Oregon Medicaid Pharmaceutical Services Prior Authorization Criteria

HEALTH SYSTEMS DIVISION

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

July 1, 2017

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/healthplan/Pages/Pharmacy-policy.aspx

Update information

Effective July 1, 2017

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

- Hepatitis C Direct-acting antivirals
- Ocular Vascular Endothelial Growth Factors
- Proton Pump Inhibitors

Clerical changes

- Sacubitril/valsartan (Entresto)
- Sedatives
- Antimigraine - Triptans

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/healthplan/pages/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://apps.state.or.us/Forms/Served/OE3978.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

Oregon Health Plan
Prior Authorization Request for Medications and Oral Nutritional Supplements

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 regards 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.

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

I Requesting Provider

Name* _____ NPI* _____

Contact name _____ Contact phone _____

Contact fax _____

Processing time frame: ☐ Routine ☐ Urgent ☐ Immediate

Supporting justification for urgent/immediate processing:

_____

II PA Request* - Assignment Code *(check appropriate box)*

☐ Pharmacy ☐ Oral Nutritional Supplements ☐ Physician-administered drug

☐ Other: _____

III Client Information

Client ID* _____ DOB _____

Last name* _____ First name MI* _____

IV Service Information

Estimated length of treatment _____ Frequency _____

Primary diagnosis _____ Primary diagnosis code* _____

Other pertinent diagnosis (for prescriptions and oral nutritional supplements, list all applicable diagnosis codes or contributing factors):

_____

V Drug/Product Information

Name* _____ Strength* _____

Quantity* _____ NDC* _____

Participating pharmacy:

Name _____ Phone number _____ Date _____

VI Date Information

Date of request* _____ Expected service begin date* _____

Expected service end date* _____

VII Code and Cost Information – *Required for oral nutritional supplements*

Line Item	Procedure Code	Modifier	Description	Units	U&C	MSRP	Total Dollars
1							
2							
3							
4							
5							
			Total Units	$ 0.00			$ 0.00

VIII Patient Questionnaire – *Complete for oral nutritional supplements only*

Question	***Yes***	***No***
Is the patient fed via G-tube?	☐	☐
Is the patient currently on oral nutritional supplements? - If Yes, date product started: - How is it supplied (*e.g.*, self-pay, friends/family supply)?	☐	☐
Does the patient have Failure to Thrive (FTT)?	☐	☐
Does the patient have a long history (more than one year) of malnutrition and cachexia?	☐	☐
Does the patient reside in a: - Long-term care facility? - Chronic home care facility? - If Yes, list name of residence:	☐ ☐	☐ ☐
Does the patient have: - Increased metabolic need from severe trauma (*e.g.*, severe burn, major bone fracture)? - Malabsorption difficulties (*e.g.*, Crohn's Disease, cystic fibrosis, bowel resection/removal, Short Gut Syndrome, gastric bypass, renal dialysis, dysphagia, achalasia)? - A diagnosis that requires additional calories and/or protein intake (*e.g.*, cancer, AIDS, pulmonary insufficiency, MS, ALS, Parkinson's, cerebral palsy, Alzheimer's)?	☐ ☐ ☐	☐ ☐ ☐

Date of last MD assessment for continued use of supplements:

Date of Registered Dietician assessment indicating adequate intake is not obtainable through regular or liquefied pureed foods:

- Serum protein level: Date taken:
- Albumin level: Date taken:
- Current weight: Normal weight:

Written justification and attachments:

Requesting Physician's signature: _____

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/pharmacy/Pages/pt-commitee.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/pharmacy/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

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**
ADHD	Age ≥6 years	Age ≥3 years	Age ≥6 years	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

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/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	6		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
Non-Stimulant	atomoxetine	6		100 mg
Non-Stimulant	clonidine LA	6	17	0.4 mg
Non-Stimulant	guanfacine LA	6	17	4 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 treated diagnosis 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 indication 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
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

Approval Criteria		
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: *5/16 (KK); 3/16 (AG); 5/14; 9/09; 12/08; 2/06; 11/05; 9/05; 5/05; 2/01; 9/00; 5/00*
Implementation: *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*

Analgesics, Non-Steroidal Anti-Inflammatory Drugs

Goal(s):
- To ensure that non-preferred 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 NSAIDs.
- Ketorolac: Maximum of one claim per 60 days, with a maximum 20 tablets/5-day supply (maximum 5-day supply 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 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 or copay. • Preferred products are evidence-based 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: *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*

Antiemetics

Goal(s):

- Promote use of preferred antiemetics.
- Restrict use of antiemetics for OHP-funded conditions.
- Restrict inappropriate chronic use.
- For patients receiving chemotherapy or radiation, approve a quantity sufficient for 3 days beyond the duration of treatment.

Length of Authorization:

- Up to 6 months, or variable depending on chemotherapy

Requires PA:

- Non-preferred drugs
- Preferred drugs when quantity limit exceeded (Table 1)

Table 1. Quantity Limits for Antiemetic Drugs.

Drug	Trade Name	Dose Limits
5-HT3 Receptor Antagonists		
Ondansetron	Zofran, Zuplenz, generic formulations	12 doses/ 7 days
Dolasetron	Anzemet	1 dose/ 7 days
Granisetron	Sancuso transdermal Generic oral	1 patch / 7 days 1 dose/ 7 days
Substance P/neurokinin 1 (NK1) Receptor Antagonists		
Aprepitant	Emend	3 doses/ 7 days
Rolapitant	Varubi	1 dose/ 7 days
Substance P/neurokinin 1 (NK1) Receptor Antagonists and 5-HT3 Receptor Antagonists Combinations		
Netupitant/palonosetron	Akynzeo	1 dose/ 7 days
Cannabinoid Receptor Agonist		
Dronabinol	Marinol	2.5 mg and 5 mg = 3 doses/day 10 mg = 2 doses/day

Covered Alternatives:

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

Approval Criteria		
1. What is the diagnosis 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 drug preferred?	**Yes**: Go to #5	**No**: Go to #4

4. Will the prescriber consider a change to the preferred product? Note: • Preferred products do not require a PA unless they exceed dose limits in **Table 1**. • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics Committee.	**Yes:** Inform prescriber of covered alternatives in class and dose limits. If dose exceeds limits, go to #5.	**No:** Go to #5
5. Is the request for doxylamine/pyridoxine (Diclegis®) for pregnancy-related nausea or vomiting?	**Yes:** Go to #6	**No:** Go to #7
6. Has the patient failed a trial of pyridoxine? Note: • Preferred pyridoxine products do not require a PA and are reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics Committee.	**Yes:** Approve for up to 3 months	**No:** Pass to RPh; deny and recommend a trial of pyridoxine.
7. Is the request for dronabinol?	**Yes:** Go to #8	**No:** Go to #9
8. Does the patient have anorexia associated with HIV/AIDS?	**Yes:** Approve for up to 6 months. Apply quantity limit for drugs listed in **Table 1**.	**No:** Go to #9
9. Does the patient have a cancer diagnosis AND receiving chemotherapy or radiation?	**Yes:** Approve for 3 days beyond length of chemotherapy regimen or radiation (not subject to quantity limits)	**No:** Go to #10
10. Does patient have refractory nausea/vomiting that has resulted in hospitalizations or ED visits in the past 6 months?	**Yes:** Approve for up to 6 months (not subject to quantity limits)	**No:** Go to #11
11. Has the patient tried and failed, or have contraindications, to at least 2 preferred antiemetics?	**Yes:** Approve for up to 6 months. Apply quantity limit for drugs listed in **Table 1**.	**No:** Pass to RPh. Deny; medical appropriateness. Must trial at least 2 preferred antiemetics

P&T/DUR Review: *1/17 (DM); 1/16; 11/14; 9/09; 2/06; 2/04; 11/03; 9/03; 5/03; 2/03*
Implementation: *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 (1/1/15)

ICD-10	Description
B373	Candidiasis of vulva and vagina
B371	Candidiasis of the lung
B377	Disseminated Candidiasis
B375-376, B3781-3782, B3784-3789	Candidiasis of other specified sites
B380-B384, B3889, B389	Coccidiomycosis various sites
B392-395, B399, G02, H32, I32, I39, J17	Histoplamosis
B409,B410, B419, B480	Blastomycosis
B420-427, B429, B439, B449-450, B457, B459, B469, B481-482, B488, B49	Rhinosporidosis, Sporotrichosis, Chromoblastomycosis, Aspergillosis, Mycotis Mycetomas, Cryptococcosis, Allescheriosis, Zygomycosis, Dematiacious Fungal Infection, Mycoses Nec and Nos
B488	Mycosis, Opportunistic
B4481	Bronchopulmonary Aspergillus, Allergic
N739-751, N759, N760-N771(except N72)	Inflammatory disease of cervix vagina and vulva
L3019,L3029, L3039, L3049	Cellulitis and abscess of finger and toe
P375	Neonatal Candida infection

Table 2: Examples of NON-FUNDED indications (1/1/15)

ICD-10	Description
L2083, L210-211, L218-219, L303	Erythematosquamous dermatosis
L22	Diaper or napkin rash
L20.0-20.82, L20.84-20.89	Other atopic dermatitis and related conditions
L240-242, L251-255, L578, L579, L230, L2381, L2481, L250, L252, L258-259, L551-552 , L568, L589	Contact dermatitis and other eczema
L530-532, L510, L518-519, L52,	Erythematous conditions

L710-711, L718, L930, L932, L490-L499, L26, L304, L538, L920, L951, L982, L539	
L438,L441-443, L449,L661	Lichen Planus
L700-702, L708	Rosacea or acne
B351	Tinea unguium (onychomycosis)
B360	Pityriasis versicolor
B362	Tinea blanca
B363	Black piedra
B368, B369	Mycoses, superficial
B372	Cutaneous candidiasis
B379	Candidiasis, unspecified
R21	Rash and other nonspecific skin eruption

Table 3: Criteria driven diagnoses (1/1/15)

ICD-10	Description
B350	Dermatophytosis of scalp and beard (tinea capitis/ tinea barbae)
B352	Dermatophytosis of hand (tinea manuum)
B356	Dermatophytosis of groin and perianal area (tinea cruris)
B353	Dermatophytosis of foot (tinea pedis)
B355	Dermatophytosis of body (tinea corporis / tinea imbricate)
B358	Deep seated dermatophytosis
B358-B359	Dermatophytosis of other specified sites - unspecified site
B361	Tinea nigra
B370,B3783	Candidiasis of mouth
B3742,B3749	Candidiasis of other urogenital sites

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?	**Yes:** Approve for 3 months or course of treatment.	**No:** Go to #5
5. Is the diagnosis not funded by OHP? (see examples in Table 2).	**Yes:** Pass to RPh. Deny; not funded by OHP	**No:** Got to #6
6. Is the diagnosis funded by OHP if criteria are met? (see examples in Table 3).	**Yes:** Go to #7	**No:** Go to #9
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.	**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.	**No:** Go to #8

Approval Criteria		
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: azathioprine / leflunomide basiliximab / mercaptopurine cyclophosphamide / methotrexate cyclosporine / mycophenolate etanercept / rituximab everolimus / sirolimus hydroxychloroquine / tacrolimus infliximab	**Yes:** Approve as follows: (immunocompromised patient) ORAL & TOPICAL • Course of treatment. • If length of therapy is unknown, approve for 3 months.	**No:** Pass to RPh. Deny; not funded by the OHP

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: *7/15 (kk); 09/10; 2/06; 11/05; 9/05; 5/05*
Implemented: *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 - Triptans

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)	9 tabs
Frovatriptan	Frova	7.5 mg	2.5 mg tab (blister pack 9)	9 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
Sumatriptan injectable	Imitrex & generics	12 mg	6 mg/0.5 mL	6 vials

Generic	Brand	Max Daily Dose	Dosage Form	Quantity Limit Per Month
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 two different oral triptans concurrently?	**Yes:** Go to #7	**No:** Approve for 6 months
7. 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.

P&T Review: *3/16 (MH); 3/10; 9/09; 11/03; 5/03*
Implementation: *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 like restless leg syndrome.

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. 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 & safety by the Pharmacy and Therapeutics (P&T) Committee.	**Yes:** Inform prescriber of covered alternatives in class.	**No:** Approve for the shorter of 1 year or length of prescription.

P&T Review: *7/16 (DE); 9/14; 9/13; 09/10*
Implementation: *8/16, 1/1/14, 1/1/11*

Antiplatelets

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 continuation of hospital treatment?	**Yes:** Approve for 30 days only and inform provider of preferred products.	**No:** Go to #5
5. Is the request for either prasugrel or 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 (July 2015)

	2º Stroke	2º PAD	2º MI	ACS	
				No PCI	PCI
ASA/DP ER	x				
clopidogrel	x	x	x	x	x
prasugrel	CI				x
ticagrelor				x	x
vorapaxar	CI	x	x		

Abbreviations: 2º = secondary prevention; ACS=Acute Coronary Syndrome; ASA/DP ER = aspirin/dipyridamole; CI=contraindication; PCI=Percutaneous Intervention; X = FDA-approved indication.

P&T / DUR Review: *7/15 (KK); 11/11*
Implementation: *10/15, 8/15; 7/31/14; 4/9/12*

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 (B002; B0089; B001; B009)?	**Yes:** Go to #4	**No:** Go to #7
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:	**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).

Immunosuppressants	
Abatacept	Infliximab
Adalimumab	Leflunomide
Anakinra	Methotrexate
Apremilast	Natalizumab
Azathioprine	Rituximab
Basiliximab	Secukinumab
Certolizumab pegol	Sirolimus
Cyclosporine	Tacrolimus
Cyclosporine	Tocilizumab
Etanercept	Tofacitinib
Golimumab	Ustekinumab
Hydroxychloroquine	Vedolizumab

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

Antivirals - Influenza

Goal:

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

Length of Authorization:

- Up to 30 days

Requires PA:

- Non-preferred neuraminidase inhibitors
- 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 (ICD10 J1100, J129, J111-112, J1181, J1189; J09X1-J09X9)?	**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 for length of therapy or 5 days, whichever is less.
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: *1/16 (AG); 1/12; 9/10*
Implementation: *10/13/16; 2/12/16; 1/11*

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*

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:

- 6 months 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. Does the patient have a seizure disorder diagnosis (ICD10 G40.xx; F44.5; R56.9; G93.81; R56.1; R56.9; G93.81; G83.8; P90)?	**Yes:** Approve for 12 months	**No:** Go to #4
4. Is the diagnosis an OHP-funded diagnosis?	**Yes:** go to #5	**No:** Pass to RPh. Deny; not funded by the OHP.
5. Is the patient on a concurrent sedative, hypnotic or opioid?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #6
6. RPh only: is there appropriate rationale to support long-term benzodiazepine use for this indication?	**Yes:** Approve for up to 6 months.	**No:** Deny; medical appropriateness.

P&T Review: *3/27/2014*
Implementation: *5/1/16*

Biologics for Autoimmune Diseases

Goal(s):

- Restrict use of biologics 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 biologics except for biologics approved by the FDA for the following indications:
    - Non-Hodgkin Lymphoma (ICD-10 C85.8x, C85.9x)
    - Chronic Lymphocytic Leukemia (ICD-10 C91.10, C91.11, C91.12)
    - Juvenile Idiopathic Arthritis (ICD-10 M08)
    - Multiple Sclerosis (ICD-10 G35)
    - Non-infectious posterior uveitis (ICD-10 H44.13)

Covered Alternatives:

- Current PMPDP preferred 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 Biologic Immunosuppressants.

Drug Name	Ankylosing Spondylitis	Crohn's Disease	Juvenile Idiopathic Arthritis	Plaque Psoriasis	Psoriatic Arthritis	Rheumatoid Arthritis	Ulcerative Colitis	Uveitis (non-infec-tious)	Other
Abatacept (ORENCIA)			≥6 yo			≥18 yo			
Adalimumab (HUMIRA)	≥18 yo	≥6 yo	≥2 yo	≥18 yo	≥18 yo	≥18 yo	≥18 yo	≥18 yo	
Alefacept (AMEVIVE)				≥18 yo					
Anakinra (KINERET)						≥18 yo			NOMID
Apremilast (OTEZLA)				≥18 yo	≥18 yo				
Canakinumab (ILARIS)			≥2 yo						FCAS ≥4 yo MWS ≥4 yo
Certolizumab (CIMZIA)	≥18 yo	≥18 yo			≥18 yo	≥18 yo			
Etanercept (ENBREL)	≥18 yo		≥2 yo	≥18 yo	≥18 yo	≥18 yo			
Golimumab (SIMPONI)	≥18 yo				≥18 yo	≥18 yo	≥18 yo		
Infliximab (REMICADE)	≥18 yo	≥6 yo		≥18 yo	≥18 yo	≥18 yo	≥6 yo		
Ixekizumab (TALTZ)				≥18 yo					
Natalizumab (TYSABRI)		≥18 yo							MS ≥18 yo
Rituximab (RITUXAN)						≥18 yo			CLL ≥18 yo NHL ≥18 yo GPA ≥18 yo
Secukinumab	≥18 yo			≥18 yo	≥18 yo				

(COSENTYX)									
Tocilizumab (ACTEMRA)			≥2 yo			≥18 yo			
Tofacitinib (XELJANZ)						≥18 yo			
Ustekinumab (STELARA)				≥18 yo	≥18 yo				
Vedolizumab (ENTYVIO)		≥18 yo					≥18 yo		

Abbreviations: CLL = chronic lymphocytic leukemia; FCAS = familial cold autoinflammatory syndrome; GPA = granulomatosis with polyangiitis (Wegener's granulomatosis); MS = multiple sclerosis; MWS = Muckle-Wells syndrome; NHL = non-Hodgkin's lymphoma; NOMID = neonatal onset multi-systemic inflammatory disease; yo = years old.

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. Will the prescriber 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 #4
4. Is the prescription for rituximab for non-Hodgkin Lymphoma (ICD-10 C85.8x; C85.9x) or Chronic Lymphocytic Leukemia (ICD-10 C91.10; C91.11; C91.12)?	**Yes:** Approve for length of treatment.	**No:** Go to #5
5. Is the prescription for natalizumab, prescribed for the management of relapsing multiple sclerosis?	**Yes:** Approve for length of treatment.	**No:** Go to #6
6. Is the diagnosis juvenile idiopathic arthritis (ICD-10 M08), non-infectious posterior uveitis, or ankylosing spondylitis (ICD-10 M45) and 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 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 #8	**No**: Go to #10

Approval Criteria		
8. Is the plaque psoriasis severe in nature, which has resulted in functional impairment (e.g., inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction) and one or more of the following: • At least 10% body surface area involvement; or • Hand, foot or mucous membrane involvement?	**Yes:** Go to #9	**No:** Pass to RPh. Deny; not funded by the OHP.
9. Has the patient failed to respond 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?	**Yes**: Document each therapy with dates: - _____ Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness.
10. Is the diagnosis rheumatoid arthritis or psoriatic arthritis and the request for a drug FDA-approved for these conditions as defined in Table 1?	**Yes:** Go to #11	**No:** Go to #14
11. Has the patient failed to respond to at least one of the following disease-modifying antirheumatic drugs (DMARD) for ≥6 months: • Methotrexate, leflunomide, or sulfasalazine or hydroxychloroquine; or • Have a documented intolerance or contraindication to DMARDs?	**Yes:** Document each therapy with dates: - _____ If applicable, document intolerance or contraindication(s): _____ Go to #12	**No:** Pass to RPh. Deny; medical appropriateness.
12. Is the request for tofacitinib?	**Yes:** Go to #13	**No:** Approve for up to 12 months

Approval Criteria		
13. Is the patient currently on other biologic therapy or on a potent immunosuppressant like azathioprine or cyclosporine? Note: Tofacitinib may be used concurrently with methotrexate or other oral DMARD drugs.	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Approve for up to 12 months
14. 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 #15	**No:** Go to #16
15. 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?	**Yes:** Document each therapy with dates: - _____ If applicable, document intolerance or contraindication(s): _____ Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness.
16. Is the diagnosis Granulomatosis with Polyangiitis and the requested drug rituximab for *induction* of remission?	**Yes:** Approve for length of treatment	**No:** Go to #19
17. Is the diagnosis Granulomatosis with Polyangiitis and the requested drug rituximab for *maintenance* of remission?	**Yes:** Go to #18	**No:** Go to #19
18. Has the patient failed to respond to at least one of the following conventional immunosuppressive therapies for maintenance of remission, in conjunction with a low-dose corticosteroid, for ≥6 months: • Azathioprine, leflunomide, or methotrexate • Have a documented intolerance or contraindication to DMARDs?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
19. Is the diagnosis a variant cryopyrin-associated periodic syndrome (Familial Cold Auto-inflammatory Syndrome, Muckle-Wells Syndrome, or chronic infantile neurologic cutaneous articular syndrome [also known as neonatal onset multi-systemic inflammatory disease]) and the request for a drug FDA-approved for one of these conditions as defined in Table 1?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness.

P&T/DUR Review: *11/16 (AG); 9/16; 3/16; 7/15; 9/14; 8/12*
Implementation: *1/1/17; 9/27/14; 2/21/13*

Bone Resorption Inhibitors and Related Agents

Goal(s):

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

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 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. Is the request for raloxifene?	**Yes:** Go to #5	**No:** Go to #6
5. Is the patient pregnant and/or at increased risk for thromboembolism or stroke?	**Yes:** Pass to RPh. Deny; medical appropriateness. Note: inform prescriber of pregnancy category X and boxed warning for venous thromboembolism and stroke.	**No:** Approve for up to 12 months

Approval Criteria		
6. Is the request for teriparatide and is the patient at high risk for fractures? Examples include: • Postmenopausal women with osteoporosis • Men with primary or hypogonadal osteoporosis • Osteoporosis associated with sustained glucocorticoid therapy	**Yes:** Go to #7	**No:** Pass to RPh. Go to #8
7. 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 12 months
8. 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: *7/16; 9/10*
Implementation: *8/16, 1/1/11*

Botulinum Toxins

Goal(s):
- Approve botulinum toxins for funded OHP conditions supported by evidence of benefit (eg, dystonia or spasticity associated with certain neurological diseases).
- Require positive response to therapy for use in chronic migraine headaches or overactive bladder.

Length of Authorization:
- From 90 days to 12 months

Requires PA:
- Use of botulinum toxins 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 over-activity (eg, overactive bladder)?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #2
2. What diagnosis is being treated?	Record ICD10 code	

Approval Criteria		
3. Does patient have diagnosis of neurological-induced dystonia or spasticity in which a botulinum toxin is a first-line treatment option? Examples: • Genetic torsion dystonia (G241); • Acquired torsion dystonia (G803; G2402; G248); • Blepharospasm (G245); • Spasmodic torticollis (G243); • Other fragments of torsion dystonia (G249); • Paralysis associated with CVD (I69931-I69969); • Multiple sclerosis (G35); • Neuromyelitis optica (G360); • Spastic hemiplegia, other specified hemiplegia (G8100-G8194); • Cerebral palsy (G800-G809); • Quadriplegia and quadraparesis (-G8250-G8254); • Paraplegia (G8220); • Diplegia of upper limbs (G830); • Monoplegia of lower limb (G8310-G8314); • Monoplegia of upper limb (G8320-G8324); • Unspecified monoplegia (G8330); • Other specified paralytic syndrome (G8381-G8389); • Muscular dystrophies (G710-G712); or • Strabismus in other neuromuscular disorders (H5089).	**Yes:** Approve for up to 12 months	**No:** Go to #4
4. Does patient have a diagnosis of chronic migraine with ≥15 headache days per month, of which ≥8 days are with migraine?	**Yes:** Go to #5	**No:** Go to #7
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.

Approval Criteria		
6. Has the patient had an inadequate response, or has contraindications, to ≥1 drugs from each of the following 3 drug classes? • Beta-blockers: (propranolol; metoprolol; atenolol; nadolol; or timolol) • Tricyclic antidepressants: (nortriptyline or amitriptyline) • Anticonvulsants: (divalproex sodium/valproic acid; carbamazepine; topiramate; or gabapentin) • Calcium channel blockers (diltiazem; verapamil; or nimodipine)	**Yes:** • Baseline headaches/month: _____. Approve no more than 2 treatments given ≥3 months apart. Additional treatment requires documented positive response to therapy from baseline (see Renewal Criteria).	**No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of preferred alternatives at www.orpdl.org/drugs/
7. Does patient have a diagnosis idiopathic or neurogenic detrusor over-activity (eg, overactive bladder syndrome) (ICD10-CM N32.81)?	**Yes:** Go to #8	**No:** Pass to RPh. Go to #9
8. Has the patient had an inadequate response to, or is intolerant of, ≥2 incontinence anti-muscarinic drugs (eg, fesoterodine, oxybutynin, solifenacin, darifenacin, tolterodine, or trospium)?	**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

9. RPh only: Medical literature with evidence for use in funded conditions must be submitted and determined to be appropriate for use before approval is granted.

Deny for the following conditions; not funded by the OHP
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 (eg, 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)
Deny for medical appropriateness for the following conditions; 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 (eg, 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); Hyperplasia of prostate (N400-N403; N4283)

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

Renewal Criteria		
2. Is there documentation of a reduction of ≥6 headache days per month compared to baseline headache frequency?	**Yes:** Approve for up to 12 months Baseline:____ headaches/month Current:____ 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 idiopathic or neurogenic detrusor over-activity?	**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: *9/16 (AG); 11/15; 9/14; 7/14*
Implementation : *10/13/16; 1/1/16*

Buprenorphine and Buprenorphine/Naloxone

Goals:

- Encourage use of buprenorphine products on the Preferred Drug List.
- Restrict use of buprenorphine products under this PA to management of opioid use disorder.
- Restrict use of oral transmucosal buprenorphine monotherapy products (without naloxone) to pregnant patients or females actively trying to conceive.

Length of Authorization:

- Up to 6 months

Requires PA:

- Buprenorphine sublingual tablets
- Suboxone® and generics (buprenorphine/naloxone) film and sublingual tablets that exceed an average daily dose of 24 mg per day of buprenorphine
- Bunavail® (buprenorphine/naloxone buccal film)
- Zubsolv® (buprenorphine/naloxone sublingual tablets)
- Probuphine® (buprenorphine subdermal implants)

Covered Alternatives:

- Current PMPDP preferred 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 prescription for opioid use disorder (opioid dependence or addiction)?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Is the patient part of a comprehensive treatment program for substance abuse that includes psychosocial support system(s)?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness. Buprenorphine therapy must be part of a comprehensive treatment program that includes psychosocial support.
4. 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 6 months that the patient has not been prescribed any opioid analgesics from other prescribers?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Is the requested medication a preferred agent?	**Yes:** Go to #7	**No:** Go to #6

Approval Criteria		
6. 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:** Go to #7
7. Is the request for the buprenorphine implant system (Probuphine)?	**Yes:** Go to #8	**No:** Go to #9
8. Has the patient been *clinically stable* on 8 mg daily or less of Suboxone or Subutex (or equivalent, see Table 1) for at least 6 months? Note: see Table 1 for definition of clinical stability and for equivalent dosing of other buprenorphine products.	**Yes:** if <u>all</u> criteria in Table 1 met, approve 4 implants for 6 months	**No:** Pass to RPh. Deny; medical appropriateness
9. 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 #10
10. Is the prescribed product a buprenorphine monotherapy product (i.e., without naloxone)	**Yes:** Go to #11	**No:** Go to #13
11. Is the patient pregnant or a female actively trying to conceive?	**Yes:** Go to #13	**No:** Go to #12
12. Does the patient have a contraindication or intolerance to buprenorphine/naloxone combination products that prevents successful management of opioid use disorder?	**Yes:** Go to #13	**No:** Pass to RPh. Deny; medical appropriateness
13. What is the expected length of treatment?	Document length of therapy: _____ Approve for anticipated length of treatment or 6 months, whichever is shorter.	

Table 1. Criteria for Approved Use of Probuphine (buprenorphine implant).[1]

PROBUPHINE implants are only for use in patients who meet ALL of the following criteria:
• Patients should not be tapered to a lower dose for the sole purpose of transitioning to PROBUPHINE • Stable transmucosal buprenorphine dose (of 8 mg per day or less of a sublingual Subutex or Suboxone sublingual tablet or its transmucosal buprenorphine product equivalent) for 3 months or longer without any need for supplemental dosing or adjustments:

- Examples of acceptable daily doses of transmucosal buprenorphine include:
  - Subutex (buprenorphine) sublingual tablet (generic equivalent) 8 mg or less
  - Suboxone (buprenorphine and naloxone) sublingual tablet (generic equivalent) 8 mg/2 mg or less
  - Bunavail (buprenorphine and naloxone) buccal film 4.2 mg/0.7 mg or less
  - Zubsolv (buprenorphine and naloxone) sublingual tablets 5.7 mg/1.4 mg or less

Consider the following factors in determining clinical stability and suitability for PROBUPHINE treatment:

- no reported illicit opioid use
- low to no desire/need to use illicit opioids
- no reports of significant withdrawal symptoms
- stable living environment
- participation in a structured activity/job that contributes to the community
- consistent participation in recommended cognitive behavioral therapy/peer support program
- stability of living environment
- participation in a structured activity/job

Reference: PROBUPHINE (buprenorphine implant for subdermal administration) [Prescribing Information]. Princeton, MJ: Braeburn Pharmaceuticals, Inc., May 2016.

P&T/DUR Review: *1/17 (AG); 9/16; 1/15; 9/09; 5/09*
Implementation: *4/1/2017; 9/1/13; 1/1/10*

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; 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; **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

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

Clobazam

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

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. Does the patient have a diagnosis of Lennox-Gastaut syndrome and is 2 years of age or older?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. 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

Limitations of Use:
• Clobazam is not indicated for other epilepsy syndromes other than Lennox-Gastaut.

P&T Review: *7/16 (DM); 3/15; 5/12*
Implementation: *8/16, 8/12*

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*

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*

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*

Daclizumab (Zinbryta™)

Goal(s):

- Restrict use of daclizumab to patients with relapsing multiple sclerosis (RMS) who have failed multiple drugs for the treatment of RMS.
- Ensure appropriate baseline monitoring to minimize patient harm.

Length of Authorization:

- 6 months

Requires PA:

- Zinbryta™ (daclizumab)

Covered Alternatives:

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

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the patient an adult (age ≥18 years) diagnosed with relapsing multiple sclerosis (RMS)?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Has the patient failed trials for at least 2 drugs indicated for the treatment of RMS?	**Yes:** Document drug and dates trialed: 1._____(dates) 2._____(dates) (3.)_____(dates) (4.)_____(dates) Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Does the patient have a higher degree of ambulatory ability (e.g., Expanded Disability Status Scale score ≤5)	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Does the patient have hepatic disease or hepatic impairment, including ALT or AST ≥2-times the upper limit of normal, or have a history of auto-immune hepatitis?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #6
6. Is the prescriber a neurologist who regularly treats RMS?	**Yes:** Approve 150 mg once monthly for 6 months	**No:** Pass to RPh. Deny; medical appropriateness

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		
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: *5/16 (DM); 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)*

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 DPP-4 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	
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 and a sulfonylurea, or have contraindications to these treatments? (document contraindication, if any)	**Yes:** Go to #4	**No:** Pass to RPh; deny and recommend trial of metformin or sulfonylurea. 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.

P&T/DUR Review: 9/16 (KS); 9/15; 9/14; 9/13; 4/12; 3/11
Implementation: 10/13/16; 10/15; 1/15; 9/14; 1/14; 2/13

Dronabinol (Marinol®)

Goal(s):

- Cover drugs only when used for covered OHP diagnoses, and restrict use to instances where medical evidence supports use (e.g. Nausea associated with chemotherapy).There is limited medical evidence supporting the use of dronabinol for many conditions.

Length of Authorization:

- 6 months to lifetime (criteria specific)

Requires PA:

- Dronabinol (Marinol®)

Quantity Limits:

- 2.5mg & 5 mg = 3 units per day
- 10mg = 2 units per day

Apply ONLY to HIV/AIDS related anorexia and Non-Oncology related antiemetic use. No quantity limits apply for Oncology (cancer) related antiemetic use.

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org
- Metoclopramide (Reglan®)
- Prochlorperazine (Compazine®)
- Promethazine (Phenergan®)
- 5 HT3 antagonists (Zofran®, Anzemet®, or Kytril®) – authorized for >3 days

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Does client have diagnosis of anorexia associated with AIDS? HIV?	**Yes:** Approve for lifetime (until 12-31-2036). Apply quantity limit (Anorexia associated with AIDS/HIV)	**No:** Go to #3.
3. Does client have current diagnosis of cancer AND receiving chemotherapy or radiation therapy?	**Yes:** Approve for length of chemo or radiation therapy. No quantity limit. (Chemotherapy or Radiation, whichever is applicable)	**No:** Go to #4.
4. Does client have refractory nausea that would require hospitalization or ER visits?	**Yes:** Go to #5.	**No:** Go to #7.

Approval Criteria		
5. Has client tried two medications listed below? 5 HT3 drugs - Zofran®, Anzemet®, Kytril®	**Yes:** Approve for up to six months. Apply quantity limit (Refractory Nausea With Failure of Alternative Meds)	**No:** Go to #6.
6. Does client have contraindications, such as allergies, or other reasons they CANNOT use these anti-emetics? Document reason.	**Yes:** Approve for up to six months. Apply quantity limit (Refractory Nausea With Contraindication of Alternative Meds)	**No:** Go to #7.
7. Does client have ONE of more of following diagnosis? Cancer associated anorexia, dystonic disorders, glaucoma, migraine, multiple sclerosis, pain.	**Yes:** Pass to RPH; Deny, (Medical Appropriateness)	**No:** Pass to RPH; Go to #8.
8. RPH only All other indications need to be evaluated to see if they are above or below the line	Above: Deny, (Medical Appropriateness)	Below: Deny, (Not-Covered by the OHP)

Generic Name	Brand Name
Metoclopramide	Reglan®
Prochlorperazine	Compazine®
Promethazine	Phenergan®

P&T / DUR Action: *2/23/06, 2/24/04, 2/11/03*
Implementation: *10/15, 7/1/06, 5/31/05*

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 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? **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])	**Yes:** Approve for 6 months.	**No:** Pass to RPh. Go to 5.

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.
   - Naloxegol (MOVANTIK): Opioid-induced constipation in patients with non-cancer pain is not approvable. Justification must be provided for not meeting criterion #4.

P&T Review: *3/15 (AG); 3/09*
Implementation: *5/1/16; 10/15, 4/18/15*

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 #3	**No:** Pass to RPh. Deny; not funded by the OHP.
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. 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: *11/15 (AG)*
Implementation *1/1/16*

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 Hermatology 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: *7/16 (DM); 5/14; 11/12; 6/12; 2/12, 9/10*
Implementation: *10/13/16; 1/1/13; 9/24/12; 5/14/12*

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.	**Yes:** Approve for up to 6 months	**No**: Pass to RPh. Deny; medical appropriateness
6. Is the medication requested for hypogonadism?	**Yes:** Approve for up to 6 months	**No**: Go to #7

Approval Criteria		
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*

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: www.oregon.gov/OHA/healthplan/pages/pharmacy-policy.aspx

Excerpt from OAR 410-121-0147 Exclusions and Limitations (DMAP Pharmaceutical Services Program)
1) The following items are not covered for payment by the Division of Medical Assistance Programs (DMAP) Pharmaceutical Services Program: (a) Drug products for diagnoses below the funded line on the Health Services Commission Prioritized List or an excluded service under Oregon Health Plan (OHP) coverage; (b) Home pregnancy kits; (c) Fluoride for individuals over 18 years of age; (d) Expired drug products; (e) Drug products from non-rebatable manufacturers, with the exception of selected oral nutritionals, vitamins, and vaccines; (f) Active Pharmaceutical Ingredients (APIs) and Excipients as described by Centers for Medicare and Medicaid (CMS); (g) Drug products that are not assigned a National Drug Code (NDC) number; (h) Drug products that are not approved by the Food and Drug Administration (FDA); (i) Drug products dispensed for Citizen/Alien-Waived Emergency Medical client benefit type; (j) Drug Efficacy Study Implementation (DESI) drugs (see OAR 410-121-0420); (k) Medicare Part D covered drugs or classes of drugs for fully dual eligible clients (see OAR 410-121-0149, 410-120-1200, & 410-120-1210).

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

Approval Criteria		
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
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

Approval Criteria		
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
DCC = B	Fertility Agents	Fertility Treatment Not Covered on OHP List
DCC = D	Diagnostics	DME Billing Required
DCC= F, except HSN = 018751 002111 002112 002070 002113 016924	Weight Loss Drugs	Weight Loss Not Covered on OHP List except In cases of co-morbidity. Exceptions are Prior Authorized
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 006081 (Podophyllin Resin)	Keratolytics	Acne, Warts, Corns/Calluses; Seborrhea Are Not Covered on OHP List
HIC3=L5B	Sunscreens	Cosmetic Indications, Acne, Atopic Dermatitis, Warts, Corns/Callouses; Diaper Rash, Seborrhea Are Not Covered on OHP List
HIC3=L5C	Abrasives	Cosmetic Indications, Acne, Atopic Dermatitis, 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	Acne Agents	Acne Not Covered on OHP List
HIC3=L5H	Acne Agents, Topical	Acne Not Covered on OHP List
HIC3=L6A; Except HSN = 002577 002576 002574 002572 (Capsaicin)	Irritants	Acne, Atopic Dermatitis, 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, Acne, Atopic Dermatitis, Warts, Corns/Callouses; Diaper Rash, Seborrhea, are Not Covered on OHP List
HIC3=L9B	Vit A Used for Skin	Acne 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=Q5K	Topical Immunosuppressants	Atopic Dermatitis 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 = 004045 + ROA = TOPICAL	Clindamycin Topical	Acne Not Covered on OHP List
HSN=003344	Sulfacetamide Sodium/Sulfur Topical	Acne Not Covered on OHP List
HSN=008712, 004022 + ROA=TOPICAL	Erythromycin Topical	Acne Not Covered on OHP List
HSN=025510	Rosacea	Acne Not Covered on OHP List
TC=93; Except HSN = 002363 (dextranomer) 002361 (zno)	Emollients/Protectants	Cosmetic Indications, Acne, Atopic Dermatitis, Warts, Corns/Callouses; Diaper Rash, Seborrhea, Psoriasis Are Not Covered on OHP List

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

Fidaxomicin (Dificid®)

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

Length of Authorization:
- 10 days

Requires PA:
- Fixaxomicin

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)? (ICD-10 A047	**Yes:** Go to #3.	**No:** Pass to RPH; Deny (medical appropriateness)
3. Will the prescriber consider changing to a preferred antibiotic? Message: • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics Committee.	**Yes:** Inform Provider of covered alternatives in class.	**No:** Go to #4
4. Does the patient have a documented trial of appropriate therapy with vancomycin or metronidazole for a first recurrence or contraindication to therapy?	**Yes:** Go to #5.	**No:** Pass to RPH; Deny (medical appropriateness)
5. 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: *5/15 (AG); 4/12*
Implementation: *10/15; 7/12*

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 GLP-1 receptor agonists

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

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code	
2. 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 do not require PA. • 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 #4
4. Has the patient tried and failed metformin and sulfonylurea therapy or have contraindications to these treatments? (document contraindication, if any)	**Yes: Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of metformin or sulfonylurea. See below for metformin titration schedule.

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: *1/17 (KS); 11/16; 9/16; 9/15; 1/15; 9/14; 9/13; 4/12; 3/11*
Implementation: *4/1/17; 2/15; 1/14*

Gonadotropin-Releasing Hormone (GnRH) Analogs

Goal(s):

- Restrict pediatric use to medically appropriate conditions funded under the Oregon Health Plan (eg, central precocious puberty or gender dysphoria)

Length of Authorization:

- Up to 6 months

Requires PA:

- GnRH analogs (i.e., goserelin, histrelin, leuprolide, nafarelin, triptorelin) prescribed for pediatric patients less than 18 years of age.

Approval Criteria		
1. 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	
2. Is the prescriber a pediatric endocrinologist?	**Yes:** Go to #3	**No:** Pass to RPh; deny for medical appropriateness
3. Is the diagnosis central precocious puberty (ICD10 E301, E308) or other endocrine disorder (E34.9)?	**Yes:** Approve for up to 6 months	**No:** Go to #4
4. Is the diagnosis gender dysphoria (ICD10 F642, F641)?	**Yes:** Go to #5	**No:** Pass to RPh; go to #6
5. 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.	**Yes:** Approve for up to 6 months	**No:** Pass to RPh; deny for medical appropriateness
6. 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: *11/15 (KS); 7/15; 5/15; 9/07*
Implementation: *1/1/16; 7/1/15; 11/07; 7/09*

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

Covered Alternatives:

- Current PMPDP preferred 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 #5
4. Has the patient tried and failed NSAID therapy or have contraindications to NSAIDs or is a candidate for combination therapy (i.e., multiple joint involvement and severe pain)?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; recommend trial of NSAID
5. Is the request for febuxostat?	**Yes:** Go to #6	**No:** Go to #7
6. Has the patient tried and failed allopurinol or has contraindications to allopurinol?	**Yes:** Approve for 12 months	**NO:** Pass to RPh. Deny; recommend trial of allopurinol
7. Is the request for lesinurad?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; Medical appropriateness

Approval Criteria		
8. Is the patient concomitantly taking a xanthine oxidase inhibitor (e.g., allopurinol, fubuxostat)?	**Yes:** Go to #9	**No:** Pass to RPh. Deny; medical appropriateness
9. Is the estimated CrCl < 45 mL/min?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Approve for 12 months at a maximum daily dose of 200 mg

P&T/DUR Review: *1/17 (KS)*
Implementation: *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 growth hormone (GH) is included only for children with: pituitary dwarfism, Turner's syndrome, Prader-Willi-syndrome, Noonan's syndrome, short stature homeobox-containing gene (SHOX), chronic kidney disease (stage 3 or higher) and those with renal transplant. Treatment with GH should continue only until adult height as determined by bone age is achieved. Treatment is not included for isolated deficiency of human growth hormone or other conditions in adults.

Length of Authorization:
- Up to 12 months

Requires PA:
- All GH products require prior authorization for OHP coverage. GH treatment 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 patient an adult (>18 years of age)?	**Yes:** Pass to RPh. Deny; not funded by the OHP	**No:** Go to #3
3. Is this a request for initiation of growth hormone?	**Yes:** Go to #4	**No:** Go to **Renewal Criteria**
4. Is the prescriber a pediatric endocrinologist or pediatric nephrologist?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. 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 #6

Initial Approval Criteria		
6. Is the diagnosis one of the following? • Turner's syndrome (ICD10 Q969) • Noonan's syndrome (ICD10 E7871-7872, Q872-873, Q875, Q8781, Q8789, Q898) • Prader-Willi syndrome (PWS) (ICD10 Q871) • Pituitary dwarfism (ICD10 E230) • Short stature homeobox-containing gene (SHOX) (ICD10 R6252) • Chronic kidney disease (CKD, Stage ≥3) (ICD10 N183-N185) • Renal transplant (ICD10 Z940)	**Yes:** Document and go to #7	**No:** Pass to RPh. Deny; not funded by the OHP.
7. If male, is bone age <16 years? If female, is bone age <14 years?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Is there evidence of non-closure of epiphyseal plate?	**Yes:** Go to #9	**No:** Pass to RPh. Deny; medical appropriateness
9. Is the product requested preferred?	**Yes:** Approve for up to 12 months	**No:** Go to #10
10. 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

Renewal Criteria		
1. Document approximate date of initiation of therapy and diagnosis (if not already done).		
2. Is growth velocity greater than 2.5 cm per year?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Is male bone age <16 years or female bone age <14 years?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Is the product requested preferred?	**Yes:** Approve for up to 12 months	**No:** Go to #5

5. 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: 9/16; 9/15; 9/14; 9/10; 5/10; 9/08; 2/06; 11/03; 9/03
Implementation: 10/13/16; 1/1/11, 7/1/10, 4/15/09, 10/1/03, 9/1/06; 10/1/03

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	
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	

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

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 selection based on disease severity, genotype, and comorbidities.

Length of Authorization:

- 8-12 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?	**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.
4. Has all of the following pre-treatment testing been documented: a. Genotype testing in past 3 years; b. Baseline HCV RNA level in past 6 months; c. Current HIV status of patient d. Current HBV status of patient e. Pregnancy test in past 30 days for a woman of child-bearing age; and f. History of previous HCV treatment and outcome? 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.	**Yes:** Record results of each test and go to #5	**No**: Pass to RPh. Request updated testing.

Approval Criteria		
5. Has the patient failed treatment with any of the following HCV NS5A inhibitors: a) Daclatasvir plus sofosbuvir; b) Ledipasvir/sofosbuvir; c) Paritaprevir/ritonavir/ombitasvir plus dasabuvir; d) Elbasvir/grazoprevir; or e) Sofosbuvir/velpatasvir)? Note: Patients who failed treatment with sofosbuvir +/- ribavirin or PEGylated interferon can be retreated (see table below).	**Yes:** Pass to RPh. Deny; medical appropriateness. Note: If urgent retreatment is needed, resistance testing must be done to indicate susceptibility to prescribed regimen. Refer to medical director for review.	**No:** Go to #6
6. Which regimen is requested?	Document and go to #7	
7. Does the patient have HIV coinfection AND: A biopsy, imaging test (transient elastography [FibroScan], acoustic radiation force impulse imaging [ARFI], or shear wave elastography [SWE], or serum test if the above are not available (enhanced liver fibrosis [ELF]; Fibrometer; FIBROSpect II) to indicate fibrosis (METAVIR F2) AND the patient is under treatment by a specialist with experience in HIV?	**Yes:** Go to #12 Note: Other imaging and blood tests are not recommended based on evidence of poor sensitivity and specificity compared to liver biopsy. Further information on coverage guidance from the Health Evidence Review Commission (HERC) is available at http://www.oregon.gov/oha/herc/Pages/CompletedGuidances.aspx	**No:** Go to #8

Approval Criteria		
8. Does the patient have: a) A biopsy, imaging test (transient elastography [FibroScan®], acoustic radiation force impulse imaging [ARFI], or shear wave elastography [SWE]) to indicate advanced fibrosis (METAVIR F3) or cirrhosis (METAVIR F4); or Clinical, radiologic or laboratory evidence of complications of cirrhosis (ascites, portal hypertension, hepatic encephalopathy, hepatocellular carcinoma)?	**Yes:** Go to #11 Note: Other imaging and blood tests are not recommended based on evidence of poor sensitivity and specificity compared to liver biopsy Further information on coverage guidance from the Health Evidence Review Commission (HERC) is available at http://www.oregon.gov/oha/herc/Pages/CompletedGuidances.aspx	**No:** Go to #9
9. Does the patient have one of the following extrahepatic manifestations of Hepatitis C (with documentation from a relevant specialist that their condition is related to HCV)? a) Type 2 or 3 cryoglobulinemia with end-organ manifestations (i.e., leukocytoclastic vasculitis); or b) Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis; or c) Porphyria cutanea tarda	**Yes:** Go to #11	**No:** Go to #10
10. Is the patient in one of the following transplant settings: a) Listed for a transplant and treatment is essential to prevent recurrent hepatitis C infection post-transplant; or b) Post solid organ transplant?	**Yes:** Go to #11	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
11. If METAVIR F4: Is the regimen prescribed by, or in consultation with, a hepatologist, gastroenterologist, or infectious disease specialist with experience in treatment of Hepatitis C? **OR** If METAVIR F3: Is the regimen prescribed by, OR is the patient in the process of establishing care with, a hepatologist, gastroenterologist, or infectious disease specialist with experience in the treatment of Hepatitis C? **OR** If METAVIR ≤F2: Is the regimen prescribed by a provider knowledgeable in the treatment of Hepatitis C?	**Yes:** Go to #12	**No:** Pass to RPh. Deny; medical appropriateness. Forward to DMAP for further manual review to determine appropriateness of prescriber.
12. In the previous 6 months: • Has the patient actively abused alcohol (>14 drinks per week for men or >7 drinks per week for women or binge alcohol use (>4 drinks per occasion at least once a month); OR • Has the patient been diagnosed with a substance use disorder; OR • Is the prescriber aware of current alcohol abuse or illicit injectable drug use?	**Yes:** Go to #13	**No:** Go to #14
13. Is the patient enrolled in a treatment program under the care of an addiction/substance use treatment specialist?	**Yes:** Go to #14	**No:** Pass to RPh. Deny; medical appropriateness.
14. Do the patient and provider agree to comply with all case management interventions and adhere to monitoring requirements required by the Oregon Health Authority, including measuring and reporting of a post-treatment viral load?	**Yes**: Go to #15	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
15. Is the prescribed drug: a) Elbasvir/grazoprevir for GT 1a infection; or b) Daclatasvir + sofosbuvir for GT 3 infection?	**Yes**: Go to #16	**No:** Go to #17
16. Has the patient had a baseline NS5a resistance test show a resistant variant to one of the agents in #16?	**Yes:** Pass to RPh; deny for appropriateness	**No:** Go to #17 Baseline testing for resistance variants is required prior to approval.
17. Is the prescribed drug regimen a recommended regimen based on the patient's genotype and cirrhosis status (Table 1)?	**Yes:** Approve for 8-24 weeks based on duration of treatment indicated for approved regimen	**No:** Pass to RPh. Deny; medical appropriateness.

Table 1: Recommended Treatment Regimens for Chronic Hepatitis C.

Genotype	Cirrhosis Status	Recommended Regimen^	Duration of Treatment
Genotype 1			
Treatment-naïve	Non-cirrhotic	• EBR/GZR • LDV/SOF	12 weeks except if LDV/SOF and *HCV RNA < 6 million IU/mL, give for 8 weeks*
	Compensated Cirrhosis	• EBR/GZR • LDV/SOF	12 weeks
	Decompensated Cirrhosis	• LDV/SOF + RBV	12 weeks
Treatment-experienced*	Non-cirrhotic	• EBR/GZR • LDV/SOF +/- RBV**	12 weeks
	Compensated Cirrhosis	• EBR/GZR • LDV/SOF + RBV	12 weeks 12 weeks – 24 weeks[c]
	Decompensated Cirrhosis	• LDV/SOF + RBV	24 weeks
Genotype 2			
Naïve or Experienced	Non-cirrhotic	• SOF/VEL	12 weeks
	Compensated Cirrhosis	• SOF/VEL + RBV**	12 weeks

	Decompensated Cirrhosis	• SOF/VEL + RBV	12 weeks
Genotype 3			
Naïve or Experienced	Non-cirrhotic	• LDV/SOF + RBV • SOF/VEL	12 weeks
	Compensated Cirrhosis	• SOF/VEL + RBV±	12 weeks
	Decompensated Cirrhosis	• SOF/VEL + RBV	12 weeks
Genotype 4			
Naïve or Experienced	Non-cirrhotic	• EBR/GZR • LDV/SOF	12 weeks
	Compensated Cirrhosis	• EBR/GZR • LDV/SOF	12 weeks
	Decompensated Cirrhosis	• LDV/SOF + RBV	12 weeks *(24 weeks if prior SOF treatment has failed)*
Genotypes 5 and 6			
Naïve or Experienced	With or Without Compensated Cirrhosis	• LDV/SOF	12 weeks

Abbreviations: EBV/GZR = elbasvir/grazoprevir (Zepatier®) ; LDV/SOF = ledipasvir and sofosbuvir (Harvoni®); RBV = ribavirin; SOF = sofosbuvir (Sovaldi®); SOF/VEL = sofosbuvir/velptasvir (Epclusa®)

*Treatment-experienced defined as previous treatment with PEG/RBV or SOF/RBV only.
**RBV required for previous treatment with SOF but not if PEG/RBV
[c] For those who have failed SOF + RBV with compensated cirrhosis: LDV/SOF + RBV for 24 weeks is recommended
±Evidence is insufficient if the addition of RBV may benefit subjects with GT3 and cirrhosis. If RBV is not used with regimen, then baseline RAV testing should be done prior to treatment to rule out the Y93 polymorphism

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

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

Sofosbuvir-containing regimens should not be used in patients with severe renal impairment (GRF < 30 mL/min) or end stage renal disease requiring dialysis.

Elbasvir/grazoprevir or ombitasvir/paritaprevir/ritonavir + dasubuvir should not be used in patients with moderate to severe hepatic impairment (CTP and C)

P&T/DUR Review: *5/17(MH); 9/16; 1/16; 5/15; 3/15; 1/15; 9/14; 1/14*
Implementation: *6/1/2017; 2/12/16; 4/15; 1/15*

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

Covered Alternatives:

- Current PMPDP preferred 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: Generic formulations of hydroxyprogesterone caproate are not approved for prevention of preterm birth	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Is the request for generic hydroxyprogesterone caproate?	**Yes:** Go to #5	**No:** Go to #6
5. 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 preferred alternatives in class.	**No**: Approve for 6 months
6. 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

Approval Criteria		
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 through week 37 of gestation or delivery, whichever occurs first (no more than 20 doses).	**No:** Pass to RPh. Deny; medical appropriateness

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

Idiopathic Pulmonary Fibrosis (IPF) Agents

Goal:
- Restrict use of IPF agent to populations in which the drug has demonstrated efficacy.

Length of Authorization:
- Up to 12 months

Requires PA:
- Non-preferred drugs

Preferred Alternatives:
- No preferred alternatives at this time

Approval Criteria		
1. Is this request for continuation of therapy previously approved by the FFS program (patient has already been on IPF drug)?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #2
2. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (ICD-10 J84112)?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness.
3. Is the treatment prescribed by a pulmonologist?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness.
4. Does the patient have a forced vital capacity (FVC) >50%?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness.
5. 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:** Go to #6
6. Are pirfenidone and nintedanib concurrently prescribed in this patient?	**Yes:** Pass to RPh. Deny; medical appropriateness. Safety and efficacy of concomitant therapy has not been established.	**No:** Approve for up to 12 months.

Renewal Criteria		
Is there evidence of disease progression (defined as ≥10% decline in percent-predicted FVC) within the previous 12 months?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Approve for up to 12 months.

Inhaled Corticosteroids (ICS)

Goals:

- Promote use that is consistent with Oregon Asthma Guidelines and the NIH EPR 3 Guidelines on Asthma. See also: http://public.health.oregon.gov/DiseasesConditions/ChronicDisease/Asthma/Pages/index.aspx and http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines/full-report
- 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. Does the patient have a diagnosis of asthma or reactive airway disease (ICD10 J4520-J4522, J45901-45998)?	**Yes:** Go to #7	**No:** Go to #4

Approval Criteria		
4. Does the patient have a diagnosis of COPD (ICD10 J449), chronic bronchitis (ICD10 J410-418, J42, J440-449) and/or emphysema (ICD10 J439)?	**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.
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 Review: *9/16 (KS); 9/15*
Implementation: *10/13/16; 10/9/15*

Initial Pediatric SSRI Antidepressant – Daily Dose Limit

Goals:

- Approve only for covered OHP diagnoses.
- Limit risk of new-onset of deliberate self-harm thoughts and behaviors, or suicidality associated with initiation of antidepressant therapy at above recommended doses

Length of Authorization:

- Up to 12 months

Requires PA:

- Any SSRI in children 0-4 years of age.
- Any daily SSRI dose higher than maximum dose in the table below for patients <25 years of age on date of first antidepressant claim (i.e. no claim for any antidepressant in Specific Therapeutic Classes H2H, H2S, H2U, H7B, H7C, H7D, H7E, H7J, H8P or H8T in the 102 days prior)

GSN	SSRI	Age-specific Maximum Initial Daily Dose (mg)			
		Age range (years)			
		5-9	10-15	16-19	20-24
70991, 46206, 46204, 46203, 46205	citalopram	10	10	20	20
50712, 51642, 51698, 50760	escitalopram	5	10	10	10
46219. 46216, 46217, 47571, 46215, 46214, 46213	fluoxetine	10	10	20	20
46222, 46224. 46225, 46223, 46226, 53387, 53390, 53389, 53388,	paroxetine (immediate release)	10	10	20	20
46229, 46228, 46227, 46230	sertraline	25	25	50	50

Note: Paroxetine extended release and fluvoxamine are restricted to use in adults

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the patient under 5 years of age?	**Yes:** Go to #3	**No:** Go to #4
3. Is the request from a child psychiatrist or was the regimen developed in consultation with a child psychiatrist?	**Yes:** Approve for 12 months	**No:** Pass to RPH; Deny Recommend provider seek a consultation with a child psychiatrist, such as the no-cost/same-day consultation service of OPAL-K. www.ohsu.edu/OPALK

Approval Criteria		
4. Is the patient being treated for funded diagnosis on the OHP List of Prioritized Services?	**Yes:** Go to #5	**No:** Pass to RPH; Deny, (Diagnosis not funded by OHP)
5. Has the patient been treated previously (within the last 6 months) with a SSRI and is the dose at or below the maximum recommended daily dose listed above?	**Yes:** Approve for 12 months.	**No:** Go to #6
6. Is the requested dose above the recommended initial dose listed in the table above for the patient's age (i.e. was the days' supply entered correctly, is the patient's age accurate)?	**Yes:** Pass to RPh. Go to #7.	**No:** Direct Pharmacy to correct and reprocess
7. Are there clinical circumstances that justify an increased dose?	**Yes:** RPh to evaluate on a case-by-case basis.	**No:** Deny for medical appropriateness Recommend provider consider lowering the initial dose and/or seek a consultation with a child psychiatrist, such as the no-cost/same-day consultation service of OPAL-K. www.ohsu.edu/OPALK

P&T/DUR Review: *9/15 (TW); 7/15; 5/15; 11/14*
Implementation: *10/15*

Insulins

Goal:

- Restrict certain insulin products to specific patient populations to ensure appropriate use.

Length of Authorization:

- Up to 12 months

Requires PA:

- Non-preferred insulins
- All pre-filled insulin pens, cartridges and syringes

Covered Alternatives:

- Current PMPDP preferred 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 request for an insulin pen or cartridge?	**Yes:** Go to #4	**No:** Go to #5
4. Is the insulin being administered by the patient or a non-professional caregiver **AND** 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 on 40 units or less of insulin per day • The patient is a child less than 18 years of age?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. 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 Approve insulin pens/cartridges for up to 12 months (other preferred products do not require PA)	**No:** Approve for up to 12 months

P&T /DUR Review: *3/16 (KS); 11/15; 9/10*
Implementation: *10/13/16; 1/1/11*

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:

- Promote use that is consistent with Oregon Asthma Guidelines and the NIH EPR 3 Guidelines on Asthma. See also: http://public.health.oregon.gov/DiseasesConditions/ChronicDisease/Asthma/Pages/index.aspx and http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines/full-report
- 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 (ICD10 J4520-J4522; J45901-45998)?	**Yes:** Go to #6	**No:** Go to #4

Approval Criteria		
4. Does the patient have a diagnosis of COPD (ICD10 J449), chronic bronchitis (ICD10 J410-418; J42; J440-449) and/or emphysema (ICD10 J439)?	**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.
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 Review: *9/16 (KS); 9/15; 5/12; 9/09; 5/09*
Implementation: *10/9/15; 8/12; 1/10*

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

Goals:

- Promote use that is consistent with Oregon Asthma Guidelines and the NIH EPR 3 Guidelines on Asthma. See also: http://public.health.oregon.gov/DiseasesConditions/ChronicDisease/Asthma/Pages/index.aspx and http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines/full-report
- Promote use that is consistent with Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines. See also: http://www.goldcopd.org/guidelines-global-strategy-for-diagnosis-management.html
- 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) or GOLD C/D COPD. 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 prescriber of covered alternatives in class	**No:** Go to #3
3. Does the patient have a diagnosis of asthma or reactive airway disease (ICD10 J4520-J4522, J45901-45998)?	**Yes:** Go to #7	**No:** Go to #4

Approval Criteria		
4. Does the patient have a diagnosis of COPD (ICD10 J449), chronic bronchitis (ICD10 J410-418, J42, J440-449) and/or emphysema (ICD10 J439)?	**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.
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), or alternatively has the patient been assessed with GOLD C/D COPD?	**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 to severe persistent asthma (Step 3 or higher per NIH EPR 3)?	**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 Review: *9/16 (KS); 11/15; 9/15; 11/14; 11/13; 5/12; 9/09; 2/06*
Implementation: *10/13/16; /1/1/16; 1/15; 1/14; 9/12; 1/1*

Long-acting Muscarinic Antagonist/Long-acting Beta-agonist Combination (LAMA/LABA)

Goals:

- Promote use that is consistent with Oregon Asthma Guidelines and the NIH EPR 3 Guidelines on Asthma. See also: http://public.health.oregon.gov/DiseasesConditions/ChronicDisease/Asthma/Pages/index.aspx and http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines/full-report
- Promote COPD therapy that is consistent with Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines. See also: http://www.goldcopd.org/guidelines-global-strategy-for-diagnosis-management.html
- Step-therapy required prior to coverage:
    - COPD: short-acting bronchodilator and previous trial of a long-acting bronchodilator (inhaled anticholinergic or beta-agonist) or GOLD C/D COPD. Preferred LAMA and LABA products do NOT require prior authorization.

Length of Authorization:

- Up to 12 months

Requires PA:

- All LAMA/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 preferred LAMA and LABA products in each class	**No:** Go to #3

Approval Criteria		
3. Does the patient have a diagnosis of asthma or reactive airway disease (ICD10 J4520-J4522, J4540-42, J4550-52, J45901-45998) without COPD?	**Yes:** 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.	**No:** Go to #4
4. Does the patient have a diagnosis of COPD (ICD10 J449), chronic bronchitis (ICD10 J410-418, J42, J440-449) and/or emphysema (ICD10 J439)?	**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.
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. Has the patient been assessed with GOLD C/D COPD?	**Yes:** Approve for up to 12 months. Stop coverage of all other LAMA and LABA inhalers.	**No:** Go to #7
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)?	**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.

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

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	
Diabetic Neuropathy	X
Postherpetic Neuropathy	X
Painful	X

Polyneuropathy	
Spinal Cord Injury Pain	
Chemotherapy Induced Neuropathy	
Non-funded	
Fibromyalgia	

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

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 <150 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/
- Zolpidem and benzodiazepine sedatives are available for short-term use (15 doses/30 days) without PA.

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

Bipolar Disorder	F3010; F302; F3160-F3164; F3177-3178; F319	
Major Depressive Disorder	F314-315; F322-323; F329; F332-333; F339; F3130	For Seroquel XR® only, Adjunctive therapy with antidepressants for Major Depressive Disorder
Schizophrenia	F205; F209; F2081; F2089	
Bipolar Mania	F3010; F339; F3110-F3113; F312	
Bipolar Depression	F3130	

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 150 mg/day? (verify days' supply is accurate)	**Yes**: Go to #3	**No:** Trouble-shoot claim processing with the pharmacy.
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 <150 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: *9/15 (KK); 9/10; 5/10*
Implementation: *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:** Pass to RPh. Deny; not funded by the OHP

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: 3/17(DM)
Implementation: 4/1/17

Mipomersen and Lomitapide

Goal(s):

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

Length of Authorization:

- 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/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the drug prescribed by or in consultation with a specialist in lipid disorders?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Is the diagnosis homozygous familial hypercholesterolemia?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Has the patient tried and failed or does the patient have a medical contraindication to maximum lipid lowering therapy with a combination of traditional drugs (high-intensity statin with ezetimibe (see Table 1)?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Has the patient failed or are they not appropriate for LDL-C apheresis; **OR** is LDL-C apheresis not available?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness

Table 1. High-intensity Statins.

High-intensity Statins (≥50% LDL-C Reduction)	
Atorvastatin 40-80 mg	Rosuvastatin 20-40 mg

Ref. Stone NJ, et al. 2013 ACC/AHA Blood Cholesterol Guideline.

P&T/DUR Review: *11/16 (DM); 5/16; 9/13; 7/13; 5/13*
Implementation: *1/1/17; 1/1/14; 11/21/2013*

Modafinil / Armodafinil

Goal(s):

- 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 OR doses above those in Table 2.

Requires PA:

- Payment for drug claims for modafinil or armodafinil without previous claims evidence of narcolepsy or obstructive sleep apnea (ICD10 G47411; G47419; G4730; G4731; G4733; G4739)

Covered Alternatives:

- Current PMPDP preferred 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™)
Excessive daytime sleepiness in narcolepsy	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
Depression augmentation (unipolar or bipolar)	Not FDA approved; Low level evidence of inconsistent benefit	Not FDA approved; insufficient evidence
Cancer-related fatigue	Not FDA approved; Low level evidence of inconsistent benefit	Not FDA approved; insufficient evidence
Multiple sclerosis-related fatigue	Not FDA approved; Low level evidence of inconsistent benefit	Not FDA approved; insufficient evidence
Drug-related fatigue	Not FDA approved; insufficient evidence	Not FDA approved;
Excessive daytime sleepiness or fatigue related to other neurological disorders (e.g. Parkinson's Disease, traumatic brain injury, post-polio syndrome)	Not FDA approved; insufficient evidence	Not FDA approved; insufficient evidence
ADHD	Not FDA approved; Insufficient evidence	Not FDA approved; insufficient evidence

Cognition enhancement for any condition	Not FDA approved; insufficient evidence	Not FDA approved; insufficient evidence

Table 2. Maximum Recommended Dose (consistent evidence of benefit with lower doses).

Generic Name	Minimum Age	Maximum Daily Dose
armodafinil	18 years	250 mg
modafinil	18 years	200 mg

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
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. Will prescriber consider a preferred alternative?	**Yes:** Inform prescriber of preferred alternatives (e.g., preferred methylphenidate)	**No:** Go to #5
5. Is the request for continuation of therapy previously approved by the FFS program?	**Yes:** Pass to RPh. Go to #13	**No:** Go to #6
6. Is the prescribed daily dose higher than recommended in Table 2?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #7

Approval Criteria		
7. Is diagnosis narcolepsy or obstructive sleep apnea (ICD10 G47411; G47419; G4730; G4731; G4733; G4739) AND is the drug prescribed by, or in consultation with, a sleep specialist or neurologist?	**Yes:** Approve for 90 days and inform prescriber further approval will require documented evidence of clinical benefit.	**No:** Go to #8
8. Is the request for armodafinil?	**Yes:** Pass to RPh. Deny; medical appropriateness. There is insufficient evidence for off-label use.	**No:** Go to #9
9. Is the diagnosis unipolar or bipolar depression?	**Yes:** Approve for 90 days and inform prescriber further approval will require documented evidence of clinical benefit.	**No:** Go to #10
10. Is the diagnosis 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.	**No:** Go to #11
11. Is the diagnosis ADHD?	**Yes:** Pass to RPh. Deny; medical appropriateness. There is insufficient evidence for benefit for ADHD. See available options at www.orpdl.org/drugs/	**No:** Go to #12
12. All other diagnoses must be evaluated as to the OHP-funding level and evidence for clinical benefit. • Evidence supporting treatment for excessive daytime sleepiness 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.		

Approval Criteria
13. Continuation of therapy requires submission of documented evidence of clinical benefit and tolerability (faxed copy or equivalent). The same clinical measure (eg, Epworth score, Brief Fatigue Inventory, or other validated measure) used to diagnose fatigue or depression is recommended to document clinical benefit. • Approve up to 12 months with chart documentation of positive response. • Deny for “medical appropriateness” in absence of documented benefit.

P&T Review: *03/16; 09/15*
Implementation: *8/16, 1/1/16*

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:

- Omalizumab
- Mepolizumab
- Reslizumab

Covered Alternatives:

- Current PMPDP preferred 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
Breo Ellipta (fluticasone/vilanterol)	200/25 mcg daily
Dulera (mometasone/formoterol)	400/10 mcg BID

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 claim for reslizumab in a patient under 18 years of age?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #4

Approval Criteria		
4. Is the claim for mepolizumab in a patient under 12 years of age?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #5
5. Is the diagnosis an OHP-funded diagnosis? Note: chronic urticaria is not an OHP-funded condition	**Yes:** Go to #6	**No:** Pass to RPh. Deny; not funded by the OHP.
6. Is the prescriber a pulmonologist or an allergist who specializes in management of severe asthma?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness.
7. Has the patient required at least 2 hospitalizations or 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, aminophylline, theophylline)?	**Yes:** Go to #8 Document number of hospitalizations or ED visits for asthma exacerbation in past 12 months: _____. This is the baseline value to compare to in renewal criteria.	**No:** Pass to RPh. Deny; medical appropriateness.
8. Has the patient been adherent to current asthma therapy in the past 12 months?	**Yes:** Go to #9	**No:** Pass to RPh. Deny; medical appropriateness.
9. Is the patient currently receiving another monoclonal antibody for asthma (e.g., omalizumab, mepolizumab or reslizumab)?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #10
10. 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 #11
11. If the claim is for mepolizumab or reslizumab, can the prescriber provide documentation of eosinophilic phenotype, confirmed by blood eosinophil count ≥300 cells/μL in the past 12 months?	**Yes:** Approve once every 4 weeks for up to 12 months. Document eosinophil count (date):_____	**No:** Pass to RPh. Deny; medical appropriateness.

Renewal Criteria		
1. Is the patient currently taking a maximally-dosed inhaled corticosteroid and 2 additional controller drugs (i.e., long-acting inhaled beta-agonist, montelukast, zafirlukast, aminophylline, theophylline)?	**Yes:** Go to #2	**No:** Pass to RPh. Deny; medical appropriateness.
2. 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.

P&T Review: *7/16*
Implementation: *8/16*

Oral Multiple Sclerosis Drugs

Goal(s):
- Promote safe and effective use of oral disease-modifying multiple sclerosis drugs
- Promote use of preferred multiple sclerosis drugs.

Length of Authorization:
- Up to 12 months

Requires PA:
- Fingolimod
- Teriflunomide
- Dimethyl Fumarate

Covered Alternatives:
- Current PMPDP preferred 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 relapsing remitting multiple sclerosis?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by the OHP. See Guideline Note 95 in the Prioritized List of Health Services.
3. 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 #4
4. Has the patient failed or cannot tolerate a trial of interferon beta 1a or interferon beta 1b, and glatiramer?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness.
5. Is the medication being prescribed by or in consultation with a neurologist?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness.
6. Is the patient on concurrent treatment with a disease modifying drug (i.e. interferon beta 1B, glatiramer acetate, interferon beta 1A, natalizumab, mitoxantrone)?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #7
7. Is the prescription for teriflunomide?	**Yes:** Go to #8	**No:** Go to #10

Approval Criteria		
8. Is the patient of childbearing potential?	**Yes:** Go to #9	**No:** Approve for up to 1 year.
9. Is the patient currently on a documented use of reliable contraception and is there documentation of a negative pregnancy test prior to initiation of teriflunomide?	**Yes:** Approve for up to 1 year.	**No:** Pass to RPh. Deny; medical appropriateness.
10. Is the prescription fingolimod?	**Yes:** Go to #11	**No:** Go to #14
11. Does the patient have evidence of macular edema?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #12
12. Does the patient have preexisting cardiac disease, risk factors for bradycardia, or is on anti-arrhythmic, beta-blockers, or calcium channel blockers?	**Yes:** Go to #13	**No:** Approve up to 1 year.
13. Has the patient had a cardiology consultation before initiation (see clinical notes)?	**Yes:** Approve up to 1 year.	**No:** Pass to RPh. Deny; medical appropriateness.
14. Is the prescription for dimethyl fumarate?	**Yes:** Go to # 15	**No:** Pass to RPh. Deny; medical appropriateness.
15. Does patient have a baseline CBC with lymphocyte count greater than 500/µL?	**Yes:** Approve for up to 1 year	**No:** Pass to RPh. Deny; medical appropriateness.

Fingolimod Clinical Notes:

- Because of bradycardia and atrioventricular conduction, patients must be observed for 6 hours after initial dose in a clinically appropriate area.
- 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 with caution. A cardiology evaluation should be performed before considering treatment.
- Injectable disease modifying treatments remain first-line agents in MS therapy.
- An ophthalmology evaluation should be repeated 3-4 months after fingolimod initiation with subsequent evaluations based on clinical symptoms.

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 women 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 feriflunomide, monitor ALT levels at least monthly for 6 months. Consider additional ALT monitoring when feriflunomide is given with other potentially hepatotoxic drugs. Consider stopping feriflunomide if serum transaminase levels increase (>3-times the ULN). 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.

Dimethyl Fumarate Clinical Notes:

- Dimethyl fumarate 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 fumurate or placebo, respectively. There was no increased incidence of serious infections observed in patients with lymphocyte counts <0.8 $x10^3$ cells/mm^3. A transient increase in mean eosinophil counts was seen during the first 2 months of therapy.
- Dimethyl fumarate 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 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 on a quarterly basis

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P&T/DUR Review: *11/16 (DM); 9/15; 9/13; 5/13; 3/12*
Implementation: *TBD; 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*

New Drug Policy

Goal:

- Restrict coverage of selected new drugs until the Oregon Pharmacy & Therapeutics Committee can review the drug for appropriate coverage.

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, in a class where existing prior authorization policies exist or that is used for a non-funded condition on the Oregon Health Plan (OHP) List of prioritized services.

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. 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: *11/15 (AG); 12/09*
Implementation: *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 12 months

Requires PA:

- Nusinersen

Covered Alternatives:

- Current PMPDP preferred 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 this a request for continuation of therapy?	**Yes**: Deny; Refer request for renewal of therapy to DMAP medical director for review.	**No:** Go to #3
3. Does the patient have Spinal Muscular Atrophy (SMA) documented by genetic testing?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness.
4. Is the drug being prescribed by a neurologist or a provider with experience treating spinal muscular atrophy?	**Yes:** Approve up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness.

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

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: http://www.oregon.gov/oha/healthplan/Pages/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: http://www.oregon.gov/oha/healthplan/Pages/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: http://www.oregon.gov/oha/healthplan/Pages/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: http://www.oregon.gov/oha/healthplan/Pages/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: http://www.oregon.gov/oha/healthplan/Pages/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: http://www.oregon.gov/oha/healthplan/Pages/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 primary biliary cholangitis?	**Yes**: Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Does the patient have no evidence of complications from cirrhosis or hepatic decompensation (e.g., MELD score less than 15; not awaiting transplant; no portal hypertension; or no hepatorenal syndrome)?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Is the total bilirubin level less than 2-times the upper limit of normal (ULN)?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Does patient have a documented intolerance or contraindication to ursodiol?	**Yes:** Document symptoms of intolerance or contraindication and approve for up to 12 months	**No:** Go to #7

Approval Criteria		
7. Has patient had a 12-month trial of ursodiol with inadequate response to therapy (ALP ≥1.67-times the ULN or total bilirubin greater than the ULN)?	**Yes**: Document baseline ALP and total bilirubin level and appprove for up to 12 months ALP:_____ units/L Total Bilirubin _____ mg/dL	**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 and approve for up to 12 months ALP:_____ units/L Total Bilirubin _____ mg/dL	**No**: Pass to RPh. Deny; medical appropriateness

P&T / DUR Review: *01/17 (SS)*
Implementation: *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: *3/17 (SS)*
Implementation: *TBD*

Omega-3 Fatty Acids

Goal(s):
- Restrict use of omega-3 fatty acids to patients at increased risk for pancreatitis.

Length of Authorization:
- Up to 12 months

Requires PA:
- Omega-3-Acid Ethyl Esters (Lovaza®)
- 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:** Pass to RPh. Deny; medical appropriateness.
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).

Table 1: Dosing of Fenofibrate and Derivatives for Hypertriglyceridemia.

Trade Name (generic)	Recommended dose	Maximum dose
Antara (fenofibrate capsules)	43-130 mg once daily	130 mg once daily
Fenoglide (fenofibrate tablet)	40-120 once daily	120 mg once daily
Fibricor (fenofibrate tablet)	25-105 mg once daily	105 mg once daily
Lipofen (fenofibrate capsule)	50-150 mg once daily	150 mg once daily
Lofibra (fenofibrate capsule)	67-200 mg once daily	200 mg once daily
Lofibra (fenofibrate tablet)	54-160 mg once daily	160 mg once daily
Lopid (gemfibrozil tablet)	600 mg twice daily	600 mg twice daily
Tricor (fenofibrate tablet)	48-145 mg once daily	145 mg once daily
Triglide (fenofibrate tablet)	50-160 mg once daily	160 mg once daily
Trilipix (fenofibrate DR capsule)	45-135 mg once daily	135 mg once daily

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

Opioid Analgesics

Goals:

- Restrict use of opioid analgesics to OHP-funded conditions with documented sustained improvement in pain and function and with routine monitoring for opioid misuse and abuse.
- Promote the safe use of 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.
- Limit the use of non-preferred opioid analgesic products.

Length of Authorization:

- 3 to 12 months (criteria-specific)

Covered Alternatives:

- Current PMPDP preferred 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 non-preferred opioids and opioid combination products.
- Any opioid listed in Table 1 or opioid combination product that contains an opioid listed in Table 1 that exceeds 90 morphine milligram equivalents (MME) per day.
- Any opioid product listed in Table 2 that exceeds quantity limits.

Note:

- Preferred opioid products that do not exceed 90 MME per day are exempt from this PA.
- Patients on palliative care with a terminal diagnosis or with cancer-related pain (ICD10 C6900-C799; C800-C802) are exempt from this PA.
- This PA does not apply to pediatric use of codeine products, which is subject to separate clinical PA criteria.

Table 1. Daily Dose Threshold (90 MME/day) of Opioid Products.

Opioid	90 MME/day	Notes
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.)
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 ER	300 mg	300 mg/day is max dose and is not equivalent to 90 MME/day.
Tramadol IR	400 mg	300 mg/day is max dose and is not equivalent to 90 MME/day.
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.

Abbreviations: ER = extended-release or sustained-release formulation(s); IR = immediate-release formulation(s); MME = morphine milligram equivalent.

Table 2. Specific Opioid Products Subject to Quantity Limits per FDA-approved Labeling.

Drug Product	Quantity Limit
AVINZA	1 dose/day
BELBUCA	2 doses/day
BUTRANS	1 patch/7 days
CONZIP	1 dose/day
DURAGESIC	1 patch/72 hr
EMBEDA	2 doses/day
EXALGO	1 dose/day

Drug Product	Quantity Limit
HYSINGLA	1 dose/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
ULTRAM ER	1 dose/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	
2. Is the request for renewal of current therapy previously approved by the FFS program?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #3
3. Is the requested medication a preferred agent?	**Yes:** Go to #5	**No:** Go to #4
4. 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. Both oral and transdermal options are available.	**Yes:** Inform prescriber of covered alternatives in class.	**No:** Go to #5
5. Is the patient being treated for cancer-related pain (ICD10 G89.3) or under palliative care services (ICD10 Z51.5) with a life-threatening illness or severe advanced illness expected to progress toward dying?	**Yes:** Approve for up to 12 months	**No:** Go to #6
6. Is the diagnosis funded by the OHP?	**Yes:** Go to #7	**No:** Pass to RPh. Go to #15
7. Is the opioid prescription for pain associated with a back or spine condition or for migraine headache?	**Yes:** Pass to RPh. Go to #15	**No:** Go to #8

8. Will the prescriber change to a preferred product, not to exceed 90 MME per day and not to exceed quantity limits in Table 2? Note: Preferred products that do not exceed 90 MME per day and do not exceed quantity limits in Table 2 do not require prior authorization.	**Yes:** Inform prescriber of covered alternatives in class.	**No:** Go to #9
9. Does the total daily opioid dose exceed 90 MME?	**Yes:** Pass to RPh. Go to #15	**No:** Go to #10
10. Is the patient concurrently on other short- or long-acting opioids (patients are permitted to be on only one opioid product total at a time)?	**Yes:** Pass to RPh. Go to #15	**No:** Go to #11
11. Does the prescription exceed quantity limits applied in Table 2 (if applicable)?	**Yes:** Pass to RPh. Go to #15	**No:** Go to #12
12. Can the prescriber provide documentation of sustained improvement of both pain and function in the past 3 months compared to baseline (e.g., validated tools to assess function include: Oswestry, Neck Disability Index, SF-MPQ, and MSPQ)?	**Yes:** Go to #13	**No:** Pass to RPh. Go to #15
13. Is the prescriber enrolled in the Oregon Prescription Drug Monitoring Program (PDMP) and has the prescriber verified at least once in the past 3 months that the patient has been prescribed analgesics by only a single prescribing practice or prescriber and has received those analgesics by only a single pharmacy?	**Yes:** Go to #14	**No:** Pass to RPh. Go to #15
14. Has the patient had a urinary drug screen (UDS) within the past 1 year to verify absence of illicit drugs and non-prescribed opioids?	**Yes:** Approve for up to 3 months. Subsequent approvals will require: ☐ Verification of patient's opioid claims history in the Oregon PDMP at least every 3 months ☐ Documentation of sustained improvement in both baseline pain and function at least every 3 months ☐ Documented UDS at least every 12 months	**No:** Pass to RPh. Go to #15

15. Is the request to initiate new opioid therapy or to increase the total daily MME dose?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Pass to RPh. Approve for 3 months. Note: Documentation of progress towards meeting all criteria in this PA will be required for approval of subsequent claims. All future opioid claims are subject to **Renewal Criteria** 3 months from this index claim.

Renewal Criteria		
1. Has the patient had a urinary drug screen (UDS) within the past 1 year to verify absence of illicit drugs and non-prescribed opioids?	**Yes:** Go to #2	**No:** Pass to RPh. Deny; medical appropriateness
2. Is the prescriber enrolled in the Oregon Prescription Drug Monitoring Program (PDMP) and has the prescriber verified at least once in the past 3 months that the patient has been prescribed analgesics by only a single prescribing practice or prescriber and has received those analgesics by only a single pharmacy?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Can the prescriber provide documentation of sustained improvement of both pain and function in the past 3 months compared to baseline (e.g., validated tools to assess function include: Oswestry, Neck Disability Index, SF-MPQ, and MSPQ)?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Does the prescription exceed quantity limits applied in Table 2 (if applicable)?	**Yes:** Approve for up to 3 months if there is documentation of an individualized taper plan with progress to meet the quantity limits applied in Table 2.	**No:** Go to #5 if not applicable. Without documentation, pass to RPh. Deny; medical appropriateness.

Renewal Criteria		
5. Is the patient concurrently on other short- or long-acting opioids (patients are permitted to be on only one opioid product total at a time)?	**Yes:** Approve for up to 3 months if there is documentation of an individualized taper plan with progress to be managed on one short- or long-acting opioid only.	**No:** Go to #6 if not applicable. Without documentation, pass to RPh. Deny; medical appropriateness.
6. Does the total daily opioid dose exceed 90 MME?	**Yes:** Approve for up to 3 months if there is documentation of an individualized taper plan with progress toward meeting ≤90 MME per day.	**No:** Go to #7 if not applicable. Without documentation, pass to RPh. Deny; medical appropriateness.
7. Is the diagnosis funded by the OHP?	**Yes:** Approve for up to 3 months. Subsequent approvals will require: • Verification of patient's opioid claims history in the Oregon PDMP at least every 3 months • Documentation of sustained improvement in both baseline pain and function at least every 3 months • Documented UDS at least every 12 months	**No:** Approve for up to 3 months if there is documentation of an individualized taper plan with progress toward tapering off opioid. Without documentation, pass to RPh. Deny; medical appropriateness.

Clinical Notes:

How to Discontinue Opioids.

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)

Selecting the optimal timing and approach to tapering depends on multiple factors. The rate of opioid taper should be based primarily on safety considerations, and special attention is needed for patients on high dose opioids, 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 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 the rate of taper based on safety considerations:

a. Immediate discontinuation 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. Start with a taper of ≤10% of the original dose per week 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 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.
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/DUR Review: *05/16 (AG)*
Implementation: *1/1/17; 7/1/16*

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:

- 90 days to 6 months

Requires PA:

- Ivacaftor (Kalydeco®)
- Lumacaftor/Ivacaftor (Orkambi®)

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. Is this a request for continuation of therapy previously approved by the FFS program (patient already on ivacaftor or lumacaftor/ivacaftor)?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #2
2. What diagnosis is being treated?	Record ICD10 code. Go to #3	
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. 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 #5	
5. Is the request for ivacaftor?	**Yes:** Go to #6	**No:** Go to #10
6. What is the patient's baseline sweat chloride level?	Prescriber must provide documentation before approval. Document baseline value. Go to #7	
7. Does the patient have a diagnosis of cystic fibrosis and is 2 years of age or older?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
8. Does the patient have a documented G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R mutation in the CFTR gene detected by an FDA-cleared CF mutation test?	**Yes:** Go to #14	**No:** Go to #9 If unknown, there needs to be a FDA-approved 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).
9. Does the patient have a documented R117H mutation in the CFTR gene detected by an FDA-cleared 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:** Pass to RPh. Deny; medical appropriateness. If unknown, there needs to be a FDA-approved 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).
10. Is the request for lumacaftor/ivacaftor?	**Yes:** Go to #11	**No:** Pass to RPh. Deny; medical appropriateness
11. Does the patient have a diagnosis of cystic fibrosis and is 6 years of age or older?	**Yes:** Go to #12	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
12. Does the patient have a documented homozygous Phe508del mutation in the CFTR gene detected by an FDA-approved CF mutation test?	**Yes:** Go to #13	**No:** Pass to RPh. Deny; medical appropriateness If unknown, there needs to be a FDA-approved 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 those who are heterozygous for the F508del mutation)
13. Is a baseline FEV1 is provided and is between ≥40% and ≤90% of predicted normal for age, sex and height for those ≥12 years of age and at least 40% for children ages 6 through 11 years?	**Yes:** If the patient is younger than 12 years of age, refer case to OHP Medical Director; otherwise, Go to #14	**No:** Pass to RPh. Deny; medical appropriateness If no baseline, request a baseline value before approving therapy.
14. 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 #15	**No:** Pass to RPh. Deny; medical appropriateness
15. Is the patient on concomitant therapy with a strong CYP3A4 inducer (see Table 1)?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #16
16. What are the baseline liver function (AST/ALT) and bilirubin levels (within previous 3 months)?	Document labs. Go to #17	

Approval Criteria		
17. Is medication dosed appropriately based on age, weight, and co-administered drugs (see dosing and administration below)?	**Yes:** Approve for 90 days. Note: Approve for 90 days to allow time for patient to have a sweat chloride test done after 30 days of treatment if on ivacaftor (see **Renewal Criteria**)	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Is this the first time the patient is requesting a renewal (after 90 days of initial approval)?	**Yes:** Go to #2	**No:** Go to #4
2. If prescription is for ivacaftor: Does the patient have a documented physiological response to therapy and evidence of adherence after 30 days of treatment, as defined by a sweat chloride test that has decreased by at least 20 mmol/L from baseline?	**Yes:** Go to #7	**No:** Go to #3 Consider patient's adherence to therapy and repeat test in 2 weeks to 45 days to allow for variability in test. If sodium chloride has still not decreased by 20 mmol/L, deny therapy for medical appropriateness
3. If the prescription is for lumacaftor/ivacaftor: Is there evidence of adherence and tolerance to therapy through pharmacy claims/refill history and provider assessment?	**Yes:** Go to #7	**No:** Pass to RPh; Deny (medical appropriateness)

Renewal Criteria		
4. 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; OR • Sweat chloride test has decreased from baseline by 20 mmol/L from baseline?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Has the patient been compliant with therapy, as determined by refill claims history?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. 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 #7 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.	
7. Is the CFTR modulator dosed appropriately based on age, weight, and co-administered drugs (see dosing and administration below)?	**Yes:** Approve for additional 3 months (total of 6 months since start of therapy)	**No:** Pass to RPh. Deny; medical appropriateness

Dosage and Administration:

<u>Ivacaftor:</u>

- Adults and pediatrics age ≥6 years: 150 mg orally every 12 hours with fat-containing foods
- Children age 2 to <6 years:

- < 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 2 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.
- Dose adjustment with concomitant medications:

Table 1. Examples of CYP3A4 inhibitors and inducers.

Drug co-administered with ivacaftor	Co-administered drug category	Recommended dosage adjustment for ivacaftor
Ketoconazole Itraconazole Posaconazole Voriconazole Clarithromycin Telithromycin	CYP3A4 strong inhibitors	Reduce ivacaftor 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 ivacaftor 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 Grapefruit Juice	CYP3A4 strong inducers	Concurrent use is **NOT** recommended

<u>Lumacaftor/ivacaftor:</u>

- Adults and pediatrics age ≥12 years: 2 tablets (lumacaftor 200 mg/ivacaftor 125 mg) every 12 hours
- Pediatric patients age 6 through 11 years: 2 tablets (lumacaftor 100mg/ivacaftor 125 mg) every 12 hours
- Hepatic impairment
  - Moderate impairment (Child-Pugh class B):
    - 2 tablets in the morning and 1 tablet in the evening
  - Severe impairment (Child-Pugh class C): Use with caution at a dose of 1 tablet twice daily, or less, after weighing the risks and benefits of treatment.
- 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.

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.

Length of Authorization:

- Based on individual factors; may extend up to 5 months (5 doses)

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 immunoprophylaxis between the months of November and March?	**Yes:** Go to #5	**No:** Go to #4
4. Is the request for immunoprophylaxis starting in October due to an early onset* of the RSV season in the region from which the patient resides (see below)? * Onset is defined as 2 consecutive weeks where % positive is ≥10%, (data are 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.

Region	Counties
NW Oregon – SW Washington	Benton, Clackamas, Clatsop, Columbia, Lane, Lincoln, Linn, Marion, Multnomah, Polk, Tillamook, Washington, Yamhill
Central Oregon	Crook, Deschutes, Grant, Harney, Jefferson, Wheeler
Columbia Gorge – NE Oregon	Baker, Gilliam, Hood River, Morrow, Sherman, Umatilla, Union, Wasco, Wallowa
Southern Oregon	Coos, Curry, Douglas, Jackson, Josephine, Klamath, Lake, Malheur

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 BIRTH DATE and GROUP based on start of RSV season:

- Immunoprophylaxis between November - March refer to **Table 1**
- Immunoprophylaxis starting in October based on above (#4) refer to **Table 2**

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 (based on criteria group from above)
Beginning **NOVEMBER 1**

MONTH OF BIRTH	ALL GROUPS
November 1 – March 31	5
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.

Table 2. Maximum Number of Doses for RSV Prophylaxis (based on criteria group from above) Beginning **OCTOBER 1**

MONTH OF BIRTH	ALL GROUPS
November 1 – March 31	5
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: *11/16 (DE); 9/14; 5/11; 5/12*
Implementation: *1/1/17; 3/30/12*

Patiromer

Goals:

- Restrict use of patiromer 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.
- Encourage use to optimize medications with demonstrated evidence of mortality reduction in heart failure with reduced ejection fraction.

Length of Authorization:

- 6 to 12 months

Requires PA:

- Patiromer

Covered Alternatives:

- Current PMPDP preferred 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)?	**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. Has the patient tried and failed or cannot tolerate sodium polystyrene?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Does the patient have hyperkalemia requiring emergency intervention (serum potassium ≥6.5 mEq/L)?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #6
6. Does the patient have hypomagnesemia (serum magnesium < 1.4 mg/dL)?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #7

Approval Criteria		
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, severe constipation)?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Approve up to 6 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 12 months	**No:** Pass to RPh. Deny; medical appropriateness

P&T Review: *05/16 (EL/MH)*
Implementation: *8/16, 7/1/16*

PCSK9 Inhibitors

Goal:
- Restrict use of PCSK9 inhibitors to populations in which the drugs have demonstrated efficacy.

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 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	
3. Does the patient have clinical atherosclerotic CV disease, defined as documented history of ≥1 of the following: • Myocardial infarction; OR • Unstable angina; OR • Coronary revascularization procedure (PCI or CABG); OR • Diagnosis of clinically significant coronary heart disease by coronary angiography, stress test using treadmill, stress echocardiography or nuclear imaging?	**Yes:** Go to #4	**No:** Go to #6
4. Has the patient taken a daily high-intensity statin (see table below) and ezetimibe 10 mg daily for at least 12 months with <50% LDL-C reduction? Prescriber to submit chart documentation of: 1) Doses and dates initiated of statin and ezetimibe; 2) Baseline LDL-C (untreated); 3) Recent LDL-C (within last 12 weeks).	**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

Approval Criteria		
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; medical appropriateness
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? 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:** Go to #7
7. Does the patient have a diagnosis of homozygous or heterozygous familial hypercholesterolemia and already takes a maximally tolerated statin and/or ezetimibe? Note: Prescriber must provide chart documentation of diagnosis and recent LDL-C (within last 12 weeks).	**Yes:** Document diagnosis and approve for up to 12 months Recent LDL-C _____ mg/dL Date:_____	**No:** Pass to RPh. Deny; 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. 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; medical appropriateness

High- and Moderate-intensity Statins. Stone NJ, et al. 2013 ACC/AHA Blood Cholesterol Guideline.

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 mg	Pitavastatin 2-4 mg Pravastatin 40-80 mg Simvastatin 20-40 mg Rosuvastatin 5-10 mg

References:
1. NICE Clinical Guideline 181. Lipid modification: CV risk assessment and the modification of blood lipids for the primary and secondary prevention of CV disease. Available at: guidance.nice.org.uk/cg181. Accessed 18 September 2015.
2. Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic CV Risk in Adults. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2013;129(25 Suppl 2):S1-45. doi: 10.1161/01.cir.0000437738.63853.7a.

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

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*

Peginterferon Beta-1a (Plegridy®)

Goal(s):
- Approve therapy for covered diagnosis which are supported by the medical literature.

Length of Authorization:
- Up to 12 months

Requires PA:
- Non-preferred drugs

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

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Does the patient have a diagnosis of relapsing-remitting 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. Additional information can be found at www.orpdl.org.	**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: *9/23/14 (KS)*
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*

Phosphate Binders

Goal(s):
- Promote use of preferred drugs.
- Reserve non-calcium-based phosphate binders for second-line therapy.

Length of Authorization:
- Up to 12 months

Requires PA:
- Non-preferred phosphate binders
- Preferred non-calcium-based 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: *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: *01/2017 (SS)*
Implementation: *4/1/17*

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

Covered Alternatives

- Current PMPDP preferred 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. Does the patient have a diagnosis of epilepsy?	**Yes:** Approve for lifetime	**No:** Go to # 4
4. Is the diagnosis an OHP-funded diagnosis with evidence supporting its use in that condition (see Table 1 below for examples)?	**Yes:** Go to # 5	**No:** Pass to RPh. Deny; not funded by the OHP.
5. 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. OHP Funded Diagnosis and Evidence Supports Drug Use in Specific Indication

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

P&T Review: *3/17 (DM)*
Implementation: *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 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 #6	No: Go to #7

6. Does the patient have recurrent, symptomatic erosive esophagitis that has resulted in previous emergency department visits or hospitalizations?	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 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
Achalasia and cardiospasm (K220) Barrett's esophagus (K22.70; K22.71x) Duodenal Ulcer (K260-K269) Dyskinesia of esophagus (K224) Esophageal hemorrhage (K228) Gastritis and duodenitis (K2900-K2901; K5281) Gastroesophageal laceration-hemorrhage syndrome (K226) Gastric Ulcer (K250-K259) 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) Peptic ulcer site unspecified (K270-K279) Perforation of Esophagus (K223) Stricture & Stenosis of Esophagus (K222) Zollinger-Ellison (E164)	1 year	

*A current list of funded conditions is available at: http://www.oregon.gov/oha/herc/Pages/PrioritizedList.aspx
† Dexlansoprazole SoluTab 30 mg (given as 2 SoluTabs at once) are not recommended for healing of erosive esophagitis.

P&T / DUR Review: *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: *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*

Oral/Inhaled Pulmonary Arterial Hypertension Agents

Goals:

- Restrict use to patients with pulmonary arterial hypertension (PAH) and World Health Organization (WHO) Functional Class II-IV symptoms.
- 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 is the diagnosis?	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 there a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)?	**Yes:** Go to #8	**No:** Go to #5
5. Is there a diagnosis of chronic thromboembolic pulmonary hypertension (WHO Group 4)?	**Yes:** Go to #6	**No:** Go to #10
6. Is the request for riociguat (Adempas®)?	**Yes:** Go to #7	**No:** Go to #10
7. Is the patient classified as having World Health Organization (WHO) Functional Class II-IV symptoms?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness.
8. Will the prescriber consider a change to a preferred product?	**Yes:** Inform prescriber of preferred alternatives in	**No:** Go to #9

Note: preferred products do not require PA.	class.	
9. Is the patient classified as having World Health Organization (WHO) Functional Class II-IV symptoms?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness.
10. 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: *3/16 (AG); 7/14; 3/14; 2/12; 9/10*
Implementation: *10/13/16; 5/1/16; 5/14/12; 1/24/12; 1/1/11*

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)?	**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: *3/16 (AG); 9/12*
Implementation: *10/13/16; 1/1/13*

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*

Repository Corticotropin Injection (Acthar Gel®)

Goal(s):
- To ensure appropriate drug use and limit to patient populations in which corticotropin has been shown to be effective and safe.

Length of Authorization:
- 4 weeks

Requires PA:
- Repository Corticotropin Injection (Acthar Gel®)

Covered Alternatives:
- Current PMPDP preferred 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 (ICD10 G40821-G40824)?	**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 (ICD10 G35)?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Has the patient tried and been unable to tolerate IV methylprednisolone or oral high-dose 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 (ICD10 L4054; L4059; M069; M0800; M459; M3210); **OR** • The following collagen diseases: systemic lupus erythematosus or systemic deramtomyositis (ICD10 M3210; M3390; M3320); **OR** • Dermatologic diseases such as erythema multiforme or Stevens-Johnson syndrome (ICD10 L510; L519; L511; L513); **OR** • Ophthalmic diseases such as keratitis, iritis, uveitis, optic neuritis, or chorioretinitis (ICD10 H2000; H20019; H20029; H20039; H20049; H20059; H2013; H209; H20819; H4040X0; H2023; H20829; H209; H469; H3093); **OR** • For the treatment of respiratory diseases, including symptomatic sarcoidosis or for treatment of an edematous state (ICD10 R600; R601; R609)?	**Yes:** Go to #6	**No:** Go to #6
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: *5/30/13 (MH)*
Implementation: *5/1/16; 1/1/14*

Rifaximin (Xifaxan®)

Goal:

- Restrict use of rifaximin to OHP-funded conditions and in populations in which the drug has demonstrated efficacy.

Length of Authorization:

- Up to 12 months

Requires PA:

- Rifaximin

Covered Alternatives:

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

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the treating diagnosis prevention or treatment of hepatic encephalopathy (K7290, K7291)?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by OHP or for medical appropriateness
3. Is the patient currently managed with a regularly scheduled daily regimen of lactulose?	**Yes:** Go to #5	**No:** Go to 4
4. Does the patient have a contraindication to lactulose?	**Yes:** Go to #5	**No:** Pass to RPh Deny; medical appropriateness Note: studies demonstrate effectiveness of rifaximin as add-on therapy to lactulose.
5. Is the patient currently prescribed a benzodiazepine drug?	**Yes:** Go to #6	**No:** Approve for up to 12 months
6. 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.

P&T/DUR Review: *7/15; 5/15 (AG)*
Implementation *10/15; 8/15*

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: *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 (GOLD 3) or very severe (GOLD 4) COPD?	**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:** Approve for up to 12 months	**No:** Pass to RPh. Deny; recommend trial of preferred long-acting bronchodilator and ICS

P&T/DUR Review: *9/15 (KS); 5/13; 2/12*
Implementation: *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:
- 60 days 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.	
3. Does the patient have stable New York Heart Association Class II or III heart failure with reduced ejection fraction less than 40% (LVEF <40%)?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Has the patient tolerated a minimum daily dose an ACE-inhibitor or ARB listed in Table 1 for at least 30 days?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. 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:** Approve for up to 60 days	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Is the patient currently taking sacubitril/valsartan at the target dose of 97/103 mg 2-times daily?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh and go to #2
2. What is the clinical reason the drug has not been titrated to the target dose of 97/103 mg 2-times daily?	Document rationale and approve for up to 60 days. Prior authorization required every 60 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	• 50 mg TID	• Candesartan	• 32 mg QDay
• Enalapril	• 10 mg BID	• Losartan	• 150 mg QDay
• Lisinopril	• 20 mg QDay	• Valsartan	• 160 mg BID
• Ramipril	• 5 mg BID	•	•
• Trandolapril	• 4 mg QDay	•	•

- 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 in order to improve chances of tolerability to the target maintenance dose of sacubitril/valsartan 97/103 mg 2-times daily.[3]
- Valsartan formulated in the target maintenance dose of sacubitril valsartan 97/103 mg 2-times daily is bioequivalent to valsartan 160 mg 2-times daily.[4]
- ACE-inhibitors and ARBs listed have demonstrated efficacy in heart failure with or without myocardial infarction.[1,2]
- Target daily doses of other ACE-inhibitors and ARBs for heart failure have not been established.[1,2]
- 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]

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.
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, July 2015.

P&T / DUR Review: *05/17(DM), 09/15*
Implementation: *10/13/16; 10/1/15*

Sapropterin

Goal(s):

- Promote safe and cost effective therapy for the treatment of phenylketonuria.

Length of Authorization:

- Initial: 1 to 2 months; Renewal: 1 year

Covered Alternatives:

- Current PMPDP preferred 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 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 diagnosis tetrahydrobiopterin-(BH4-) responsive phenylketonuria?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
5. Is the patient currently compliant with a Phe-restricted diet and unable to achieve target blood phenylalanine level?	**Yes:** Go to #6	**No:** Pass to RPh. Deny and recommend Phe-restricted diet.
6. 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.

Renewal Criteria		
1. Did the patient meet the target phenylalanine level set by the specialist (see Clinical Notes)?	**Yes:** Go to #2	**No:** Pass to RPh. Deny for lack of treatment response.
2. Is the patient remaining compliant with the Phe-restricted diet?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny and recommend Phe-restricted diet.

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 nonresponder and will not benefit from sapropterin therapy.

Doses above 20 mg/kg/day have not been studied in clinical trials.

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: *5/16 (DM); 11/13; 9/13; 7/13*
Implementation: *8/16; 1/1/14*

Sedatives

Goal(s):

- 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, benzodiazepines, and opioids.
- Restrict long-term sedative use to due to insufficient evidence and to limit adverse effects.
- Limit zolpidem use the maximum FDA recommended daily dose based on gender.

Length of Authorization:

- Up to 12 months (criteria specific)

Requires PA:

- All sedatives
- Concomitant use of more than one benzodiazepine, more than one non-benzodiazepine sedative, or the combination of a benzodiazepine and non-benzodiazepine sedative in the prior 30 days.
- Sedatives that exceed a total quantity of 30 doses within 60 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/

Zolpidem Daily Quantity Limits

Generic	Brand	Max Daily Dose	
		Male	Female
Zolpidem IR	Ambien	10 mg	5 mg
Zolpidem ER	Ambien CR	12.5 mg	6.25 mg

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. 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 #3
3. 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 #4
4. Does patient have diagnosis of insomnia with obstructive sleep apnea?	**Yes:** Go to #5	**No:** Go to #6

Approval Criteria		
5. Is patient on CPAP?	**Yes:** Approve for up to 12 months.	**No:** Pass to RPh. Deny; medical appropriateness. Sedative/hypnotics, due to depressant effect, are contraindicated.
6. 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:** Go to #7
7. Has the patient been treated with another non-benzodiazepine sedative, benzodiazepine, or opioid within the past 30 days?	**Yes:** Go to #8	**No:** Pass to RPh; Go to #9
8. 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.
9. 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 #10
10. 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: *3/17 (SS); 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: *TBD; 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 6 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/

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 have a diagnosis of T2DM?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Has the patient tried and failed metformin and a sulfonylurea, have contraindications to these treatments or is requesting a SGLT-2 inhibitor to be used with metformin and a sulfonylurea? (document contraindication, if any)	**Yes:** Go to #5	**No:** Pass to RPh. Deny and recommend trial of metformin or sulfonylurea. See below for metformin titration schedule.
5. Is the request for the following treatments (including combination products) with an associated estimated glomerular filtration rate (eGFR): • Canagliflozin and eGFR <45 mL/min/ 1.73 m^2, or • Empagliflozin and eGFR <45 mL/min/ 1.73 m^2, or • Dapagliflozin and eGFR <60 mL/min/ 1.73 m^2?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #6

Approval Criteria		
6. Has the patient tried and failed (unable to maintain goal A1c) all of the following drugs, or have contraindications to all of these drugs? 1. Insulin 2. Thiazolidinedione 3. DPP-4 inhibitor 4. GLP-1 receptor agonist 5. Amylin analog	**Yes:** Approve for up to 6 months	**No:** Pass to RPh. Deny and require a trial of insulin, thiazolidinedione, DPP-4 inhibitor, GLP-1 agonist, and amylin analog.

Renewal Criteria		
Is the request for the following treatments (including combination products) with an associated estimated glomerular filtration rate (eGFR): • Canagliflozin and eGFR <45 mL/min/ 1.73 m^2, or • Empagliflozin and eGFR <45 mL/min/ 1.73 m^2, or • Dapagliflozin and eGFR <60 mL/min/ 1.73 m^2?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Approve for up to 6 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 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: *9/16 (KS); 3/16; 9/15; 1/15; 9/14; 9/13*
Implementation: *10/13/16; 2/3/15; 1/1/14*

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: *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*

Smoking Cessation

Goal(s):

- Promote use that is consistent with National Guidelines and medical evidence.
- Promote use of high value products

Length of Authorization:

- 3-6 months

Requires PA:

- Non-preferred drugs
- Nicotine replacement therapy (NRT) for more than 6 months in the absence of behavioral counseling
- Varenicline treatment for more than 12 weeks

Covered Alternatives:

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

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code	
2. Is the diagnosis for tobacco dependence (ICD10 F17200)?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Is the request for a preferred NRT product?	**Yes:** Go to #5	**No:** Go to #4
4. Is the request for varenicline?	**Yes:** Go to #5	**No:** Go to #7
5. Has patient quit?	**Yes:** Approve NRT for 6 additional months or approve varenicline for 12 additional weeks	**No:** Go to #6
6. 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 additional months or approve varenicline for 12 additional weeks	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
7. Will the prescriber change to a preferred product? Message: • Preferred products do not require a PA for initial treatment. • 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:** Approve treatment for up to 6 months

P&T Review: *7/16 (MH); 4/12*
Implementation: *8/16, 7/23/12*

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 topical testosterone products and non-preferred injectable testosterone products in adults
- All testosterone products in pediatric 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. Does the diagnosis for the medication requested include any of the following? • Testicular Hypofunction; or • Hypopituitarism and related disorders; or • AIDS-related cachexia?	**Yes:** Go to #5	**No:** Go to #3
3. Is the medication requested for gender dysphoria (ICD10 F642, F641)?	**Yes:** Go to #4	**No:** Go to #6
4. 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.	**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 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.
6. 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 not funded: Deny; not funded by the OHP

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

Topical Antipsoriasis Drugs

Goal(s):

- Restrict topical antipsoriasis drugs only for funded OHP diagnoses. Moderate/Severe psoriasis treatments are funded on the OHP. Treatments for mild psoriasis (L400-404,L408-418, L448), seborrheic dermatitis (L2083,L210-219,L303), keroderma (L110, L83, L850-852, L870-872, L900-902, L906, L940, L943) and other hypertrophic and atrophic conditions of skin (L119, L572, L574, L664, L908-909, L918-919, L922, L985) are not funded.

Length of Authorization:

- Up to 12 months

Requires PA:

- Non-preferred drugs
- TC = 92 and HIC = L1A, L5F, L9D, T0A

Covered Alternatives:

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

Approval Criteria		
1. What diagnosis is being treated?	Record ICD 10 code.	
2. Is the diagnosis for seborrheic dermatitis (L2083,L210-219,L303), keroderma (L110, L83, L850-852, L870-872, L900-902, L906, L940, L943) or other hypertrophic and atrophic conditions of skin (L119, L572, L574, L664, L908-909, L918-919, L922, L985)?	**Yes:** Pass to RPh; deny, not funded by the OHP.	**No:** Go to #3
3. Is the diagnosis Psoriasis? (ICD-10 L400-404,L408-418,, L448)	**Yes:** Go to #4	**No:** Go to #7
4. Is the Psoriasis Moderate/Severe? Defined as: • At least 10% body surface area involved or with functional impairment? • Hand, foot or mucous membrane involvement	**Yes:** Go to #5	**No:** Pass to RPh; deny, not funded by the OHP.
5. Is the product requested preferred?	**Yes:** Approve for length of treatment; maximum 1 year.	**No:** Go to #6

Approval Criteria		
6. 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.
7. 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 length of treatment.	**If not funded:** Deny, not funded by the OHP.

P&T/DUR Review: *7/15; 1/15; 09/10; 9/09; 3/09; 5/07; 2/06*
Implementation: *10/15; 8/15; 9/13; 6/12; 9/10; 1/10; 7/09; 6/07; 9/06*

Topiramate

Goal(s):

- Approve topiramate only for funded diagnoses which are supported by the medical literature (e.g. epilepsy and migraine prophylaxis).

Length of Authorization:

- 90 days to lifetime

Requires PA:

- Non-preferred topiramate products

Covered Alternatives:

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

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code	
2. Does the patient have diagnosis of epilepsy?	**Yes:** Approve for lifetime (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	**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: *3/17 (DM); 7/16; 3/15; 2/12; 9/07; 11/07*
Implementation: *4/18/15; 5/12, 1/12*