If symptoms not resolved after 24 hours, complete a 3 day course 3-day course[b]
Rifaximin[c]	200 mg orally three times a day	3-days (in patients > 12 years old)

a. Use empirically as first-line in Southeast Asia and India to cover fluoroquinolone resistant *Campylobacter* or in other geographic areas if *Campylobacter* or resistant enterotoxigenic *E. coli* are suspected.
b. Preferred regimen for dysentery or febrile diarrhea.
c. Do not use if clinical suspicion for *Campylobacter, Salmonella, Shigella*, or other causes of invasive diarrhea.

1. Riddle MS, DuPont HL, Connor BA. ACG Clinical Guideline: Diagnosis, Treatment, and Prevention of Acute Diarrheal Infections in Adults. Am J Gastroenterol. 2016;111(5):602-622

P&T/DUR Review: 11/19 (DM), 7/15; 5/15 (AG)
Implementation: 1/1/20; 10/15; 8/15

Risdiplam

Goal(s):

- Approve risdiplam for funded OHP conditions supported by evidence of benefit (e.g. Spinal Muscular Atrophy)

Length of Authorization:

- 6 months

Requires PA:

- Risdiplam

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 and Body Weight	Recommended Daily Dosage
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 ICD10 code.	
2. Is this a request for continuation of therapy approved by the FFS program?	**Yes**: Go to **Renewal Criteria**	**No:** Go to #3
3. Are the patient's age and the prescribed dose within the limits defined in Table 1?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness. Recommended FDA-approved dosage is determined by age and body weight.

Approval Criteria		
4. 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 #5	**No:** Pass to RPh. Deny; not funded by the OHP.
5. Is the patient experiencing symptoms of SMA?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness.
6. Does the patient have advanced SMA disease (ventilator dependence >16 hours/day or tracheostomy)?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #7
7. Has the patient had previous administration of onasemnogene 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 patient on concomitant therapy with a SMN2-targeting antisense oligonucleotide, SMN2 splicing modifier or gene therapy?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #9
9. Is the drug being prescribed by a pediatric neurologist or a provider with experience treating spinal muscular atrophy?	**Yes:** Go to #10	**No:** Pass to RPh. Deny; medical appropriateness.
10. Is a baseline motor assessment available such as one of the following assessments? • Hammersmith Infant Neurological Examination (HINE-2) • The Motor Function Measure 32 (MFM32) • Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) • Upper Limb Module (ULM) or Revised Upper Limb Module (RULM) • Current status on motor milestones: ability to sit or ambulate	**Yes:** Document baseline results. Go to #11	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
11. 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. Approve for 6 months. 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
2. Has the patient shown a positive treatment response in one of the following areas? • Within one month of renewal request, documented improvement from the baseline motor function assessment score with more areas of motor function improved than worsened -OR- • 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 -OR- • Documentation of an improvement or lack of decline in pulmonary function compared to baseline	**Yes:** Approve for additional 6 months.	**No:** Pass to RPh. Deny; medical appropriateness.

P&T/DUR Review: 12/20 (DE)
Implementation: 1/1/2021

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? • Medication lost • Medication dose contaminated • Increase in dose or decrease in dose • Medication stolen • Admission to a long term care facility • 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: *2/22 (DM); 9/18 (DM); 9/17; 9/16; 5/05*
Implementation: *10/13/16; 11/18/04*

Roflumilast

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

Covered Alternatives:

- Preferred alternatives listed at http://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 #3	**No:** Pass to RPh. Deny; not covered by the OHP
3. Does the patient have documented severe or very severe COPD (e.g., FEV_1 of $\leq$ 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

P&T/DUR Review: *10/20 (KS), 9/15 (KS); 5/13; 2/12*
Implementation: *11/1/10; 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? *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
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 *Note: Benefits of therapy are most clearly evident in patients with left ventricular ejection fraction below normal. Use judiciously with higher baseline ejection fraction*

Approval Criteria		
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? *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
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*

Satralizumab-mwge (Enspryng™)

Goal(s):

- Restrict use to OHP funded conditions and according to OHP guidelines for use.
- Promote use that is consistent with national clinical practice guidelines and medical evidence.

Length of Authorization:

- Up to 12 months

Requires PA:

- Enspryng™ (Satralizumab-mwge) (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 the diagnosis funded by OHP?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP.
3. Is this request for continuation of therapy?	**Yes:** Go to **Renewal Criteria**	**No:** Go to # 4
4. Is the request for Neuromyelitis Optica Spectrum Disorder (NMOSD) in an adult who is anti-aquaporin-4 (AQP4) antibody positive?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Has the patient been screened for Hepatitis B and tuberculosis infection?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Does the patient have active Hepatitis B or untreated latent tuberculosis?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Approve for 12 months

Renewal Criteria		
1. Is there objective documentation of treatment benefit from baseline? Appropriate measures will vary by indication (e.g., hemoglobin stabilization, decreased transfusions, symptom improvement, functional improvement, etc.).	**Yes:** Approve for 12 months Document baseline assessment and physician attestation received.	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 4/21 (DM)
Implementation: 5/1/21

Sedatives

Goals:

- Restrict use of sedatives to OHP-funded conditions. Treatment of uncomplicated insomnia is not funded; insomnia contributing to covered co-morbid conditions is funded.
- 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? 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.	**No:** Go to #5
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 lifetime.	**No:** Go to #6

Approval Criteria		
6. Has the patient been treated with another non-benzodiazepine sedative, benzodiazepine, or opioid within the past 30 days?	**Yes:** Go to #7	**No:** Go to #8
7. Is this a switch in sedative therapy due to intolerance, allergy or ineffectiveness?	**Yes:** Document reason for switch and approve duplication for 30 days.	**No:** Pass to RPh. Deny; medical appropriateness.
8. Does the patient have a diagnosis of insomnia with obstructive sleep apnea?	**Yes:** Go to #9	**No:** Go to #10
9. Is patient on CPAP?	**Yes:** Approve for up to 12 months.	**No:** Pass to RPh. Deny; medical appropriateness. Sedative/hypnotics are contraindicated due to depressant effect.
10. Is the patient being treated for co-morbid: • Depression; • Anxiety or panic disorder; or • Bipolar disorder? **AND** Is there an existing claim history for treatment of the co-morbid condition (e.g., antidepressant, lithium, lamotrigine, antipsychotic, or other appropriate mental health drug)?	**Yes:** Approve for up to 12 months.	**No:** Pass to RPh; Go to #11
11. RPh only: Is diagnosis being treated a funded condition and is there medical evidence of benefit for the prescribed sedative?	**Funded:** Document supporting literature and approve up to 6 months with subsequent approvals dependent on follow-up and documented response.	**Not Funded:** Go to #12
12. RPh only: Is this a request for continuation therapy for a patient with a history of chronic benzodiazepine use where discontinuation would be difficult or unadvisable?	**Yes:** Document length of treatment and last follow-up date. Approve for up to 12 months.	**No:** Deny; medical appropriateness

P&T/DUR Review: *12/20 (AG); 7/18 (JP); 3/17; 11/20/14, 3/27/14, 5/18/06, 2/23/06, 11/10/05, 9/15/05, 2/24/04, 2/5/02, 9/7/01*
Implementation: *1/1/21; 8/15/18; 1/1/15, 7/1/14; 1/1/07, 7/1/06, 11/15/05*

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 SGLT-2 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/

Table 1. Approved Indications for SGLT2 Inhibitors (in addition to glucose lowering)

Drug Name	CV risk reduction in patients with T2D and established CV disease	Reduction in risk of end-stage kidney disease in patients with T2D and diabetic nephropathy with albuminuria >300 mg/day	Reduction in risk of eGFR decline and end-stage kidney disease CV death and hospitalization for HF in patients with CKD at risk of progression	HF risk reduction in patients with T2D and established CV disease or multiple CV risk factors	HF risk reduction in patients with HF and HFrEF
Canagliflozin	X	X			
Dapagliflozin			X	X	X
Empagliflozin	X				X
Ertugliflozin					

Abbreviations: CKD – chronic kidney disease; CV – cardiovascular; eGFR – estimated glomerular filtration rate; HF – heart failure; HFrEF – heart failure with reduced ejection fraction; T2D – type 2 diabetes

Approval Criteria		
1. Is this a request for renewal of a previously approved prior authorization?	**Yes:** Go the **Renewal Criteria**	**No:** Go to #2
2. What diagnosis is being treated?	Record ICD10 code	
3. Does the patient qualify for the requested therapy based on diagnoses and requirements in Table 1?	**Yes:** Go to #5	**No:** Go to #4
4. Does the patient have T2D and failed, or have contraindications to, metformin or is requesting a SGLT2 inhibitor to be used in combination with metformin? (document contraindication, if any)	**Yes:** Go to #5	**No:** Pass to RPh. Deny and recommend trial of metformin. See below for metformin titration schedule.

Approval Criteria		
5. Is the request for a SGLT2 inhibitor (including combination products) and there is a documented estimated glomerular filtration rate (eGFR) showing the product is not contraindicated? Products listed below should not be used in the following patients: • Canagliflozin and on dialysis, or • Empagliflozin and on dialysis , or • Dapagliflozin and eGFR on dialysis, or • Ertugliflozin and eGFR <30 mL/min/ 1.73 m^2?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Is the request for the renewal of a SGLT2 inhibitor (including combination products) and there is a documented eGFR showing the product is not contraindicated? : Products listed below should not be used in the following patients: • Canagliflozin and on dialysis, or • Empagliflozin and on dialysis, or • Dapagliflozin and on dialysis, or • Ertugliflozin and eGFR <30 mL/min/ 1.73 m^2?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness

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 but is often 850 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: *8/21 (KS), 8/20 (KS), 6/20, 7/18, 9/17; 9/16; 3/16; 9/15; 1/15; 9/14; 9/13*
Implementation: *9/1/20; 8/15/18; 10/13/16; 2/3/15; 1/1/14*

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 SGLT-2 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/

Table 1. Approved Indications for SGLT2 Inhibitors (in addition to glucose lowering)

Drug Name	CV risk reduction in patients with T2D and established CV disease	Reduction in risk of end-stage kidney disease in patients with T2D and diabetic nephropathy with albuminuria >300 mg/day	Reduction in risk of eGFR decline and end-stage kidney disease CV death and hospitalization for HF in patients with CKD at risk of progression	HF risk reduction in patients with T2D and established CV disease or multiple CV risk factors	HF risk reduction in patients with HF and HFrEF
Canagliflozin	X	X			
Dapagliflozin			X	X	X
Empagliflozin	X				
Ertugliflozin					

Abbreviations: CKD – chronic kidney disease; CV – cardiovascular; eGFR – estimated glomerular filtration rate; HF – heart failure; HFrEF – heart failure with reduced ejection fraction; T2D – type 2 diabetes

Approval Criteria		
1. Is this a request for renewal of a previously approved prior authorization?	**Yes:** Go the **Renewal Criteria**	**No:** Go to #2
2. What diagnosis is being treated?	Record ICD10 code	
3. Does the patient qualify for the requested therapy based on diagnoses and requirements in Table 1?	**Yes:** Go to #5	**No:** Go to #4
4. Does the patient have T2D and failed, or have contraindications to, metformin or is requesting a SGLT2 inhibitor to be used in combination with metformin? (document contraindication, if any)	**Yes:** Go to #5	**No:** Pass to RPh. Deny and recommend trial of metformin. See below for metformin titration schedule.

Approval Criteria		
5. Is the request for a SGLT2 inhibitor (including combination products) and there is a documented estimated glomerular filtration rate (eGFR) showing the product is not contraindicated? Products listed below should not be used in the following patients: • Canagliflozin and on dialysis, or • Empagliflozin and on dialysis , or • Dapagliflozin and eGFR on dialysis, or • Ertugliflozin and eGFR <30 mL/min/ 1.73 m^2?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Is the request for the renewal of a SGLT2 inhibitor (including combination products) and there is a documented eGFR showing the product is not contraindicated? : Products listed below should not be used in the following patients: • Canagliflozin and on dialysis, or • Empagliflozin and on dialysis, or • Dapagliflozin and on dialysis, or • Ertugliflozin and eGFR <30 mL/min/ 1.73 m^2?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness

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 but is often 850 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: *8/21 (KS), 8/20 (KS), 6/20, 7/18, 9/17; 9/16; 3/16; 9/15; 1/15; 9/14; 9/13*
Implementation: *9/1/20; 8/15/18; 10/13/16; 2/3/15; 1/1/14*

Sickle Cell Anemia Drugs

Goal(s):

- Approve the use of drugs for sickle cell disease for medically appropriate indications funded by the OHP.

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 the diagnosis funded by OHP?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP.
4. Is this a renewal request for voxelotor, crizanlizumab or l-glutamine (ENDARI)?	**Yes:** Go to renewal criteria below.	**No:** Go to #5
5. Will the prescriber consider a change to a preferred product? Message: • Preferred products/formulations do not require PA. • 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 #6
6. Has the patient received a 3-month trial of hydroxyurea at stable doses or have contraindications to hydroxyurea?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; Recommend trial of hydroxyurea (stable dose for 3 months)
7. Is the request for voxelotor and the patient is 4 years or older?	**Yes:** Go to #8	**No:** Go to #9

Approval Criteria		
8. 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
9. Is the request for crizanlizumab and the patient is 16 years or older?	**Yes:** Go to #10	**No:** Go to #11
10. 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
11. Is the request for L-glutamine (ENDARI) and the patient is 5 years or older?	**Yes:** Go to #12	**No:** Pass to RPh. Deny; medical appropriateness
12. 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 a 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 #3	**No:** Pass to RPh. Deny; not funded by the OHP
3. Will the prescriber consider a change to a preferred product? Message: • Preferred products do not require PA • 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 #4
4. Is drug requested carisoprodol?	**Yes:** Go to #5	**No:** Approve for up to 3 months
5. Has an opioid been prescribed within the past 30 days?	**Yes:** Deny; medical appropriateness	**No:** Go to #6

Approval Criteria		
6. Does total quantity of carisoprodol exceed 56 tablets in 90 days? From claims, document product, dose, directions, and amount used during last 90 days.	**Yes:** Go to #7	**No:** Approve for up to 3 months
7. 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 #8

8. Pharmacist's statement:
 	
• Carisoprodol cannot be approved for long term usage.
• Patients are limited to 56 tablets in a 90 day period.
• It is recommended that the patient undergo a "taper" of the carisoprodol product of which a supply may be authorized for this to occur.
• The amount and length of taper depends upon the patient's condition. Does the patient meet one or more of the following:
  ○ >65 years of age; or
  ○ renal failure; or
  ○ hepatic failure; or
  ○ take > 1400 mg per day?
	Yes: Document reason and approve long taper:
	
	• Authorize 18 tablets
	• Reduce dose over 9 days
	• 350 mg TID X 3 days, then
	• 350 mg BID X 3 days, then
	• 350 mg daily x 3 days then evaluate
		No: Approve short taper:
		
		• Authorize 10 tablets
		• Reduce dose over 4 days
		• 350 mg TID x 1 day, then
		• 350 mg BID x 2 days, then
		• 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.
- 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 or obstructive sleep apnea
- 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 Indications.

Indication	Modafinil (Provigil™)	Armodafinil (Nuvigil™)	Solriamfetol (Sunosi™)	Pitolisant (Wakix™)
• Excessive daytime sleepiness in narcolepsy	FDA approved for Adults 18 and older	FDA approved for Adults 18 and older	FDA approved for Adults 18 and older	FDA approved for Adults 18 and older
• Residual excessive daytime sleepiness in obstructive sleep apnea patients treated with CPAP.	FDA approved for Adults 18 and older	FDA approved for Adults 18 and older	FDA approved for Adults 18 and older	Not FDA approved; insufficient evidence
• Depression augmentation (unipolar or bipolar I or II acute or maintenance phase) • Cancer-related fatigue • Multiple sclerosis-related fatigue	Not FDA approved; Low level evidence of inconsistent benefit	Not FDA approved; insufficient evidence	Not FDA approved; insufficient evidence	Not FDA approved; insufficient evidence
• Drug-related fatigue • Excessive daytime sleepiness or fatigue related to other neurological	Not FDA approved; insufficient evidence	Not FDA approved; insufficient evidence	Not FDA approved; insufficient evidence	Not FDA approved; insufficient evidence

disorders (e.g. Parkinson's Disease, traumatic brain injury, post-polio syndrome) • ADHD • Cognition enhancement for any condition				

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	18 years	17.8 mg (poor CYP2D6 metabolizers)

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the patient 18 years of age or older?	**Yes:** Go to #3	**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.
3. Is this a funded diagnosis? Non-funded diagnoses: • Shift work disorder (ICD10 G4720-4729; G4750-4769; G478) • Unspecified hypersomnia (ICD10 G4710)	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by OHP
4. Is the request for continuation of therapy at maintenance dosage previously approved by the FFS program?	**Yes:** Go to Renewal Criteria	**No:** Go to #5

Approval Criteria		
5. 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 #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Will prescriber consider a preferred alternative?	**Yes:** Inform prescriber of preferred alternatives (e.g., preferred methylphenidate)	**No:** Go to #7
7. Is the prescribed daily dose higher than recommended in Table 2?	**Yes:** Go to #8	**No:** Go to #9
8. Is the request for pitolisant in a patient with documentation of all the following: • CYP2D6 testing which indicates the patient is not a poor metabolizer • Chart notes or provider attestation indicating lack of hepatic or renal impairment	**Yes:** Go to #9 Max dose for pitolisant is 35.6 mg daily.	**No:** Pass to RPh. Deny; medical appropriateness.
9. 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 #10 Document baseline scale and score	**No:** Pass to RPh. Deny; medical appropriateness
10. Is the request for solriamfetol or pitolisant?	**Yes:** Go to #11	**No:** Go to #15
11. Does the patient have a diagnosis of end stage renal disease?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #12
12. Is the request for solriamfetol?	**Yes:** Go to #13	**No:** Go to #15
13. Is the request for concurrent use with a monoamine oxidase inhibitor?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #14

Approval Criteria		
14. Is there documentation of a recent cardiovascular risk assessment (including blood pressure) with physician attestation that benefits of therapy outweigh risks?	**Yes:** Go to #18 Document recent blood pressure within the last 3 months and physician attestation of cardiovascular risk assessment	**No:** Pass to RPh. Deny; medical appropriateness Use of solriamfetol is not recommended in patients with uncontrolled hypertension or serious heart problems.
15. Is the patient of childbearing potential?	**Yes:** Go to #16	**No:** Go to #18
16. Is the patient pregnant or actively trying to conceive?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #17
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:** Go to #18	**No:** Pass to RPh. Deny; medical appropriateness.
18. Is the request for treatment of narcolepsy for a drug FDA-approved for the condition (Table 1)?	**Yes:** Approve for 90 days and inform prescriber further approval will require documented evidence of clinical benefit.	**No:** Go to #19
19. Is the request for treatment of obstructive sleep apnea (OSA) (without narcolepsy) for a drug FDA-approved for the condition (see Table 1)?	**Yes:** Go to #20	**No:** Go to #21
20. 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

Approval Criteria		
21. Is the request for off-label use of armodafinil, solriamfetol, or pitolisant (see Table 1)?	**Yes:** Pass to RPh. Deny; medical appropriateness. There is insufficient evidence for off-label use.	**No:** Go to #22
22. Is the primary diagnostic indication for modafinil fatigue secondary to major depression (MDD), MS or cancer-related fatigue? Note: Methylphenidate is recommended first-line for cancer.	**Yes:** Inform prescriber of first-line options available without PA. May approve for 90 days and inform prescriber further approval will require documented evidence of clinical benefit and assessment of adverse effects.	**No:** Go to #23
23. All other diagnoses must be evaluated as to the OHP-funding level and evidence for clinical benefit. • 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”. • Evidence to support cognition enhancement is insufficient and should be denied for “medical appropriateness”. 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

Renewal Criteria		
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? 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: *10/1/2020 (DE); 2/2020; 7/19; 03/16; 09/15*
Implementation: *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. Will the prescriber change to a preferred product? Message: • Preferred products do not require a PA. • 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 #4
4. Is the request for varenicline for a patient less than 17 years old?	**Yes:** Pass to RPh. Deny; medical appropriateness	**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*

Stiripentol

Goal(s):

- To ensure appropriate drug use and restrict to indications supported by medical literature and funded by Oregon Health Plan.

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 2 years of age and older 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? Note: Labs should be assessed every six months while receiving stiripentol therapy.	**Yes:** Approve for 12 months Document results here: Date of lab work_____ WBC_____ Platelets_____	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
5. Are recent WBC and platelet counts documented in patient records? Note: Labs should be assessed every six months while receiving stiripentol therapy.	**Yes:** Go to #2 Document results here: Date of lab work_____ WBC_____ Platelets_____	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
6. Has seizure frequency decreased since beginning therapy?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny for lack of treatment response.

P&T/DUR Review: 10/21 (DM); 10/20 (DM); 6/2020 (DM); 1/19 (DM)
Implementation: 3/1/2019

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

Drug	FDA-Approved Indications	Maximum 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	18
doxepin HCl	Depression Anxiety	150 mg	12
imipramine HCl	Depression Nocturnal enuresis	75 mg	6
imipramine pamoate	Depression	200 mg	18
maprotiline HCl	Depression Bipolar depression Dysthymia 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. Is the diagnosis funded by OHP?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP.
3. Does the dose exceed the maximum FDA-approved dose (**Table 1**)?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #4

Approval Criteria		
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: 2/21(SS); 11/19
Implementation: 2/1/2020

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 **active** TED? • Defined as Clinical Activity Score (CAS) of 4 or higher on 7 point scale within past 3 months.	**Yes:** Go to #5 CAS score:_____ Score date:_____	**No:** Pass to RPh. Deny; medical appropriateness
5. Does the patient have **moderate**, **severe**, or **sight-threatening** TED? • Defined by the Graves' Orbitopathy Severity Assessment • Possible severity ratings are mild, moderate, severe, and sight-threatening.	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Is the patient currently euthyroid (thyroid hormone levels no more than 50% above or below of normal range) within past 3 months?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
7. Does the patient have any of the following: • a contraindication or severe side effect* to corticosteroids or • failed to respond to 6 weeks of low-dose corticosteroid prophylaxis after radioactive iodine treatment or • failed to respond/relapsed after at least 3 weeks of high-dose (IV or oral) corticosteroids *Note: • 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.	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Is the patient of childbearing potential? Not considered of childbearing potential any of the following: • Onset of menopause >2 years before current date or • Non-therapy-induced amenorrhea >12 months before current date or • Surgically sterile (absence of ovaries and/or uterus, or tubal ligation) or • Not sexually active	**Yes:** Go to #9	**No:** Go to #11
9. Is there documentation of negative pregnancy test within past 4 weeks?	**Yes:** Go to #10 Type of test (urine or serum): _____ Date of test:_____	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
10. Has patient 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? • Reliable forms of birth control have less than 1% failure rate/year with consistent and correct use • Examples include: implants, injectables, combined oral/intravaginal/transdermal contraceptives, intrauterine devices, sexual abstinence, or vasectomized partner • Hormonal methods should be started at least one full menstrual cycle prior to initiation of teprotumumab.	**Yes:** Go to #11 Date of Counselling: _____ Contraceptive method:_____	**No:** Pass to RPh. Deny; medical appropriateness
11. Has the patient previously received any doses of teprotumumab?	**Yes:** Approve balance to allow 8 total lifetime doses† (8 doses – previous # doses = current approval #) Previous number of doses_____	**No:** Approve 8 doses†

† All approvals will be referred for and offered optional case management

P&T/DUR Review: 12/20 (SF)
Implementation: 1/1/2021

Tesamorelin (Egrifta®)

Goal(s):
- Restrict to indications funded by the OHP and supported by medical literature.

Length of Authorization:
- Up to 12 months

Requires PA:
- Tesamorelin (Egrifta®)

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:** Pass to RPh. Deny; not funded by the OHP.	**No:** Go to #3
3. RPh only: All other diagnoses must be evaluated as to funding level on OHP and evidence for must be provided by the prescriber that supports use. Evidence will be forwarded to Oregon DMAP for consideration.		

P&T/DUR Review: *9/15 (AG); 4/12*
Implementation: *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)

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 #8	**No:** Go to #3

Approval Criteria		
3. Is the medication requested for one of the following diagnoses? • 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 • 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
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: • Total serum testosterone level less than 300ng/dL (10.4nmol/L); OR • Total serum testosterone level less than 350ng/dL (12.1nmol/L) AND free serum testosterone level less than 50pg/mL (or 0.174nmol/L)	**Yes:** Go to #5	**No:** Deny; medical appropriateness

Approval Criteria		
5. Is there documentation based on submitted chart notes of any of the following diagnoses: • A recent major cardiovascular event (i.e., myocardial infarction, stroke or acute coronary syndrome) within the past 6 months • Heart failure with uncontrolled symptoms (i.e., NYHA Class III-IV, presence of edema, or evidence of fluid retention) • 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) • Breast cancer • Prostate cancer (known or suspected) or elevated PSA with prior use of testosterone • Untreated obstructive sleep apnea with symptoms • Elevated hematocrit (>50%)	**Yes:** Deny; medical appropriateness	**No:** Go to #8
6. Is the medication requested for gender dysphoria (ICD10 F642, F641)?	**Yes:** Go to #7	**No:** Go to #9

Approval Criteria		
7. Have **all** of the following criteria been met? • Patient has the capacity to make fully informed decisions and to give consent for treatment; and • If patient <18 years of age, the prescriber is a pediatric endocrinologist; and • The prescriber agrees criteria in the Guideline Notes on the OHP List of Prioritized Services have been met. See: https://www.oregon.gov/oha/HPA/DSI-HERC/SearchablePLdocuments//Prioritized-List-GN-127.docx	**Yes:** Go to #8	**No**: Pass to RPh. Deny; medical appropriateness
8. Will the prescriber consider a change to a preferred product? Message: • 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 and approve for up to 12 months.	**No:** Approve for up to 12 months.
9. RPh only: all other indications need to be evaluated to see if funded under the OHP. Note: Testosterone should not be prescribed to patients who have any contraindicated diagnoses listed in question #5.	If funded and prescriber provides supporting literature: Approve for up to 12 months.	If not funded: Deny; not funded by the OHP

P&T Review: *11/18 (SS); 11/15; 2/12; 9/10; 2/06; 2/01; 9/00*
Implementation: *1/1/19; 5/1/16; 1/1/16; 7/31/14; 5/14/12, 1/24/12, 1/1/11, 9/1/06*

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 the diagnosis funded by OHP?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP.
4. Is this for a renewal therapy for a patient previously prescribed fostamatinib?	**Yes:** Go to Renewal Criteria	**No:** Go to #5
5. Will the prescriber consider a change to a preferred product? Message: • 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:** Go to #6

Approval Criteria		
6. 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 #7
7. 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 #7.

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

Targeted Immune Modulators

Goal(s):

- Restrict use of targeted immune modulators to OHP funded conditions and according to OHP guidelines for use.
- Promote use that is consistent with national clinical practice guidelines and medical evidence.
- Promote use of high value products.

Length of Authorization:

- Up to 12 months

Requires PA:

- All targeted immune modulators for autoimmune diseases (both 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/

Table 1. Approved and Funded Indications for Targeted Immune Modulators

Drug Name	Ankylosing Spondylitis	Crohn's Disease	Juvenile Idiopathic Arthritis	Plaque Psoriasis	Psoriatic Arthritis	Rheumatoid Arthritis	Ulcerative Colitis	Other
Abatacept (ORENCIA)			≥2 yo		≥18 yo	≥18 yo		aGVHD ≥ 2 yo
Adalimumab (HUMIRA) and biosimilars	≥18 y	≥6 yo (Humira) ≥18 yo (biosimilars)	≥2 yo (Humira) ≥4 yo (biosimilars)	≥18 yo	≥18 yo	≥18 yo	≥5 yo (Humira) ≥18 yo (biosimilars)	Uveitis (non-infectious) ≥2 yo (Humira) HS ≥ 12 yo
Anakinra (KINERET)						≥18 yo		NOMID DIRA
Apremilast (OTEZLA)				≥18 yo	≥18 yo			Oral Ulcers associated with BD ≥ 18 yo
Baricitinib (OLUMIANT)						≥18 yo		
Brodalumab (SILIQ)				≥18 yo				
Canakinumab (ILARIS)			≥2 yo					FCAS ≥4 yo MWS ≥4 yo TRAPS ≥ 4 yo HIDS ≥ 4 yo MKD ≥ 4 yo FMF ≥ 4 yo Stills Disease
Certolizumab (CIMZIA)	≥18 yo	≥18 yo		≥18 yo	≥18 yo	≥18 yo		Nr-axSpA ≥ 18 yo
Etanercept (ENBREL) and biosimilars	≥18 yo		≥2 yo	≥4 yo (Enbrel) ≥4 yo (biosimilars)	≥18 yo	≥18 yo		
Golimumab (SIMPONI and SIMPONI ARIA)	≥18 yo		≥2 yo active polyarticular course		≥2 yo	≥18 yo	≥18 yo (Simponi)	
Guselkumab (TREMFYA)				≥18 yo	≥18 yo			
Infliximab (REMICADE) and biosimilars	≥18 yo	≥6 yo		≥18 yo	≥18 yo	≥18 yo	≥6 yo	

Drug Name	Ankylosing Spondylitis	Crohn's Disease	Juvenile Idiopathic Arthritis	Plaque Psoriasis	Psoriatic Arthritis	Rheumatoid Arthritis	Ulcerative Colitis	Other
Ixekizumab (TALTZ)	≥ 18 yo			≥6 yo	≥18 yo			Nr-axSpA ≥ 18 yo
Risankizumab-rzaa (SKYRIZI)				≥18 yo				
Rituximab (RITUXAN) and biosimilars						≥18 yo		CLL ≥18 yo NHL ≥18 yo GPA ≥2yo MPA ≥ 2 yo Pemphigus Vulgaris ≥18 yo (Rituxan only)
Sarilumab (KEVZARA)						≥18 yo		
Secukinumab (COSENTYX)	≥18 yo			≥6 yo	≥18 yo			Nr-AxSpA ≥18 yo
Tildrakizumab-asmn (ILUMYA)				≥18 yo				
Tocilizumab (ACTEMRA)			≥2 yo			≥18 yo		CRS ≥2 yo GCA ≥18 yo SSc-ILD ≥18 yo
Tofacitinib (XELJANZ)			≥2 yo active polyarticular course		≥18 yo	≥18 yo	≥18 yo	
Upadacitinib (RINVOQ)						≥18 yo		
Ustekinumab (STELARA)		≥ 18 yo		≥6 yo	≥18 yo		≥18 yo	
Vedolizumab (ENTYVIO)		≥18 yo					≥18 yo	

Abbreviations: aGVHD = acute Graft Versus Host Disease; BD = Behcet's Disease; CLL = Chronic Lymphocytic Leukemia; CRS = Cytokine Release Syndrome; DIRA = Deficiency of Interleukin-1 Receptor Antagonist; FCAS = Familial Cold Autoinflammatory Syndrome; FMF = Familial Mediterranean Fever; GCA = Giant Cell Arteritis; GPA = Granulomatosis with Polyangiitis (Wegener's Granulomatosis); HIDS: Hyperimmunoglobulin D Syndrome; HS: Hidradenitis Suppurativa; MKD = Mevalonate Kinase Deficiency; MPA = Microscopic Polyangiitis; MWS = Muckle-Wells Syndrome; NHL = Non-Hodgkin's Lymphoma; NOMID = Neonatal Onset Multi-Systemic Inflammatory Disease; Nr-axSpA = Non-Radiographic Axial Spondyloarthritis; SSc-ILD = Systemic Sclerosis-Associated Interstitial Lung Disease; TRAPS = Tumor Necrosis Factor Receptor Associated Periodic Syndrome; yo = years old.

Approval Criteria		
1. What diagnosis is being treated?	Record ICD-10 code.	
2. Is the diagnosis funded by OHP? Notes: A. Mild-to-moderate psoriasis is unfunded, severe psoriasis is funded. B. Mild Hidradenitis Suppurativa (HS) is unfunded, moderate-to-severe HS (e.g., Hurley Stage II or III) is funded.	**Yes:** Go to # 3	**No:** Pass to RPh. Deny; not funded by the OHP.

Approval Criteria		
3. Has the patient been annually screened for latent or active tuberculosis and if positive, started tuberculosis treatment?* *(Note: this requirement does not apply to requests for apremilast.)	**Yes:** Go to # 4	**No:** Pass to RPh. Deny; medical appropriateness. If patient meets all other criteria, pharmacist may approve once for up to 3 months to allow time for screening for ongoing therapy to avoid interruptions in care.
4. Is this a request for continuation of therapy?	**Yes**: Go to **Renewal Criteria**	**No:** Go to # 5
5. Is the request for a non-preferred product and will the prescriber consider a change to a preferred product? Message: • Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics Committee.	**Yes:** Inform prescriber of preferred alternatives. Go to #6	**No:** Go to # 6
6. Is the request for a medication and corresponding diagnosis indicated according to the "Other" column of table 1? AND Is the request for a drug FDA-approved for one of these conditions as defined in Table 1?	**Yes:** Approve for length of treatment.	**No:** Go to # 7
7. Is the diagnosis ankylosing spondylitis and the request for a drug FDA-approved for this condition as defined in Table 1?	**Yes:** Go to # 8	**No:** Go to # 9
8. Is this a request for a preferred agent OR if the request is for a non-preferred agent, has the patient failed to respond or had inadequate response to a Humira® branded product or an Enbrel® branded product after a trial of at least 3 months?	**Yes:** Approve for up to 6 months. Document therapy with dates.	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
9. Is the diagnosis plaque psoriasis and the request for a drug FDA-approved for this condition as defined in Table 1? Note: Only treatment for *severe* plaque psoriasis is funded by the OHP.	**Yes:** Go to # 10	**No**: Go to #12
10. Is the plaque psoriasis severe in nature, which has resulted in 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: • At least 10% body surface area involvement; or • Hand, foot or mucous membrane involvement?	**Yes:** Go to # 11	**No:** Pass to RPh. Deny; not funded by the OHP.
11. Has the patient failed to respond or had inadequate response to each of the following first-line treatments: • 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%); and • At least one other topical agent: calcipotriene, tazarotene, anthralin; and • Phototherapy; and • At least one other systemic therapy: acitretin, cyclosporine, or methotrexate; and • One biologic agent: either a Humira® product or an Enbrel® product for at least 3 months?	**Yes**: Approve for up to 6 months. Document each therapy with dates.	**No:** Pass to RPh. Deny; medical appropriateness.
12. Is the diagnosis rheumatoid arthritis, juvenile idiopathic arthritis, or psoriatic arthritis and the request for a drug FDA-approved for these conditions as defined in Table 1?	**Yes:** Go to # 13	**No:** Go to # 16

Approval Criteria		
13. Has the patient failed to respond or had inadequate response to at least one of the following medications: • Methotrexate, leflunomide, sulfasalazine or hydroxychloroquine for ≥ 6 months; or • Have a documented intolerance or contraindication to disease-modifying antirheumatic drugs (DMARDs)? AND • Had treatment failure with at least one biologic agent: a Humira® branded product or an Enbrel® branded product for at least 3 months? • AND • Is the patient on concurrent DMARD therapy with plans to continue concomitant use?	**Yes:** Go to # 14 Document each therapy with dates. If applicable, document intolerance or contraindication(s).	**No:** Pass to RPh. Deny; medical appropriateness. Biologic therapy is recommended in combination with DMARDs (e.g. methotrexate) for those who have had inadequate response with DMARDs.
14. Is the request for tofacitinib, baricitinib, or upadacitinib?	**Yes:** Go to # 15	**No:** Approve for up to 6 months
15. Is the patient currently on other biologic therapy or on a potent immunosuppressant like azathioprine, tacrolimus or cyclosporine? 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. Approve tofacitinib for up to 6 months at a maximum dose of 10 or 11 mg daily for Rheumatoid Arthritis OR 10 mg twice daily for 8 weeks then 5 or 10 mg twice daily for Ulcerative Colitis
16. Is the request for adalimumab in an adult with moderate-to-severe Hidradenitis Suppurativa (HS)?	**Yes:** Go to # 17	**No:** Go to # 18

Approval Criteria		
17. Has the patient failed to respond, had inadequate response, or do they have an intolerance or contraindication to a 90 day trial of conventional HS therapy (e.g. oral antibiotics)? Note: Treatment of moderate-to-severe HS with adalimumab is funded on the Prioritized List of Health Services per Guideline Note 198 OHA Prioritized List	**Yes:** Approve for up to 12 weeks of therapy	**No:** Pass to RPh. Deny; medical appropriateness.
18. Is the diagnosis Crohn's disease or ulcerative colitis and the request for a drug FDA-approved for these conditions as defined in Table 1?	**Yes:** Go to # 19	**No:** Go to # 21
19. Has the patient failed to respond or had inadequate response to at least one of the following conventional immunosuppressive therapies for ≥6 months: • Mercaptopurine, azathioprine, or budesonide; or • Have a documented intolerance or contraindication to conventional therapy?	**Yes:** Go to #20	**No:** Pass to RPh. Deny; medical appropriateness.
20. Is the request for a preferred product or has the patient tried and failed a 3 month trial of a Humira® product?	**Yes:** Approve for up to 12 months. Document each therapy with dates. If applicable, document intolerance or contraindication(s).	**No:** Pass to RPh. Deny; medical appropriateness.
21. Is the diagnosis for an FDA approved diagnosis and age as outlined in Table 1, and is the requested drug rituximab for *induction or maintenance* of remission?	**Yes:** Approve for length of treatment.	**No:** Pass to RPh. Deny; medical appropriateness.

Renewal Criteria		
1. Is the request for treatment of psoriatic arthritis or rheumatoid arthritis?	**Yes:** Go to # 4	**No:** Go to # 2
2. Is the request for continuation of adalimumab to treat moderate-to-severe Hidradenitis Suppurativa in an adult?	**Yes:** Go to # 3	**No:** Go to # 5
3. Has the patient had clear evidence of response to adalimumab therapy as evidenced by: A) a reduction of 25% or more in the total abscess and inflammatory nodule count, AND B) no increase in abscesses and draining fistulas.	**Yes:** Approve for an additional 12 weeks of therapy	**No:** Pass to RPh. Deny; medical appropriateness.
4. 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 #5	**No:** Pass to RPh. Deny; medical appropriateness.
5. Has the patient's condition improved as assessed by the prescribing provider and provider attests to patient's improvement.	**Yes:** Approve for 6 months. Document baseline assessment and provider attestation received.	**No:** Pass to RPh; Deny; medical appropriateness.

P&T/DUR Review: 10/21 (DM); 10/20 (DM); 2/20; 5/19; 1/19; 1/18; 7/17; 11/16; 9/16; 3/16; 7/15; 9/14; 8/12
Implementation: 1/1/22; 1/1/2021; 7/1/2019; 3/1/19; 3/1/18; 9/1/17; 1/1/17; 9/27/14; 2/2

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 (until 12-31-2036)	**No:** Go to #3
3. Does the patient have a diagnosis 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? • Lithium • Valproate and derivatives • Lamotrigine • Carbamazepine • Atypical antipsychotic 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.
6. Is the patient using the medication for weight loss? (Obesity ICD10 E669; E6601)?	**Yes:** Pass to RPh. Deny; not funded by the OHP AND weight loss drugs excluded by state plan.	**No:** Pass to RPh. Go to #7

Approval Criteria	
7. All other indications need to be evaluated for appropriateness: • Neuropathic pain • Post-Traumatic Stress Disorder (PTSD) • Substance abuse	Use is off-label: Deny; medical appropriateness. Other treatments should be tried as appropriate. Use is unfunded: Deny; not funded by the OHP. 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: *10/21 (DM); 10/20 (DM); 6/2020 (DM); 5/19 (KS); 1/19 (DM); 7/18; 3/18; 3/17; 7/16; 3/15; 2/12; 9/07; 11/07*
Implementation: *4/18/15; 5/12, 1/12*

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? a. History of previous heart failure hospitalization within the last 6 months 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: a. Angiotensin converting enzyme inhibitor (ACE-I) b. Angiotensin receptor blocker (ARB) 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? *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.

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 and product labeling.

Length of Authorization:
- Initial: Up to 2 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 treatment for an OHP-funded condition?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by OHP
3. Is the request for continuation of vesicular monoamine transporter 2 (VMAT2) inhibitor therapy previously approved by FFS criteria (patient has completed 2-month trial)?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #4
4. Is the request for tetrabenazine or deutetrabenazine in a patient 18 and older with a diagnosis of chorea as a result of Huntington's disease?	**Yes:** Go to #5	**No:** Go to #7
5. Does the patient have a baseline total maximal chorea score of 8 or higher?	**Yes:** Go to #6 Document baseline score: _____	**No:** Pass to RPh. Deny; medical appropriateness
6. Has it been determined that the patient does not have uncontrolled depression or at risk of violent or suicidal behavior?	**Yes:** Go to #11	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
7. Is the request for deutetrabenazine in a patient 18 and older with a diagnosis of moderate to severe tardive dyskinesia?	**Yes:** Go to #8 Document baseline modified AIMS* score: _____	**No:** Go to #9
8. Has it been determined that the patient does not have uncontrolled depression or at risk of violent or suicidal behavior?	**Yes:** Go to #10	**No:** Pass to RPh. Deny; medical appropriateness
9. Is the request for valbenazine in a patient 18 and older with a diagnosis of moderate to severe tardive dyskinesia?	**Yes:** Go to #10 Document baseline modified AIMS* score: _____	**No:** Pass to RPh. Deny; medical appropriateness
10. Is the medication being prescribed by, or in consultation with, a neurologist or psychiatrist?	**Yes:** Go to #11	**No:** Pass to RPh. Deny; medical appropriateness
11. Has the patient recently been evaluated and determined to not be at risk for a prolonged QT interval?	**Yes:** Approve for 2 months. Documented evidence of benefit required for renewal consideration (see renewal criteria).	**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 >2 months and has there been documented evidence of improvement by a reduction in AIMS dyskinesia score (items 1-7) by at least 50%?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
3. Is the request for tetrabenazine or deutetrabenazine in a patient with chorea as a result of Huntington's disease?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
4. Has the patient been taking the requested VMAT2 inhibitor for >2 months and has there been documented evidence of improvement in total maximal chorea score 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

P&T/DUR Review: 11/2017(KS)
Implementation: 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 the diagnosis funded by OHP?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP.
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. Does the patient have Class III, Class IV, or Class V lupus nephritis AND is a baseline assessment with one of the following: Urinary protein to creatinine ratio eGFR	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Is the drug being prescribed by or in consultation with a rheumatologist, nephrologist, or a provider with experience treating lupus nephritis?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness

• Approval Criteria		
7. Is the patient currently on cyclophosphamide? 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 #8
8. Is the patient currently taking or have a contraindication to ALL of the following: Mycophenolate OR Azathioprine Glucocorticoids (e.g. prednisone) Hydroxychloroquine	**Yes:** Go to #9	**No:** Pass to RPh. Deny; medical appropriateness
9. Does the patient have proteinuria with a urine protein: creatinine ratio of >500 mg/g?	**Yes:** Go to #10	**No:** Go to #11
10. 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 #11	**No:** Pass to RPh. Deny; medical appropriateness.
11. Is the patient of childbearing potential?	**Yes:** Go to #12	**No:** Approve for 6 months
12. Is the patient pregnant or actively trying to conceive?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #13
13. 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? Note: Should be monitored monthly per package labeling.	**Yes:** Go to #2 Record eGFR value & date _____	**No:** Pass to RPh. Deny; medical appropriateness
2. Has the voclosporin dose been adjusted appropriately based on baseline eGFR and current eGFR? • 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. • 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. • 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: • Urinary protein to creatinine ratio • eGFR	**Yes:** Approve for 12 months.	**No:** Pass to RPh; Deny; medical appropriateness.

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 physician 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 diagnosis funded by OHP?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP.
3. 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 #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Is the patient greater than 1 year of age?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. 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 #6
6. 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 #7

Approval Criteria		
7. Does the patient have retinal dystrophy with confirmed biallelic RPE65 mutations?	**Yes:** Go to #8 Document genetic testing	**No:** Pass to RPh. Deny; medical appropriateness
8. 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 #9	**No:** Pass to RPh. Deny; medical appropriateness
9. Does the patient have visual acuity of less than 20/60 OR a visual field of less than 20 degrees?	**Yes:** Go to #10 Document baseline visual function	**No:** Pass to RPh. Deny; medical appropriateness
10. 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. 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	Vial Strength for Reconstitution*	Dose	Injection Volume
10-11 kg	0.4 mg	0.24 mg	0.3 mL
12-16 kg	0.56 mg	0.28 mg	0.35 mL
17-21 kg	0.56 mg	0.32 mg	0.4 mL
22-32 kg	0.56 mg	0.4 mg	0.5 mL
33-43 kg	1.2 mg	0.5 mg	0.25 mL
44-59 kg	1.2 mg	0.6 mg	0.3 mL
60-89 kg	1.2 mg	0.7 mg	0.35 mL
≥90 kg	1.2 mg	0.8 mg	0.4 mL

*=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 diagnosis funded by OHP?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; not funded by the OHP

Approval Criteria		
4. Is the prescribed agent being dosed according to actual body weight (ABW) as outlined in Table 1?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
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 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 #7	**No:** Pass to RPh. Deny; medical appropriateness
7. 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 #8	**No:** Pass to RPh. Deny; medical appropriateness
8. 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 #9
9. 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 OR 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