Oregon Medicaid Pharmaceutical Services Prior Authorization Criteria

DIVISION OF MEDICAL ASSISTANCE PROGRAMS

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

January 1, 2016

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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 January 1, 2016

The Division of Medical Assistance Programs (DMAP) made substantive changes to listed criteria, deleted criteria, and made minor, non-substantive formatting updates to the entire guide.

Substantive updates and new criteria

- Botulinum Toxins
- Drugs for non-funded conditions
- Drugs selected for manual review by OHP
- Estrogen Derivatives
- GnRH Analogs
- Intranasal Allergy Drugs
- Ivabradine
- LABA / ICS
- LABA / LAMA
- Oral Cystic Fibrosis Modulators
- PCSK9 Inhibitors
- Testosterone

Clerical changes

- Cysteamine Delayed Release
- Drugs for Non-Funded Pain
- Inhaled Corticosteroids
- Insulins
- LABAs
- New Drug Policy
- Opioid Analgesics – High Dose

For questions, contact the DMAP 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

DMAP 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) or OHP managed care plan, contact the CCO/plan for their PA procedures.

For prescriptions covered by DMAP 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 DMAP's utilization guidelines require PA from DMAP:

DMAP – Medical Management Unit
500 Summer St NE, E44
Salem, OR 97301-1078
503-945-6821 (direct)
800-642-8635 (in-state only)

Use the DHS 3971 form to submit PA requests. Fax the completed form using an EDMS Coversheet (DHS 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 DMAP 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 DMAP'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.

DMAP prior authorization policy is reviewed by the Oregon Pharmacy and Therapeutic Committee (P&T Committee) and is subject to the DMAP 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 DMAP'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 Division of Medical Assistance Programs
500 Summer Street NE, E-35
Salem, OR 97301-1079

citron@ohsu.edu
roger.a.citron@state.or.us

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

Attention Deficit Hyperactivity Disorder (ADHD) Safety Edit

Goal(s):

- Cover ADHD medications only for OHP covered diagnoses 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

Triggers:

- Regimens prescribed by a non-psychiatric specialists which are:
  - Outside of standard age (Table 2)
  - Outside standard dose (Table 2)
  - Non-standard polypharmacy (Table 3)
- Non-preferred drugs on the enforceable preferred drug list. Preferred alternatives listed at www.orpdl.org

Table 1. Approved and Funded Indications for ADHD Medications

Indication	Methylphenidate and derivatives	Amphetamines	Modafinil (Provigil™)	Armodafinil (Nuvigil™)	Atomoxetine (Strattera™)	Clonidine ER (Kapvay™)	Guanfacine ER (Intuniv™)
ADHD	Six and Older except methyphenidate IR which is approved for four and older	Six and older	Not approved	Not approved	Six and older	Children 6-17 only	Children 6-17 only
Narcolepsy	Six and older	Six and older	Adults 18 and older	Adults 18 and older	Not approved	Not approved	Not approved
Drug Induced Sedation	Six and older	Six and older	Not approved	Not approved	Not approved	Not approved	Not approved
Obstructive sleep apnea	Not approved	Not approved	Adults 18 and older	Adults 18 and older	Not approved	Not approved	Not approved

Table 2. Standard Age and Dose Ranges for ADHD Medications

Drug Type	Generic Name	Minimum Age	Maximum Age	Maximum Daily Dose
Non-Traditional Stimulant	armodafinil	18		250mg
Non-Stimulant	atomoxetine	6		100mg
Non-Stimulant	clonidine	6	17	0.4mg
CNS Stimulant	dexmethylphenidate	6		20mg or 2mg/kg/day if under 18yrs
CNS Stimulant	dextroamphetamine	6		40 mg or 0.5mg/kg/ day if under 18yrs
CNS Stimulant	dextroamphetamine/amphetamine	6		60 mg or 0.5mg/kg/ day if under 18yrs
Non-Stimulant	guanfacine	6	17	4mg
CNS Stimulant	lisdexamfetamine	6		70mg or 0.5mg/kg/ day if under 18yrs
CNS Stimulant	methylphenidate immediate release	4		90mg or 2mg/kg/ day if under 18yrs
CNS Stimulant	methylphenidate sustained release	6		90mg or 2mg/kg/ day if under 18yrs
CNS Stimulant	methylphenidate transdermal	6		30mg
Non-Traditional Stimulant	modafinil	18		200mg

Table 3. Standard Combination Therapy for ADHD

Age Group	Standard Combination Therapy
Under 6 years old*	Combination therapy not recommended
6-17 years old*	CNS Stimulant + Guanfacine CNS Stimulant + Clonidine
18 and older**	Combination therapy not recommended

* As recommended by the American Academy of Pediatrics 2011 Guidelines
**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.
3. Is the requested agent a non-preferred agent?	**Yes:** Go To #4	**No:** Go To #5
4. Is the provider willing to switch to a preferred agent?	**Yes:** Inform the provider of preferred alternatives	**No:** Go To #5
5. Is the request for an approved indication? (Table 1)	**Yes:** Go To #6	**No:** Pass to RPH. Deny. Medical Appropriateness. May approve continuation of existing therapy once up to 90 days to allow time to appeal.
6. Is the request from a psychiatrist or was the regimen developed in consultation with a psychiatrist, developmental pediatrician, psychiatric nurse practitioner or Neurologist?	**Yes:** Go to #7	**No:** Go To #8
7. Are all CNS stimulants that the client is to be on prescribed by or in consultation with the same psychiatrist or specialist?	**Yes:** Approve 12 months	**No:** Pass to RPH. Confirm that the requesting specialist approves of the full regimen or deny for medical appropriateness.
8. Are the age and the dose within the limits in Table 2? Note: For children under 18, the maximum dose for some medications may require a recent weight.	**Yes:** Go To #9	**No:** Pass to RPH. Deny for medical appropriateness. Doses exceeding defined limits are only approved when prescribed by a psychiatrist or in consultation with a psychiatrist. May approve continuation of existing therapy once up to 90 days to allow time to schedule appointment with a psychiatrist.
9. Is the requested agent the only ADHD treatment that has been filled within the last 30 days?	**Yes:** Approve 12 months	**No:** Go To #10

Approval Criteria		
10. Have all other recent ADHD medications been discontinued or are they in the process of being discontinued / tapered?	**Yes:** Approve 12 months	**No:** Go To #11
11. Is the request for a single short acting CNS stimulant and a single long acting CNS stimulant?	**Yes:** Approve 12 months	**No:** Pass to RPH. Deny for medical appropriateness. Non-standard polypharmacy regimens are only approved when prescribed by a psychiatrist or in consultation with a psychiatrist. May approve continuation of existing therapy once up to 90 days to allow time to schedule appointment with a psychiatrist.

P&T / DUR Action: *5/29/14 (TW), 9/24/09 (DO), 12/4/08 (reh), 2/23/06, 11/10/05, 9/15/05, 5/12/05, 2/21/01, 9/6/00, 5/10/00*
Implementation: *10/9/15, 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 above the line conditions and restrict ketorolac to short-term use (5 days every 60 days) per the FDA black boxed warning:

WARNING - Ketorolac is indicated for the short-term (up to 5 days) management of moderately severe acute pain that requires analgesia at the opioid level. It is not indicated for minor or chronic painful conditions. Ketorolac is a potent NSAID analgesic, and its administration carries many risks. The resulting NSAID-related adverse events can be serious in certain patients for whom ketorolac is indicated, especially when the drug is used inappropriately. Increasing the dose beyond the label recommendations will not provide better efficacy but will result in increasing the risk of developing serious adverse events.

Length of Authorization:

Up to 12 months

Requires PA:

- Non-preferred NSAIDs
- Ketoralac: Maximum of one claim per 60 days. That claim can be a maximum of 20 tablets / 5 days, i.e. there is a 5 day maximum per 60 days.

Preferred Alternatives:

Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the diagnosis covered by the Oregon Health Plan? All indications need to be evaluated as to whether they are above the line or below the line.	**Yes:** Go to #3.	**No:** Pass to RPH; Deny (Not covered 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 ketorolac greater than a 5 day supply within 60 days (200mg total over 5 days for tablets, 630mg total over 5 days for the nasal spray)?	**Yes:** Pass to RPH; Deny, (Medical Appropriateness). Review FDA warnings	**No:** Go to #5.

Approval Criteria		
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 provider of covered alternatives in class.	**No:** Approve for 1 year or length of prescription, whichever is less.

P&T / DUR Action: *11/20/14 (MH), 9/21/13, 2/23/12 (TW), 9/24/09 (DO/KK), 2/23/06*
Implementation: *10/15, 1/1/15, 1/1/14, 5/14/12, 1/1/10*

Antiemetics, New

Goal(s):

- Promote preferred drugs.
- Reserve costly antiemetics for appropriate indications.
- Restrict chronic use (> 3 days per week).
- If chemotherapy is more frequent than once weekly, approve a quantity sufficient for three days beyond the duration of chemotherapy.

Length of Authorization:

3 days to 6 months (criteria specific)

Requires PA:

- Non-preferred drugs

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

Check the Reason for PA:

- Non-Preferred drugs will deny on initiation
- Preferred drugs will deny only when maximum dose exceeded (www.orpdl.org)

HICL	Generic	Brand	Quantity Limit
025058	Aprepitant	Emend	3 doses/ 7 days
016576	Dolasetron	Anzemet	9 doses/ 7 days
007611	Granisetron	Kytril Tablets Kytril solution	6 doses / 7 days (30 ml liquid)

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the drug requested preferred?	**Yes:** Go to #4.	**No:** Go to #3.
3. Will the prescriber consider a change to a preferred product? Message: • Preferred products do not require PA for <4 days/week. • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&T) Committee.	**Yes:** Inform provider of covered alternatives in class and dose limits. If dose > limits, continue to #4.	**No:** Go to #4.

Approval Criteria		
4. Is client currently diagnosed with cancer AND receiving chemotherapy or radiation therapy more frequently than every 7 days?	**Yes:** Approve for 3 days past length of therapy. (Chemo regimen more frequently than weekly)	**No:** Go to #5.
5. Does client have refractory nausea that would require hospitalization or ER visits?	**Yes:** Go to #6.	**No:** Go to #8.
6. Has client tried and failed two conventional antiemetics, listed below? Generic Name / Brand Name Metoclopramide / Reglan Prochlorperazine / Compazine Promethazine / Phenergan	**Yes:** Approve up to 6 months.	**No:** Go to #7.
7. Does client have contraindications to conventional antiemetics, e.g. Allergy; or cannot tolerate?	**Yes:** Document reason and approve up to 6 months. (Contraindications to required alternative medications)	**No:** Pass to RPH; Go to #8.
8. RPH only All other indications need to be evaluated as to whether they are above the line or below the line. • Above: Deny, (Medical Appropriateness) • Below: Deny, (Not Covered by the OHP)		

P&T / DUR Action: *11/20/14 (MH), 9/24/09(DO/KK), 2/23/06, 2/24/04, 11/18/03, 9/9/03, 5/13/03, 2/11/03*
Implementation: *10/15, 1/1/15, 1/1/14, 1/1/10, 7/1/06, 3/20/06, 6/30/04 (added aprepitant), 3/1/04 (removed injectables), 6/19/03,*

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:

Preferred alternatives 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, Opportinistic
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-9	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, L710-711, L718, L930, L932, L490-L499	ERYTHEMATOUS CONDITIONS

L26,L304,L538,L920,L951,L982, L539	
L438,L441-443, L449,L661	Lichen Planus
L700-702, L708	ROSACEA; ACNE
B351	Dermatophytosis of nail (onychomycosis)
B360	Pityriasis versicolor
B362	Tinea blanca
B363	Black piedra
B368	Dermatomycoses nec
B369	Dermatomycosis nos
B372	Cutaneous candidiasis
B379	Candidiasis site nos
R21	Nonspecif skin erupt nec

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

ICD-9	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 provider 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 above the line, then may be approved for treatment course with PRN renewals. If length of therapy is unknown, approve for 3-month intervals only.

- If below the line: Deny (Not Funded by the OHP).
  - Deny Non-fungal diagnosis (Medical Appropriateness)
  - Deny Fungal ICD-9 codes that do not appear on the OHP list pending a more specific diagnosis code (Not Funded by the OHP).
  - Forward any fungal ICD-9 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 / DUR Review: *7/15 (kk); 09/10; 2/06; 11/05; 9/05; 5/05*
Implemented *10/15, 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:

Preferred alternatives listed at www.orpdl.org

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 Health Resource Commission (HRC).	**Yes:** Inform provider of covered alternatives in class.	**No:** Go to #3.
3. Does client have diagnosis of allergic rhinitis, allergic conjunctivitis, or chronic rhinitis/pharyngitis/nasopharyngitis?	**Yes:** Go to #4.	**No:** Go to #8.
4. Does the client 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 client have other co-morbid conditions or complications that are above the line? • Acute or chronic inflammation of the orbit • Chronic Sinusitis • Acute Sinusitis • Sleep apnea • Wegener's Granulomatosis	**Yes:** Document ICD-10 codes and Go to #7.	**No:** Pass to RPH; Deny, (Not Covered by the OHP).
7. Does client have contraindications (e.g. Pregnant), or had insufficient response to available alternatives? Document.	**Yes**: Approve 6 months.	**No:** Pass to RPH; Deny, (Cost-Effectiveness).
8. Is the diagnosis COPD (496) 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 Covered 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 Covered by the OHP (e.g., acute upper respiratory infections or urticaria).		

P&T / DUR Review: *5/15 (AG); 9/10; 9/08; 2/06; 9/04; 5/04; 2/02*
Implementation: *10/15, 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.

Initiative:

- Anti-migraine PDL, Quantity Limits & Duplicate Therapy.

Length of Authorization:

Up to 6 months

Requires PA:

- Non-preferred drugs

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

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.i.e. oral + nasal, oral + injectable, nasal + Injectable)

Quantity Limits Per Labeling

Generic	Brand	Initial Dose	Max Daily Dose	Dosage Form	Max # has/Month	Limit
Almotriptan	Axert	6.25-12.5 mg. Rpt in 2 hr	25 mg	6.25 mg tab 12.5 mg tab (blister pack 6, 12)	4	12/45d
Eletriptan	Relpax	20-40 mg. Rpt in 2 hr	80 mg	20 mg tab 40 mg tab (blister pack 6, 12)	3	12/60d
Frovatriptan	Frova	2.5-5 mg Rpt in 4 hr	7.5 mg	2.5 mg tab (blister pack 9)	4	9/30d
Naratriptan	Amerge	1-2.5 mg Rpt in 4hr	5 mg	1 mg tab 2.5 mg tab (blister pack 9)	4	9/30d
Rizatriptan	Maxalt Maxalt MLT	5-10 mg Rpt in 2hr	30 mg	5 mg tab 10 mg tab (blister pack 6, 12)	4	12/30d

Generic	Brand	Initial Dose	Max Daily Dose	Dosage Form	Max # has/Month	Limit
Sumatriptan	Imitrex & generics	25-100 mg po rpt In 2 hr 5-10 mg NS Rpt in 2 hr 3-6 mg SQ Rpt in 2hr	200 mg 40 mg 12 mg	25 mg tab, 50mg tab, 100 mg tab (blister pack 9) 5 mg, 10 mg NS (box of 6) 6 mg SQ (box 2 syr), kit (2 syr per kit), 6mg/0.5ml vials	4 4 4	9/30d 6/30d 6/30d 3mls/30d
Sumatriptan	Sumavel	6 mg SQ	12 mg	6mg/0.5ml units (package of 6)	4	3ml/30d
Sumatriptan / Naproxen	Treximet	85mg / 500mg	170 mg / 1000 mg	85mg/500mg tab (box of 9)	4	9/30d
Zomitriptan	Zomig Zomig ZMT Zomig NS	1.25-5 mg Rpt in 2hr 5mg NS Rpt in 2hr	10 mg 10mg	2.5 mg tab (blister pack, 6) 5 mg tab (blister pack, 3) 5mg NS (box of 6)	3 4	6/30d 6/30d

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Does patient have diagnosis of migraine?	**Yes:** Go to #3.	**No:** Pass to RPH, Deny, (Medical Appropriateness) There is no evidence to support the use of triptans for non-migraine diagnoses.
3. Is drug requested preferred?	**Yes:** Go to #5.	**No:** Go to #4.

Approval Criteria		
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 & safety by the Health Resources Commission (HRC).	**Yes:** Inform provider of covered alternatives in class and dose limits.	**No:** Go to #5.
5. Is request for higher dose than listed in quantity limit chart?	**Yes:** Pass to RPH; Deny, (Medical Appropriateness) • Can recommend use of migraine prophylactic therapy and reinforce that doses above those recommended by the manufacturer increase the incidence of medication overuse headache (may refer to DUR Board Newsletter above). • One life-time 90-day taper may be approved at pharmacist discretion. • Document.	**No:** Trouble-shoot claim payment (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:** Go to #8.

Approval Criteria		
8. Does patient request more triptan due to supply lost or stolen or a vacation/travel supply?	**Yes:** Document reason and approve for date of service.	**No:** Pass to RPH, (Medical Appropriateness). There is no evidence to support the use of two different ORAL triptans concurrently.

P&T / DUR Action: *3/18/10(KK), 9/24/09(DO/KK), 11/18/03, 5/13/03*
Implementation: *10/15, 3/23/10, 1/1/10, 7/1/06, 5/31/05*

Anti-Parkinsons Agents

Goals:

- Cover preferred products when feasible for covered diagnosis. Preferred products are selected based on evidence based reviews.
- OHP does not cover treatment for restless leg syndrome (coverage line 624).

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. 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 Covered by the OHP).	**No:** Go to #4.
4. RPH only All other indications need to be evaluated as to whether they are above the line or below the line.	Above: Go to #5	Below: Deny, (Not Covered 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 provider of covered alternatives in class.	**No:** Approve for the shorter of 1 year or length of prescription.

P&T / DUR Action: *9/26/13 (MH/ BL), 09/16/2010(DO)*
Implementation: *10/15, 1/1/14 (MH/BL)*

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 - Influenza

Goal(s):

- To ensure appropriate extended influenza drug use by authorizing utilization in specified patient population.

Length of Authorization:

Date of Service

Requires PA:

- Non-preferred drugs

Name of Drug	Brand	Quantity Limits
Zanamivir	Relenza	NA
Oseltamivir	Tamiflu	>5 days therapy requires a PA
Amantadine Tablets		NA

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

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 covered by the OHP)
3. Is the antiviral being used to treat influenza?	**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 a PA. Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Health Resource Commission (HRC).	**Yes:** Inform provider of covered alternatives in class. Current recommended treatment duration: • 5 days for the following: Relenza, Tamiflu, • Amantadine: Continue for at least 10 days.	**No:** Approve for 5 days

Approval Criteria		
5. Does the patient have any of the following putting them at increased risk for complications requiring prophylaxis? (Risk groups acquired from most recent CDC recommendations and IDSA guidelines.) • High-risk persons during 2 weeks after vaccination before adequate immunity develops • Patients >1 years of age at high risk for complications for whom the vaccine is contraindicated, unavailable or expected to have low effectiveness • Residents in institutions such as nursing homes or long-term care facilities that are experiencing an influenza outbreak • Persons at high-risk of complications of influenza, such as transplant and immunocompromised patients • Unvaccinated children and adults, including health care workers, that are in close contact with persons at high risk of developing complications during periods of influenza activity • Persons within a household with suspected or confirmed influenza cases if any family member is at high risk of complications • 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. Current recommended duration of prophylaxis; Relenza: 10 days for prophylaxis in a household setting, up to 28 days in a community outbreak setting. Tamiflu: at least 10 days following close contact with an infected individual; up to 6 weeks in a community outbreak setting. Amantadine: Up to 4 weeks.	**No:** Pass to RPH; Deny, (Not Medically Appropriate)

References:

1. **Relenza** [package insert]. Research Triangle Park, NC: GlaxoSmithKline; March 2010. http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021036s019lbl.pdf

2. **Tamiflu** [package insert]. Nutley, NJ: Roche Laboratories, Inc; February 2010. http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021087s048s049,021246s034s035lbl.pdf

3. **Amantadine** [package insert]. Minneapolis, MN: UPSHER-SMITH LABORATORIES, INC.; October 2009. http://www.upsher-smith.com/PDFs/Amantadine_Tab_Insert.pdf.

P&T / DUR Action: *9/16/10 (KS)*
Implementation: *10/15*

Antivirals, Oral and Topical - HSV

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:

Criteria specific - up to 12 months

Requires PA:

- Non-preferred drugs
- HIC3 = Q5V

Generic	Brand	Route
Famciclovir	Famvir	Oral
Valacyclovir	Valtrex	Oral
Acyclovir	Zovirax	Topical
Penciclovir	Denavir	Topical
Docosanol	Abreva	Topical

Covered Alternatives:

- Oral acyclovir DOES NOT require PA
- Preferred alternatives listed at www.orpdl.org

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 Health Resource Commission (HRC).	**Yes:** Inform provider of covered alternatives in class.	**No:** Go to #3.
3. Is the diagnosis uncomplicated herpes simplex ICD10: B002, B0089, B001, and B009?	**Yes:** Go to #4.	**No:** Pass to RPH; Go to #7.

Approval Criteria		
4. Is the patient immune compromised? Document ICD10 code. • Current (not history of) diagnosis of cancer AND is currently undergoing Chemotherapy or Radiation? Document therapy and length of treatment • Diagnosis of HIV/AIDS?	**Yes:** Approve for the shorter of expected therapy duration or: 1 year (applies to topical or oral antivirals; immunocompromised client).	**No:** Go to #5.
5. Is client currently taking an immunosuppressive drug? Document drug: (If drug not in list below, Pass to RPh for evaluation) Immunosuppressive drugs include, but are not limited to: **Generic Names** / **Brand Names** Azathioprine / Imuran Basiliximab / Simulect Cyclosporine / Sandimmune, Cyclosporine / Neoral Sirolimus / Rapamune Tacrolimus / Prograf Methotrexate / Rheumatrex Hydroxychloroquine / Plaquenil Etanercept / Enbrel Leflunomide / Arava	**Yes:** Approve for the shorter of expected therapy duration or: 90 days (applies to topical or oral antivirals; immunocompromised client).	**No:** If Diabetes or Sickle-Cell disease-go to #6. All others go to #7.
6. Does client have Diabetes or Sickle-Cell disease? Note: Diabetes and Sickle-Cell is not considered as immunocompromising for antivirals as it is for antifungals.	**Yes:** Pass to RPH; Deny, (Not Covered by the OHP).	**No:** Pass to RPH to evaluate for immunosuppression. • If not immuno-compromised deny (Not Covered by the OHP). • If immuno-compromised approve for 1 year.

Approval Criteria		
7. RPH only All other indications need to be evaluated as to whether they are above the line or below the line diagnosis. • If above, viral diagnoses can be approved for treatment course with "prn" renewals. If length of therapy is unknown, please approve for 3 months intervals only (This is an exception to above guidelines and should be discussed with Lead Pharmacist) • If below, Deny, (Not Covered by the OHP). • Deny Non-viral diagnoses (Medical Appropriateness). • Deny Viral ICD-10 codes that do not appear on the OHP list pending a more specific diagnosis code. (Not Covered by the OHP)	If above the line and clinic provides supporting literature: Approve for length of treatment.	If below the line: Deny, (Not Covered by the OHP).

P&T / DUR Action: *9/16/10 (KS)*
Implementation: *10/15*

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 treatment is covered by OHP only when post-void residuals are at least 150ml.
- Cosmetic use for baldness is NOT covered.
- Erectile dysfunction is NOT covered.

* Note: Finasteride is also available as Propecia®, which is FDA-approved for alopecia/male pattern baldness. Alopecia and male pattern baldness are not approvable diagnoses for 5-Alpha Reductase (5AR) Inhibitors.

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. 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 Health Resource Commission (HRC).	**Yes:** Inform Provider of covered alternatives in class.	**No:** Go to #3.
3. Is the request for renewal of current therapy?	**Yes:** Go to “Renewal Therapy”	**No:** Go to #4.

Approval Criteria		
4. Is the request for an alpha blocker, and does client have a diagnosis related to functional and mechanical disorders of the genitourinary system including bladder outlet obstruction? (N201, N3010, N3011, N320, , N312,N323596.5, N319, N99510-99512, N99518,N3289, N329, N35014,N35028,N35111,N358-359, N37, N99110, N3641-3642, N368, N398)	**Yes:** Go to #5.	**No:** Go to #6.
5. Has the client tried and failed a 2-month trial of a covered alternative alpha blocker (terazosin, doxazosin, prazosin, tamsulosin)?	**Yes:** Approve an alpha blocker only for 1 year	**No:** Deny until client has tried and failed a covered alternative
6. Does client have a diagnosis of BPH (Benign Prostatic Hypertrophy) or enlarged prostate with obstruction? (N400, N403, N401,; R338-339, R3914, N40x + see RPH notes)	**Yes:** Approve for the shorter of 1 year or length of the prescription	**No:** Go to #7.
7. Does client have a diagnosis of unspecified urinary obstruction or benign prostatic hyperplasia without obstruction? (N139, N400, N402, ,)	**Yes:** Pass to RPH; Deny, (Not Covered by the OHP)	**No:** Pass to RPH; Go to #8.

8. RPH Notes only - All other indications need to be evaluated to see if they are above or below the line:

Above the line covered diagnoses related to prostate may be approved for 1 year

Below the line diagnoses (e.g. Hair growth, erectile dysfunction) should be denied (Not Covered by the OHP).

Alpha Blockers and 5-alpha reductase inhibitors (ARI) may be used concurrently for BPH up to 1 year. Alpha-blockers may be discontinued once prostate is reduced to normal size.

- R338-339, R3914 (retention of urine, obstructive); Ask for more specific diagnosis. If along with N400, N403, N401 or, then may approve.

Refer questions of coverage to DMAP.

Renewal Therapy		
1. Is the request for an alpha blocker, and does client have a diagnosis related to functional and mechanical disorders of the genitourinary system including bladder outlet obstruction? N201,N3010, N3011, N320, N312,N323, N319,N99510-99512, N99518,N3289, N329, N35014,N35028,N35111,N358-359, N37, N99110, N3641-3642, N368, N398)	**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 1 year or length of the prescription
3. Does client have a diagnosis of BPH (Benign Prostatic Hypertrophy) or enlarged prostate with obstruction? N400, N403,N401,R338-339, R3914, N40x 600.xx see RPH notes)	**Yes:** Approve for 1 year	**No:** Go to #4.
4. Does client have a diagnosis of unspecified urinary obstruction or benign prostatic hyperplasia without obstruction? (N139, N400,N402)	**Yes:** Pass to RPH; Deny, (Not Covered 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 above the line or below the line diagnosis. • Alpha Blockers and 5-alpha reductase inhibitors (ARI) may be used concurrently for BPH up to 1 year. Alpha-blockers may be discontinued once prostate is reduced to normal size. • R338-339, R3914 (retention of urine, obstructive); Ask for more specific diagnosis. If along with N400, N403, N401or, then may approve.	If above the line and clinic provides supporting literature: Approve for one year.	If below the line: Deny, (Not Covered by the OHP).

P&T / DUR Action: *11/29/12 (MH), 9/16/10 (KS), 3/18/10(KK), 5/22/08, 2/23/06*
Implementation: *10/15, 2/21/13, 1/1/11, 4/20/10, 5/22/08 (Aebi), 7/1/06, 9/30/05*

Benzodiazepines

Goal(s):

- Approve only for covered OHP diagnoses.
- Prevent inappropriate long-term benzodiazepine use (beyond 4 weeks) on newly started patients (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:

- Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Does the client have a malignant neoplasm or other end of life diagnosis?	**Yes:** Approve for 12 months	**No:** Go to #3
3. Does client have diagnosis of epilepsy?	**Yes:** Approve for 12 months	**No:** Go to #4.
4. Is the diagnosis an OHP covered diagnosis?	**Yes:** go to #5	**No:** Pass to RPH; Deny, (Medical appropriateness). Sedative/hypnotics, due to depressant effect, are contraindicated for this diagnosis and are not approvable.
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 / DUR Action: *3/27/2014*
Implementation: *10/15, 1/1/15*

Biologicals for RA, Psoriasis, or Crohn's Disease

Goal(s):

- Cover biologicals according to OHP list guidelines.
- Promote use that is consistent with National Guidelines and medical evidence.
- Promote use of high value products.

Length of Authorization:

Up to 12 months

Requires PA:

- Non-preferred drugs

Covered Alternatives:

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

Generic Name	Trade Name	Indication
Abatacept	Orencia	RA, juvenile RA, juvenile idiopathic arthritis
Adalimumab	Humira	RA, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, Crohn's disease, plaque psoriasis, ulcerative colitis
Anakinra	Kineret	RA
Apremilast	Otezla	Psoriatic arthritis, plaque psoriasis
Certolizumab	Cimzia	RA, Crohn's disease, psoriatic arthritis, ankylosing spondylitis
Etanercept	Enbrel	RA, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, plaque psoriasis
Golimumab	Simponi	RA, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis
Infliximab*	Remicade	RA, Crohn's disease, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, plaque psoriasis
Natalizumab*	Tysabri	Crohn's disease, multiple sclerosis
Rituximab*	Rituxan	RA, CLL, Wegnener granulomatosis, Microscopic polyangiitis, non-Hodgkin lymphoma
Secukinumab	Cosentyx	Plaque psoriasis
Tocilizumab*	Actemra	RA, juvenile idiopathic arthritis
Tofacitinib	Xeljanz	RA
Ustekinumab	Stelara	Plaque psoriasis, psoriatic arthritis
Vedolizumab	Entyvio	Ulcerative colitis, Crohn's disease

Abbreviations: CLL: chronic lymphocytic leukemia; RA: rheumatoid arthritis
* Must be billed via HCPC J-code and payment requires trial of preferred self-administered drug first.

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the diagnosis covered by OHP?	**Yes:** Go to #3	**No:** Pass to RPH; Deny for medical appropriateness.
3. Will the provider change to a preferred product?	**Yes:** Inform provider of preferred alternatives.	**No:** Go to #4

Approval Criteria		
4. Is the diagnosis chronic plaque psoriasis (ICD-10: L400-404,L408-418 , L448) and the product requested FDA approved for psoriasis (see table above)? * Moderate/Severe psoriasis treatments are covered by the OHP	**Yes:** Go to #5	No: Go to #7. Note: 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) are not covered by OHP.
5. Is the Psoriasis Moderate/Severe? Defined as functional impairment and one or more of the following: • At least 10% body surface area involved or with functional impairment? • Hand, foot or mucous membrane involvement	**Yes:** Go to #6	**No:** Pass to RPh; deny, not covered by the OHP.
6. Has the patient tried and not had an adequate response to standard systemic therapies or has a contraindication to ALL of the following: • High-potency topical corticosteroids: betamethasone dipropionate, clobetasol, fluocinonide • At least one other topical agent: calcipotriene, tazarotene, anthralin • At least one other systemic therapy: cyclosporine, methotrexate or acitretin	**Yes**: Approve for length of treatment; maximum 1 year.	**No:** Pass to RPh; deny for medical appropriateness.
7. Is the diagnosis ankylosing spondylitis (ICD-10 M459) and the product requested is FDA approved for ankylosing spondylitis?	**Yes:** Approve treatment for up to 1 year.	**No:** Go to #8
8. Is the diagnosis rheumatoid arthritis (ICD-10 M069, M0500, M0530, M0560, M061, M0800, M083, M0840, M1200, M0510, M064) or psoriatic arthropathy (ICD-10 L4054,L4059) and the product requested FDA approved for rheumatoid arthritis (see table above)?	**Yes:** Go to #9	**No:** Go to #12

Approval Criteria		
9. Has the patient had a trial and inadequate response to methotrexate or other first line DMARDs (leflunomide, sulfasalazine, hydroxychloroquine, penicillamine) and a disease duration of ≥6 months? **OR** An intolerance or contraindication to oral DMARDs?	**Yes:** Go to #10	No: Pass to RPh; deny for medical appropriateness.
10. Is the request for tofacitinib?	**Yes:** Go to #11	**No:** Approve treatment for up to 1 year.
11. Has the patient had a trial and inadequate response or intolerance to 1 or more biologic TIM (Humira, Enbrel, Cimzia, Simponi, Orencia)?	**Yes:** Approve treatment for up to 1 year.	**No:** Pass to RPh; deny for medical appropriateness.
12. Is the diagnosis Crohn's disease (ICD-10 K5000,K5010,K5080,K5090) or ulcerative colitis (ICD-10 K5100, K5120,K5130,K5140,K5150,K5180,K5190) and the product requested FDA approved for the indication (see table above)?	**Yes:** Go to #13	**No:** Pass to RPh; deny for medical appropriateness.
13. Has the patient had a trial and inadequate response to conventional therapy including immunosuppressive therapy (mercaptopurine, azathioprine) and/or corticosteroid treatments? **OR** Has an intolerance or contraindication to conventional therapy?	**Yes:** Approve treatment for up to 1 year.	**No:** Pass to RPh; deny for medical appropriateness.

P&T/DUR Review: *7/15; 9/14; 8/12*
Implementation: *10/15; 9/27/14; 2/21/13*

Bone Resorption Suppression and Related Agents

Goal(s):

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

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. Is this an OHP covered diagnosis?	**Yes:** Go to #3.	**No:** Pass to RPH; Deny, (Not covered by the OHP)
3. Will the prescriber consider a change to a preferred product? Message: • Preferred products do not require a PA. • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Health Resource Commission (HRC).	**Yes:** Inform provider of covered alternatives in class.	**No:** Go to #4.
4. Is the request for raloxifene (Evista)?	**Yes:** Go to #5.	**No:** Go to #6.
5. Is the patient pregnant and/or at increased risk for thromboembolism or stroke?	**Yes:** Deny, (Medical Appropriateness) Inform provider of pregnancy category X and black box warning of thromboembolism and stroke risk	**No:** Approve for shorter of 1 year or length of prescription

Approval Criteria		
6. Is the request for teriparatide (Forteo) 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:** Go to #8.
7. Is the patient also taking a bisphosphonate, a pediatric or young adult patient with open epiphyses, at increased risk of osteosarcoma or a history of skeletal malignancies, metabolic bone disease, underlying hypercalcemic disorders, or unexplained elevations of alkaline phophatase?	**Yes:** Deny, (Medical Appropriateness)	**No:** Approve for shorter of 1 year or length of prescription
8. RPH only All other indications need to be evaluated as to whether they are above the line or below the line diagnosis.	If above the line and clinic provides supporting literature: approve for length of treatment.	If below the line: Deny, (Not Covered by the OHP).

P&T / DUR Action: *9/16/10 (KS)*
Implementation: *10/15*

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:

- Preferred alternatives 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 333.6x; • Acquired torsion dystonia 333.7x; • Blepharospasm 333.81; • Spasmodic torticollis 333.83; • Other fragments of torsion dystonia 333.89; • Paralysis associated with CVD 438.2x-432.5x; • Multiple sclerosis 340.xx; • Neuromyelitis optica 341.0; • Spastic hemiplegia, other specified hemiplegia 342.xx; • Cerebral palsy 343.xx; • Quadriplegia and quadraparesis 344.0x; • Paraplegia 344.1; • Diplegia of upper limbs 344.2; • Monoplegia of lower limb 344.3x; • Monoplegia of upper limb 344.4x; • Unspecified monoplegia 344.5; • Other specified paralytic syndrome 344.89; • Muscular dystrophies 359.0x-359.2x; or • Strabismus in other neuromuscular disorders 378.73.	**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 for 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 for medical appropriateness and 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 and 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 or RPh. Deny for 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 (333.82; 333.84; 333.94-333.99); Facial nerve disorders (351.xx); Spastic dysphonia (478.79); Anal fissure (565.0); Disorders of sweat glands (eg, focal hyperhidrosis) (705.xx); Other disorders of cervical region (723.xx, EXCEPT 723.4): Disorders of sweat glands (705.0-705.1; 705.21-705.9; 780.8); Acute and chronic disorders of the spine without neurologic impairment (724.1; 724.2; 724.4-724.6; 727.70-724.9); Disorders of soft tissue (729.0-729.2); Headaches (307.81; 339.xx; 784.0); Gastroparesis (536.3)
Deny for medical appropriateness for the following conditions; evidence of benefit is insufficient
Dysphagia (787.2x); Other extrapyramidal disease and abnormal movement disorders (333.xx, EXCEPT 333.6x; 333.7x; 333.81; 333.83; 333.89); Other disorders of binocular eye movements (eg, esotropia, exotropia, mechanical strabismus, etc.) (378 EXCEPT 378.73); Tics (307.2x); Laryngeal spasm (478.75); Spinal stenosis in cervical region or brachial neuritis or radiculitis NOS (723.0 and 723.4); Spasm of muscle in absence of neurological diagnoses (728.85); Contracture of tendon (sheath) in absence of neurological diagnoses (727.81); Amyotrophic sclerosis (335.20); Clinically significant spinal deformity or disorders of spine with neurological impairment (724.00-724.09; 724.4); Hyperplasia of prostate (600.xx)

Renewal Criteria		
1. Is this a request for renewal of a previously approved prior authorization for management of migraine headache?	**Yes:** Go to #2	**No:** Go to #3
2. Is there documentation of a reduction of >7 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 for medical appropriateness

Renewal Criteria		
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 for medical appropriateness

P&T / DUR Review: 11/15 (AG); 9/14; 7/14
Implementation : 1/1/16

Buprenorphine and Buprenorphine/Naloxone Fixed-combinations

Goal(s):

- Expand access to opioid dependence / addiction treatment
- Treatment of pain remains a priority, including opioid-dependent patients with injury or illness. Buprenorphine must be held during opioid treatment, especially with long-acting opioids.
- Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction, TIP 40, available at http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf.

Initiative: Opioid Addiction Therapies

Length of Authorization: up to 6 months; 2 months if the prescription is for immediate need pending certification.

Requires PA:

Brand	Generic
Buavail, Suboxone, Zubsolv	buprenorphine/naloxone
Buprenex, Butrans, Subutex	buprenorphine

Covered Alternatives: See PDL list at http://www.orpdl.org

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is diagnosis one of the following? • Opioid type dependence unspecified use • Opioid type dependence continuous use • - • Combinations of opioid type drug with other drug dependence unspecified use • Combinations of opioid type drug with any other drug dependence continuous.	**Yes:** Go to 3.	**No:** Pass to RPH**;** deny for medical appropriateness.
3. Is prescriber a Physician's Assistant or Nurse Practitioner? (NP's & PA's may not prescribe.)	**Yes:** Pass to RPH. Deny for medical appropriateness.	**No:** Go to #4.

Approval Criteria		
4. Does prescribing physician have a Drug Addiction Treatment Act (DATA)-2000 waiver ID number (also termed a special X-DEA license or certification)? OR Prescriber provides copy of SAMSHA certification request pending with "Immediate Need" checked? (once prescriber meets criteria SAMHSA may take 45 days to process.) *Note: Physicians do not have to list their license on the SAMHSA Buprenorphine Physician Locator website, which is publicly available. Pharmacists may call the Buprenorphine Information Center at 1-866-BUP-CSAT to verify unlisted or application under review prescribers.*	**Yes:** Document number or attach coy of SAMSHA request to PA record. Go to 6.	**No:** Go to #5.
5. Does the prescriber qualify for waiver from separate registration? a) Must have a valid DEA license AND b) Board certified in addiction medicine OR c) Employed by an opioid treatment program OR d) Federally employed physicians (e.g. IHS or VA)	**Yes:** Go to #6.	**No:** Pass to RPH, Deny for medical appropriateness. Encourage physician to get training and register at SAMSHA http://buprenorphine.samhsa.gov/howto.html or FAX "intent" form to 240-276-1630 at DEA.

Approval Criteria		
6. Is patient concurrently on long-acting opioids (check claim record & inform prescriber of any current claims)? Examples of long-acting opioids include: • methadone (e.g. Dolophine, Methadose) • levorphanol (e.g. Levo-Dromoran) • morphine, extended-release (e.g. MS Contin, Oramorph SR, Kadian, Avinza) • oxycodone, extended-release (e.g. OxyContin) • Fentanyl transdermal (e.g. Duragesic) • Oxymorphone, extended release (Opana® ER)	**Yes:** Pass to RPH. Deny for medical appropriateness. DO NOT GIVE methadone, or any long-acting opiate CONCURRENTLY with buprenorphine. If currently on methadone, reduce to stable state of 30 mg methadone equivalent (methadone 40 mg = buprenorphine 6 mg), then wait 24 hours to initiate buprenorphine.	**No:** Go to #7.
7. Is patient concurrently on other opioids (check claim record and prescriber of any current claims in STC 40)?	**Yes:** Pass to RPH. Deny for medical appropriateness. If physician can provide rationale for concurrent therapy document in PA and record and continue to #8.	**No:** Go to #8.
8. Is dose ≤ 24 mg/day (may average every other day therapy, e.g., 48 mg every other day)?	**Yes:** Go to #9.	**No:** Pass to RPH. Deny for medical appropriateness.
9. What is patients' pharmacy of choice? Document pharmacy name and NPI or address in PA record. Lock patient into their pharmacy of choice for 6 months. **Use reason code: Suboxone**	Inform prescriber patient will be locked into a single pharmacy for all prescriptions. Go to #10.	
10. What is the expected length of treatment? Document treatment length in PA record.	a) If prescriber is waiting for SAMSHA certification subsequent approvals dependent on certification: Approve for 2 months. b) If prescriber is certified: Approve for anticipated length of treatment or 6 months, whichever is shorter.	

P&T / DUR Action: *1/29/15 (AG), 9/24/09 (REH), 5/21/09, 9/24/09*
Implementation: *10/15, 2/3/15, 9/1/13*

Clobazam (Onfi®)

Goal(s):

- To ensure appropriate drug use and restrict to indications supported by medical literature.

Length of Authorization:

- 12 months

Requires PA:

- Non-preferred drugs
- Clobazam (Onfi®)

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Does the client 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.

DUR / P&T Action: *3/15 (AG); 5/12*
Implementation: *10/15*

Central Nervous System (CNS) – Sedative Non-Benzodiazepines

Goal(s):

- Approve only for covered OHP diagnoses.
- Treatment of uncomplicated insomnia is not covered; insomnia contributing to covered co-morbid conditions is.
- Prevent adverse events associated with long-term sedative use. Clients coming onto the plan on chronic sedative therapy (continuously for >90) are "grandfathered." (Refer to criteria).
- See related Sedative Therapy Duplication edit. The safety and effectiveness of chronic sedative use is not established in the medical literature. There is a documented increased risk of serious adverse events in the elderly.

Length of Authorization:

6 months to 12 months (criteria specific)

Requires PA:

- Non-preferred drugs

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

• Zolpidem tablets (GSN = 019187, 019188) • Trazodone • Mirtazapine • Diphenhydramine • Tricyclic antidepressants	NDC's priced as generic and <15 tablets per month May be alternatives for some clients.

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Does client have diagnosis of insomnia with sleep apnea,?	**Yes:** Go to #3.	**No:** Go to #4.
3. Is client on CPAP?	**Yes:** Approve for up to 1 year. The use of CPAP essentially negates the sedative contraindication and they are often prescribed to help clients cope with the mask.	**No:** Pass to RPH; Deny, (Medical appropriateness). Sedative/hypnotics, due to depressant effect, are contraindicated for this diagnosis and are not approvable.

Approval Criteria		
4. Is the client being treated for: • Co-morbid depression, • Anxiety, • Bipolar disorder or • Panic (i.e. Is there an existing claim history of: • Antidepressants, • Lithium, • Antipsychotics, or • Other appropriate mental health drugs)?	**Yes:** Approve for up to 1 year	**No:** Pass to RPH; Go to #5.
5. RPH only: Is diagnosis being treated a covered indication on the OHP and is there medical evidence of benefit of the prescribed sedative? All indications need to be evaluated as to see if they are above the line or below the line.	Above: Document supporting literature and approve up to 6 months with subsequent approvals dependent on f/u and documented response.	Below: Go to #6.
6. RPH only: Is this a request for continuation therapy for client with history of chronic use where discontinuation would be difficult or unadvisable? NOTE: Clients coming onto the plan on chronic sedative therapy are "grandfathered."	**Yes:** Document length of treatment and last follow-up date. Approve for up to 1 year.	**No:** Deny, (Medical Appropriateness)

P&T / DUR Action: *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: *10/15, 1/1/15, 7/1/14; 1/1/07, 7/1/06, 11/15/05*

Central Nervous System (CNS) Sedatives – Quantity Limit

Goal(s):

- Approve only for covered OHP diagnoses.
- Treatment of uncomplicated insomnia is not covered, but insomnia contributing to covered comorbid conditions is.
- Prevent adverse events associated with long-term sedative use.
- Clients coming onto the plan on chronic sedative therapy are grandfathered.(refer to criteria). Also see related Sedative Therapy Duplication edit. The safety and effectiveness of chronic sedative use is not established in the medical literature.

Length of Authorization:

- 6 to 12 months (criteria specific)

Requires PA:

- All CNS sedatives in Standard Therapeutic Class 47 that exceed 15 doses per 30 days.

Covered Alternatives:

- Trazodone, mirtazapine, diphenhydramine or tricyclic antidepressants may be alternatives for some clients.

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Does client have diagnosis of insomnia with sleep apnea?	**Yes:** Go to #3.	**No:** Go to #4.
3. Is client on CPAP?	**Yes:** Approve for up to 1 year. The use of CPAP essentially negates the sedative contraindication and they are often prescribed to help clients cope with the mask.	**No:** Pass to RPH, Deny, Medical appropriateness. Due to the depressant effects of sedative/ hypnotics, sedative/hypnotics are contraindicated for this diagnosis and are not approvable.
4. Is the client being treated for co-morbid depression, bipolar disorder OR panic disorder AND Is there an existing claim history of antidepressants, lithium, antipsychotics, or other appropriate mental health drugs?	**Yes:** Approve for up to 1 year.	**No:** Pass to RPH; Go to #5.

Approval Criteria		
5. RPH only: Is diagnosis being treated a covered indication on the OHP and is there medical evidence of benefit of the prescribed sedative? All indications need to be evaluated as to whether they are above the line or below the line.	Above: Document supporting literature and approve up to 6 months with subsequent approvals dependent on f/u and documented response.	Below: Go to #6.
6. RPH only: Is this a request for continuation therapy for client with history of chronic use where discontinuation would be difficult or unadvisable? NOTE: Clients coming onto the plan on chronic sedative therapy are "grandfathered."	**Yes:** Document length of treatment and last follow-up date. Approve for up to 1 year.	**No:** Deny, (Medical Appropriateness)

P&T / DUR Action: *3/27/14, 5/18/06, 2/23/06, 11/10/05, 9/15/05, 2/24/04, 2/5/02, 9/7/01*
Revision(s): *10/15, 7/1/14, 1/1/07, 7/1/06, 11/15/05*

Central Nervous System (CNS) – Sedatives-Therapeutic Duplication

Goal(s):

- Prevent duplicate sedative use.
- Approve only for covered OHP diagnoses.
- Treatment of uncomplicated insomnia is not covered; insomnia contributing to covered comorbid conditions is.
- Also see related Benzo Quantity edit and Non-benzo Sedative edit.
- The safety and effectiveness of chronic sedative use is not established in the medical literature.

Length of Authorization:

1 month

Requires PA:

- Concurrent therapy with more than one sedative drug in Class 47.
- The plan prohibits the client from receiving two oral sedative medications at the same time. POS system screens duplicate oral sedative claims in the prior 30 days. If client has a covered diagnosis, treatment with any single agent is approvable.

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

Trazodone Mirtazapine Diphenhydramine Tricyclic antidepressants	May be alternatives for some clients.

Approval Criteria		
1. What diagnosis is being treated?	Record the diagnosis, ICD10 code and reject the internal error code.	
2. 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). There is no evidence to support the use of two different sedatives concurrently. Continuous use of a single sedative is approvable for covered diagnoses. (See benzo quantity limit sedative and non-benzo PA)

P&T / DUR Action: *5/18/06*
Revision(s): *10/15, 7/1/14*

Codeine

Goal(s):

- Promote safe use of codeine in pediatric patients

Length of Authorization:

- Up to 3 days

Requires PA:

- All codeine products for patients under 13 years of age
- All codeine *analgesic* products for patients aged 13 through 17 years

Covered Alternatives:

- Preferred alternatives 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 13-17 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 / DUR Review: *9/15; 7/15 (AG)*
Implementation: *10/15*

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.

Length of Authorization:

- 6-12 months

Requires PA:

- Conjugated estrogens/bazedoxifene

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org in the hormone replacement class.

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 for 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 are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&T) Committee. Reports are available at: http://www.orpdl.org/drugs	**Yes:** Inform provider of covered alternatives in class. (www.orpdl.org)	**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 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 12 months	**No:** Pass to RPH; Deny (Medical Appropriateness)

P&T / DUR Action: *11/14*
Implementation: *10/15*

Cough and Cold Preparations

Goal(s):

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

Length of Authorization:

Up to 12 months

Requires PA:

- All drugs (antihistamines and combinations) in TC = 16, 17 except those listed below.
- All codeine-containing products for patients under 13 years of age.

Covered Alternatives:

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

HSN	Generic Drug Name
001929	Benzonatate
000271	Guaifenesin
000206	Guaifenesin/Codeine PHOS
000223	Guaifenesin/D-methorphan HB
002091	Pseudoephedrine HCL

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the diagnosis an OHP covered diagnosis? All indications need to be evaluated to see if they are covered diagnoses on the Oregon Health Plan list of prioritized services.	**Yes:** Above the line diagnosis: Go to #3.	**No:** Below the line diagnosis: Pass to RPH; Deny, (Not Covered by the OHP). Offer alternatives
3. Has the client tried and failed or are they contraindicated to one of the covered alternatives listed above?	**Yes:** document failure. Approve for one year.	**No:** Pass to RPH; Deny, Cost Effectiveness

P&T / DUR Review: *2/23/06*
Implementation: *10/15, 1/10/08*

Cysteamine Delayed Release (Procysbi®)

Goal(s):

- To promote preferred drugs
- To ensure appropriate use of costly agents by authorizing utilization in a specified patient population.

Length of Authorization:

Up to 6 months

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 for medical appropriateness.
3. Is the patient receiving medications through a gastrostomy tube?	**Yes:** Pass to RPh. Deny for medical appropriateness.	**No:** Go to #4.
4. Has the patient had an adequate trial of cysteamine immediate release (Cystagon) AND A physician experienced in managing metabolic diseases such as nephropathic cystinosis has documented that the patient has justified nonadherence to cysteamine IR that is preventing the patient from achieving adequate WBC cysteine levels (< 1 nmol ½ cysteine per mg protein)?	**Yes:** Approve for up to 6 months.	**No:** Pass to RPh; Deny for medical appropriateness.

P&T / DUR Action: *3/27/14 (MH)*
Implementation: *1/1/16; 10/15*

Dalfampridine (Ampyra®)

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:

- 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 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? (Patient has completed two month trial)	**Yes:** Go to "Continuation of Therapy"	**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 to severe renal impairment (CrCl <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 with moderate ambulatory dysfunction who do not require a walking aid AND • Is able to complete the baseline timed 25 foot walk between 8 and 45 seconds	**Yes:** Approve initial fill for 2 month trial.	**No:** Pass to RPH; Deny (medical appropriateness)

Continuation of Therapy		
1. Has the patient been taking dalfampridine for 2 months or longer and has demonstrated that walking speed has improved while on dalfampridine (documentation of ≥20% improvement in timed 25 foot walk).	**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 / DUR Action: *3/29/12*
Implementation: *10/15*

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:
- Preferred alternatives 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 do not require a copay. • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics (P&T) Committee.	**Yes:** Inform prescriber of covered alternatives in class	**No:** 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 as doses advanced, 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/DUR Review: *9/15 (KS); 9/14; 9/13; 4/12; 3/11*
Implementation: *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? Generic Name / Brand Name Metoclopramide / Reglan® Prochlorperazine / Compazine® Promethazine / Phenergan® 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)

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, 839.40)

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 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 / DUR Action: 3/15 (AG); 3/09
Implementation: 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

Drugs Used for Non-Funded Pain Conditions

Goal(s):

- Provide coverage only for funded diagnoses that are supported by the medical literature (e.g. major depressive disorder, epilepsy, diabetic neuropathy, post-herpetic neuralgia).

Length of Authorization:

- 90 days to lifetime (criteria specific)

Requires PA:

- milnacipran, pregabalin

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code	
2. Is the drug requested pregabalin AND does the patient have a diagnosis of epilepsy (ICD10: G40101-G40311; G40401-G40509; G40802; G40804; G40901-G40919; R569 or S069X9S)?	**Yes:** Approve for lifetime (until 12-31-2036)	**No:** Go to #3
3. Is the diagnosis funded on the OHP list of prioritized services (See Table below for examples)?	**Yes:** Approve for 90 days to 1 year	**No:** Pass to RPh; go to #4
4. Pass to RPh: • For Bipolar affective disorder: there are no data to support use of any of these drugs for this indication (Deny Medical Appropriateness). Recommend other alternatives (lithium, valproate, carbamazepine, lamotrigine). • For Migraine prophylaxis: there are no data to support use of any of these drugs for this indication (Deny Medical Appropriateness). Recommend other alternatives (beta-blockers, calcium channel blockers, valproate, gabapentin, TCAs). Refer to American Academy of Neurology Guideline. • If clinically warranted, may DENY yesterday's date (Medical Appropriateness) and use clinical judgment to APPROVE for 1 month starting today to allow time for appeal. All other indications need to be evaluated to see if diagnosis is funded: • Funded neuropathies found in table (list is not all-inclusive) may be approved for 90 days with subsequent approvals dependent on documented positive response (documented response means that follow-up and response is noted in client's chart per clinic staff). • **Forward any neuropathy/neuralgia ICD-10 codes not found in the Table to the Lead Pharmacist. These codes will be forwarded to DMAP for consideration.**		

Table

NON-FUNDED DIAGNOSES	ICD10
DISORDERS OF SOFT TISSUE	
Myalgia and myositis, unspecified (includes fibromyalgia syndromes)	M609; M791; M797
Neuralgia, neuritis, and radiculitis, unspecified	M792
ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT	
Sacroiliitis, not elsewhere classified	M461
Inflammatory spondylopathies in diseases classified elsewhere	M4980
Cervical spondylosis without myelopathy	M47812
Thoracic spondylosis without myelopathy	M47814
Lumbosacral spondylosis without myelopath	M47817
Traumatic spondylopathy	M4830
Other allied disorders of spine	M489
Spondylosis of unspecified site, without mention of myelopathy	M47819
Intervertebral disc disorders*	M4640; M4647; M5020; M5030; M5080; M5090; M5104-M5107; M519; M5124-5127; M5134-5137; M5144-5147; M5184-5187; M961
Cervicalgia	M542
Other disorders of cervical region	M5402, M5382
Pain in thoracic spine/Lumbago	M545-546
Backache, unspecified	M4327-4328; M533; M539; M5408; M5489; M549
Nonallopathic lesions not elsewhere classified	M9900-9908
Closed dislocation thoracic and lumbar vertebra	S33101A; S23101A
Sprains and strains of other and unspecified parts of back	S134XXA; S138XXA; S233XXA; S238XXA; S239XXA; S335XXA; S338XXA
CHRONIC PAIN (EXCLUDED DIAGNOSES)	
Chronic pain d/t trauma	G8921
Other chronic pain	G8929
Chronic pain syndrome	G894
FUNDED DIAGNOSES	**ICD9**
Hereditary and idiopathic peripheral neuropathy	G600-601; G603; G608-609
Diabetes with neurological manifestations	E1040; E1065; E1140; E1165
Herpes zoster with nervous system complications	B0221-B0229
Syringomyelia and syringobulbia	G950
Disorders of meninges, not elsewhere classified	G9612; G9619
Brachial neuritis or radiculitis NOS	M5412-5413

Other specified congenital anomalies of spinal cord	Q060-061; Q063; Q068

= the following diagnoses have coverage under current funding line
Intervertebral disc disorders: M5000, M5104-5106
Other disorders of cervical region: M6788
Backache, unspecified: M5414-5417

***= the following codes require use of HERC guideline notes to determine coverage*
Intervertebral disc disorders: M5020; M5125-5127
Backache, unspecified: M438X9; M532X7-532X8
Congenital musculoskeletal deformities of sternocleidomastoid muscle: Q680

P&T / DUR Action: *3/15; 5/09; 9/07; 11/07*
Implementation: *1/16; 10/15; 4/18/15; 1/11; 1/10*

Erythropoiesis Stimulating Agents (ESAs)

Goal(s):

- Cover ESAs according to OHP guidelines[1] 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:

- Preferred alternatives listed at www.orpdl.org

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 covered by the OHP).
3. Is this continuation therapy?	**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?	**Yes:** Inform provider of covered alternatives in class.	**No:** Go to #6
6. Is the diagnosis anemia due to chronic renal failure[2] or chemotherapy[3,4] ?	**Yes:** Go to #7	**No:** Go to #8
7. Is Hb < 10g/dl or Hct < 30% AND Transferrin saturation >20% and/or ferritin >100ng/ml?	**Yes:** Approve for 12 weeks with additional approval based upon adequate response.	**No:** Pass to RPH; Deny (not medically appropriate).
8. Is the diagnosis anemia due to HIV[5]?	**Yes:** Go to #9	**No:** Go to #10
9. Is the Hb < 10g/dL or Hct < 30% AND Transferrin saturation > 20% AND Endogenous erythropoietin < 500 iu/L AND If on Zidovudine is dose < 4200mg/week?	**Yes:** Approve for length of Rx or 12 months, whichever is less.	**No:** Pass to RPh; Deny (not medically appropriate).

Approval Criteria		
10. Is the diagnosis anemia due to ribavirin treatment[6]?	**Yes:** Go to #11	**No:** Pass to RPh; Deny, (not medically appropriate).
11. Is the Hb < 10g/dL or Hct < 30% AND Is the transferrin saturation >20% and/or ferritin >100ng/ml AND Has the dose of ribavirin been reduced by 200mg/day and anemia persisted > 2 weeks?	**Yes:** Approve up to the length of ribavirin treatment.	**No:** Pass to RPh; Deny (not medically appropriate).
12. Has the patient responded to initial therapy?	**Yes:** Approve for length of Rx or 12 months, whichever is less.	**No:** Pass to RPh; Deny (not medically appropriate).

References:

1. Oregon Health Policy and Research Current Prioritized List of Health Services. Available at: http://cms.oregon.gov/oha/OHPR/pages/herc/current-prioritized-list.aspx Accessed September 12.2012
2. 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.
3. 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.
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5. 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.
6. 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 / DUR Board Action: 11/29/12(MH), 6/28/12(KK); 2/23/12, 09/16/2010 (DO)
Implementation: 10/15, 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:

- Preferred alternatives 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 for 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 covered by the OHP)

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

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.

- 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, 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 Covered 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 Dy 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 / DUR Action: *2/23/06*
Implementation: *10/15; 9/1/06; 1/1/12*

Fentanyl Buccal, Intranasal and Sublingual Products

Goal(s):

The purpose of this prior authorization policy is to ensure that fentanyl for breakthrough pain is appropriately prescribed in accordance to FDA black box warnings:

- Short-acting fentanyl is indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.
- Patients considered opioid-tolerant are those who are taking at least 60 mg/day morphine, 50 mcg/hour transdermal fentanyl, or an equianalgesic dose of another opioid for a week or longer.
- Because life-threatening respiratory depression can occur at any dose in patients not taking chronic opioids, transmucosal and buccal fentanyl is contraindicated in the management of acute or postoperative pain.
- This product must not be used in opioid-naïve patients. Short acting (SA) fentanyl is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable and skilled in the use of Schedule II opioids to treat cancer pain.
- When prescribing, do not convert patients from other fentanyl products on a mcg per mcg basis. Pharmacokinetic differences between products could cause fatal over-dose.
- Caution should be used when combining these agents with CYP3A4 inhibitors. Increases in fentanyl concentrations can cause fatal respiratory depression.
- Patients and their caregivers must be instructed that fentanyl products contain a medicine in an amount which can be fatal to a child. Patients and their caregivers must be instructed to keep all units out of the reach of children and to discard opened units properly.

Length of Authorization:

- Up to 6 months (with quantity limit)

Requires PA:

- Non-preferred short-acting fentanyl buccal, intranasal and sublingual products

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. What is the diagnosis for which fentanyl is being requested?	Record ICD10 code.	
2. Is the pain diagnosis above the line or below the line? (for DMAP, short acting fentanyl is not limited to cancer pain but must be severe chronic pain)	**Above the line:** go to #3.	**Below the line:** No, Pass to RPH; Deny, (Not Covered by the OHP).

Approval Criteria		
3. Is the prescriber an oncologist or pain specialist?	**Yes:** Go to #4.	**No:** Pass to RPH; Deny, (Medical Appropriateness), with message: "The described use is not consistent with the FDA labeling which SA fentanyl be used only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain."
4. Is client tolerant to opioids (**Check profile)**, defined as chronic long-acting opioid dose of: • Morphine greater than 60 mg per day? OR • Transdermal fentanyl 50 mcg per hour? OR • Equianalgesic dose of another opioid for at least one week?	**Yes:** Go to #5.	**No:** Pass to RPH; Deny, (Medical Appropriateness), *with message:* *"Your request was reviewed and denied because it is not consistent with the FDA labeling. A trial of immediate release morphine or oxycodone is recommended prior to use of SA fentanyl."*
5. Has the client tried and failed immediate release morphine or oxycodone? OR is the client allergic, unable to swallow or intolerant to morphine and oxycodone?	**Yes:** Go to #6.	**No:** Pass to RPH; Deny, (Medical Appropriateness), *with message:* *"Your request was reviewed and denied based on the following: A trial of immediate release morphine or oxycodone is recommended prior to use of SA fentanyl."*
6. Is the quantity >4 doses per day?	**Yes:** Pass to RPH; Deny, (Medical Appropriateness), *with message:* *"Your request for a quantity greater than 4 doses per day has been denied because it exceeds limits."*	**No:** Approve for up to 6 months with quantity limit of 4 lollipops/tablets per day (i.e. 120/30 days).

P&T/DUR Review: *5/15; 6/13; 3/10; 12/09, 9/05, 5/05*
Implementation: *10/15; 1/14; 4/10; 4/08, 6/08, 1/10*

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:
- Preferred alternatives 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 or a copay. • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics (P&T) Committee.	**Yes:** Inform prescriber of covered alternatives in class	**No:** Go to #4
4. Has the patient tried and failed metformin and sulfonylurea therapy or have contraindications to these treatments? (document contraindication, if any)	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of metformin or sulfonylurea. See below for metformin titration schedule.
5. Is the patient currently taking insulin?	**Yes:** Go to #6	**No:** Approve for up to 12 months
6. Is the patient requesting exenatide, liraglutide or albiglutide and using basal insulin?	**Yes:** Approve for up to 12 months	**No:** Go to #7

Approval Criteria		
7. Is the patient requesting dulaglutide and using prandial insulin?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness. The safety and efficacy of other insulin formations and GLP-1 agonists have not been studied.

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 as doses advanced, 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/DUR Review: *9/15 (KS); 1/15; 9/14; 9/13; 4/12; 3/11*
Implementation: *10/15; 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*

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:

- Non-preferred drugs

Covered Alternatives:

- All GH products require prior authorization for OHP coverage. GH treatment for adults is not funded by the OHP.
- Preferred alternatives are 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 to not require a copay. • 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 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 do not require a copay. • 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 and approve for up to 12 months	**No:** Approve for up to 12 months

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P&T / DUR Review: 9/15; 9/14; 9/10; 5/10; 9/08; 2/06; 11/03; 9/03
Implementation: 10/15; 1/1/11, 7/1/10, 4/15/09, 10/1/03, 9/1/06; 10/1/03

Hepatitis B Antivirals

Goal(s):

- Cover hepatitis B agents according to OHP guidelines. Cover preferred products when feasible for covered diagnosis.
- Preferred products are selected based on evidence based reviews.

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 www.orpdl.org

Pediatric Age Restrictions:

- lamivudine (Epivir HBV) - 2 years and up
- adefovir dipivoxil (Hepsera) - 12-17 years
- entecavir (Baraclude) – 2 years and up
- telbivudine (Tyzeka) - safety and effectiveness not approved in pediatrics
- tenofovir (Viread) – 12 -17 years

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the diagnosis an OHP covered diagnosis?	**Yes:** Go to #3.	**No:** Pass to RPh, Deny for OHP Coverage.
3. Is the request for an antiviral for the treatment of HIV/AIDS?	**Yes:** Approve for up to 1 year	**No:** Go to #4
4. Is the request for treatment of Chronic Hepatitis B?	**Yes:** Go to #5	**No:** Pass to RPh, Deny for Appropriateness
5. Is this a continuation of current therapy (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

Approval Criteria		
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's supply.	**No:** Go to #7
7. Will the prescriber consider a change to a preferred product?	**Yes:** Inform provider of covered alternatives in class.	**No:** Approve requested treatment for 6 months with monthly quantity limit of 30 day's supply.

Renewal Criteria	
1. Is client compliant with requested treatment (see refill history)?	**Yes:** Go to 2.
2. Is HBV DNA undetectable (below 10-15 IU/ml by real time PCR) or the patient has decompensated cirrhosis? Note: Antiviral treatment is indicated irrespective of HBV DNA level in patients with decompensated cirrhosis to prevent reactivation.	**Yes:** Approve for up to 1 year with monthly quantity limit of 30 day's supply

P&T / DUR Action: *4/26/12*
Implementation: *10/15; 5/29/2014 (MH), 1/1/13(HK)*

Hepatitis C Direct-Acting Antivirals

Goal(s):

- Approve cost effective treatments of chronic Hepatitis C, which are supported by the medical literature when there is available evidence.
- Treat the patient population in greatest need of treatment and who will benefit the most from therapy.
- Provide consistent patient evaluations across all hepatitis C treatments.

Length of Authorization:

- 8-12 weeks

Requires PA:

- All drug regimens in the Hepatitis C PDL Class

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for treatment of Chronic Hepatitis C Virus?	**Yes:** Go to #3	**No:** Pass to RPh; deny for appropriateness.
3. What regimen is requested?	**Document and Go to #4.**	
4. Does the regimen contain a drug not yet reviewed by P&T?	**Yes:** Go to #5	**No:** Go to #6
5. Will the prescriber change to a preferred product already reviewed for efficacy and safety by the P&T Committee?	**Yes:** Inform Provider of covered alternatives in class	**No:** Pass to RPh; deny for appropriateness. Forward to DMAP for further review to determine appropriateness and coverage in light of most recent community standards and comorbidity.
6. Is the medication being prescribed by or in consultation with a hepatologist or gastroenterologist with experience in Hepatitis C?	**Yes:** Go to #7.	**No:** Pass to RPh; deny for appropriateness. Forward to DMAP for further review to determine appropriateness of prescriber.

Approval Criteria		
7. Does the patient have a biopsy or other non-invasive technology (Fibroscan), including serum tests (Fibrosure, Fibrotest) to indicate Advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4) OR radiologic, laboratory, or clinical evidence of cirrhosis without ongoing progressive decompensation (MELD score between 8 and 11), and expected survival from non-HCV associated morbidity should be greater than 5 years?	**Yes:** Go to #8.	**No:** Go to #9. **<u>Note:</u>** Patients with a MELD score >11 may be eligible for therapy, but only after review by the DMAP medical director. If patient has Metavir F0-F2, a treatment option remains pegylated interferon and ribavirin; refer to that specific PA Criteria
8. Does the patient have decompensated cirrhosis?	**Yes:** Pass to RPh; deny for appropriateness	**No:** Go to #11
9. Does the patient have one of the following extrahepatic manifestations of hepatitis C and who have formal documentation from a relevant specialist that their condition is HCV related, and expected survival from non-HCV associated morbidity should be greater than 5 years? a. Type 2 or 3 cryoglobulinemia with end-organ manifestations (vasculitis) b. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis	**Yes:** Go to #11.	**No:** Go to 10.
10. Does the patient have Hepatitis C Virus in the transplant setting, including the following scenarios: a) Patient is listed for a transplant and it is essential to prevent recurrent hepatitis C infection post-transplant b) Post-transplant patients with Stage 4 fibrosis c) Post-transplant patients with fibrosing cholestatic hepatitis due to HCV infection **And** expected survival from non-HCV associated morbidity should be greater than 5 years?	**Yes:** Go to #11.	**No:** Pass to RPh; deny for medical appropriateness. Note: Other scenarios not included can be brought to the Medical Director on a case by case basis.

Approval Criteria		
11. Has the patient been abstinent from IV drug, illicit drugs and marijuana use, AND alcohol abuse for ≥ 6 months? AND If the patient has a history of alcohol abuse, has the patient been abstinent from alcohol use for ≥ 6 months?	**Yes:** Go to #12.	**No:** Pass to RPh; deny for appropriateness.
12. Does the patient have significant renal impairment (CrCl ≤30 mL/min) or end state renal disease (ESRD)?	**Yes:** Pass to RPh; deny for appropriateness.	**No:** Go to #13.
13. Does the patient have a baseline HCV RNA level?	**Yes:** Record value and go to #14	**No:** Pass to RPH. Request provider obtains baseline lab value.
14. What Hepatitis C genotype is the patient? Record Genotype:	Record Genotype and go to #15.	
15. Is the prescribed drug ledipasvir/sofosbuvir (Harvoni®) and is the regimen and duration appropriate for patient genotype based on the dosing and administration table below?	**Yes:** Approve for 8-12 weeks based on dosing and administration table.	**No:** Go to #16 If prescribed other DAA, encourage prescriber to use our preferred product
16. Is the prescribed drug sofosbuvir (Solvaldi®)?	**Yes:** Go to #17	**No:** Go to #18
17. Does the patient have Genotype 2 hepatitis C infection?	**Yes:** Approve for 12 weeks based on dosing and administration table below	**No:** Go to #18 If prescribed other DAA, encourage prescriber to use our preferred product
18. Is the prescribed drug ombitasvir, paritaprevir, and ritonavir; dasabuvir (Viekira Pak®)?	**Yes:** Go to #19	**No:** Pass to RPh; deny for appropriateness. Encourage prescriber to use our preferred DAA.
19. Has the patient been off all ethinyl estradiol containing products for at least a week OR is willing to discontinue any products one week prior to starting therapy? If the patient is not on any ethinyl estradiol medications, go to #20.	**Yes:** Go to #20	**No:** Pass to RPh; deny for appropriateness.

Approval Criteria		
20. If the patient was or is on any other medications that due to drug-drug interactions are contraindicated with the use of Viekira Pak (See Table 2 below), has the patient stopped this medication at least a week ago or is willing to discontinue this medication (and it is appropriate) at least one week prior to starting therapy? If the patient is not on any medications in Table 2 that are contraindicated, go to #21.	**Yes:** Go to #21	**No:** Pass to RPh; deny for appropriateness.
21. Does the patient have HIV coinfection?	**Yes:** Go to #22	**No:** Go to #23
22. Is the patient not receiving suppressive antiretroviral therapy (who may be at increased risk of HIV-1 protease inhibitor drug resistance) OR on therapy with significant antiretroviral drug-interactions (efavirenz, darunavir/ritonavir, lopinavir/ritonavir, rilpivirine).	**Yes:** Pass to RPh; deny for appropriateness.	**No:** Go to #23
23. Is the patient treatment naïve with or without cirrhosis or treatment experienced without cirrhosis?	**Yes:** Approve for 12 weeks based on appropriate dosing and administration from table below	**No:** Go to #24
24. Has the patient failed previous therapy with a direct acting antiviral?	**Yes:** Pass to RPh; deny for appropriateness. Use of Viekira has not been studied in this population.	**No:** Go to #25
25. If the patient failed previous therapy with peginterferon/ribavirin dual therapy, did the patient relapse or have a partial response?	**Yes:** Approve for 12 weeks based on dosing and administration table below	**No:** Go to #26
26. Does the patient have cirrhosis and had a previous null response to dual therapy with peginterferon and ribavirin therapy or a post-liver transplant patient?	**Yes:** Approve for 24 weeks based on dosing and administration table below	**No:** Pass to RPh; deny for appropriateness. Encourage

Table 1: Dosage and Administration:

Genotype 1			
Naïve	Without Cirrhosis and HCV RNA < 6 million IU/mL	LDV/SOF 1 tablet QDay	8 weeks

	Without Cirrhosis and HCV RNA ≥ 6 million IU/mL	LDV/SOF 1 tablet QDay	12 weeks
	Without Cirrhosis; Genotype 1b	Paritaprevir/R+Ombitasvir+Dasabuvir	12 weeks
	Without Cirrhosis; Genotype 1a	Paritaprevir/R+Ombitasvir+Dasabuvir + RBV	12 weeks
	With Cirrhosis	LDV/SOF 1 tablet QDay Paritaprevir/R+Ombitasvir+Dasabuvir + RBV	12 weeks 12 weeks
Experienced	Without Cirrhosis	LDV/SOF 1 tablet QDay Paritaprevir/R+Ombitasvir+Dasabuvir + RBV	12 weeks 12 weeks
	With Cirrhosis	LDV/SOF 1 tablet QDay + RBV Paritaprevir/R+Ombitasvir+Dasabuvir + RBV	12 weeks 12 weeks-24 weeks*
Genotype 2			
Naïve and Experienced	With or Without Cirrhosis	SOF 400 mg QDay + RBV	12 weeks**
Genotype 3			
Naïve or Experienced	With or Without Cirrhosis	LDV/SOF 1 tablet QDay + RBV	12 weeks
Genotype 4 and 6			
Naïve or Experienced	With or Without Cirrhosis	LDV/SOF 1 tablet QDay	12 weeks

*24 weeks of therapy with Paritaprevir/R+Ombitasvir+Dasabuvir + RBV should be reserved for treatment experienced, genotype 1a, null responders or post-liver transplant patients
**Previous nonresponders to PEG/RBV with cirrhosis may benefit by extension of therapy to 16 weeks
Abbreviations: LDV/SOF: Ledipasvir and sofosbuvir (Harvoni®); RBV: ribavirin; SOF: sofosbuvir (Sovaldi®)

Table 2: Drugs Contraindicated with Viekira Pak	
Alfuzosin HCL Carbamazepine Phenytoin Phenobarbital Gemfibrozil Rifampin Ergotamine Dihydroergotamine Ergonovine	Methylergonovine St. John's Wort Lovastatin Pimozide Efavirenz Sildenafil* Triazolam Midazolam

*When dosed as REVATIO for the treatment of pulmonary arterial hypertension (PAH)

P&T/DUR Review: *5/15; 3/15; 1/15; 9/14; 1/14*
Implementation: *10/15; 4/15, 1/15; 9/14; 7/14; 3/14*

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:

Up to 20 weeks

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the client between 16 weeks and 0 days and 36 weeks 6 days gestation with a singleton pregnancy?	**Yes:** Go to #3.	**No:** Pass to RPH; Deny (medical appropriateness)
3. Has the patient had a prior history of preterm delivery before 37 weeks gestation (spontaneous preterm singleton birth)?	**Yes:** Go to #4	**No:** Pass to RPH; Deny (medical appropriateness)
4. 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 Action: *5/31/2013 (BF/MH)*
Implementation: *10/15*

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 1 year

Requires PA:
- Non-preferred drugs

Preferred Alternatives:
- No preferred alternatives at this time

Approval Criteria		
1. Is this request for continuation of therapy (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 for medical appropriateness.
3. Is the treatment prescribed by a pulmonologist?	**Yes:** Go to #4	**No:** Pass to RPH; Deny for medical appropriateness.
4. Does the patient have a forced vital capacity (FVC) >50%?	**Yes:** Go to #5	**No:** Pass to RPH; Deny for medical appropriateness.
5. Is the patient a current smoker?	**Yes:** Pass to RPH; Deny for 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 for 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 for 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:

- Preferred alternatives listed at http://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 PA or a copay. • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&T) Committee.	**Yes:** Inform prescriber of covered alternatives in class.	**No:** Go to #3
3. 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/DUR Review: *9/15 (KS/AG)*
Implementation: *10/15*

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 specified patients populations to ensure appropriate and safe use.

Length of Authorization:

- Up to 12 months

Requires PA:

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

Covered Alternatives:

- Preferred alternatives 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 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 for medical appropriateness
5. Will the prescriber consider a change to a preferred product? Message: • Preferred products do not require a copay • 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. Approve insulin pens/cartridges for up to 12 months (other preferred products do not require PA)	**No:** Approve for up to 12 months

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:

- Preferred alternatives listed at http://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 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 do not require co-pay and are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics (P&T) Committee.	**Yes:** Inform provider of preferred alternatives; go to #5	**No:** Go to #5
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

Approval Criteria		
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 for medical appropriateness	**No:** Approve for up to 6 months
8. RPh only: Is the diagnosis funded by the OHP?	Funded: Deny for 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: *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:

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

Approval Criteria		
1. Is this a request for continuation of therapy (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 for 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 for 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 for 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 for 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 for 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 for 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 for 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.

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:

- Preferred alternatives listed at http://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 do not require PA or a copay. • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&T) Committee.	**Yes:** Inform provider of covered alternatives in class	**No:** Go to #3
3. Does the patient have a diagnosis of asthma or reactive airway disease (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/DUR Review: *11/15 (KS); 9/15; 11/14; 11/13; 5/12; 9/09; 2/06*
Implementation: *1/1/16; 1/15; 1/14; 9/12; 1/10*

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:

- Preferred alternatives listed at http://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 PA or a copay. • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the 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, J45901-45998)?	**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) (ie, 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.

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:

- Preferred alternatives listed at http://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 PA or a copay. • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&T) Committee.	**Yes:** Inform prescriber of covered alternatives in class	**No:** Go to #3
3. 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
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.

Approval Criteria		
5. Does the patient have an active prescription for an on-demand short-acting bronchodilator (anticholinergic or beta-agonist)?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness.
6. Does the patient have an active prescription for an on-demand short-acting beta-agonist (SABA) or an alternative rescue medication for acute asthma exacerbations?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness
7. Does the patient have an active prescription for an inhaled corticosteroid (ICS) or an alternative asthma controller medication?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: *9/15 (KS/AG); 5/12; 9/09; 5/09*
Implementation: *10/15; 8/12; 1/10*

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*

Methadone – New Starts @ doses ≥20mg

Goal(s):

- Promote safe use of methadone upon initiation

Initiative:

Prescribing Recommendations

- Opioid naïve or patients receiving codeine preparations: start at low dose and increase slowly:
- 2.5 mg BID-TID; upward titration by 2.5 mg q8h no sooner than weekly

Conversion from other opioids

- Starting dose 2.5mg-5mg q8h; upward titration by 2.5 mg q8h no sooner than weekly
- Use short-acting opioid for breakthrough pain until optimum dose reached.

Length of Authorization:

- Up to 6 months

Requires PA:

- Patients initiated on methadone (i.e. no previous claim within 90 days) on a daily dose of > 20mg

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Has patient had a recent urinary drug screen (within the past 90 days)?	**Yes**: Go to #3	**No:** Pass to RPH; Deny (Medical Appropriateness) Recommend UDS.
3. Has patient been continuously on opioids other than codeine over the past 90 days?	**Yes:** Go to #4 Document previous opioid therapy.	**No:** Pass to RPH; Deny (Medical Appropriateness) Opioid naïve or patients receiving codeine preparations should start methadone @ 2.5 mg BID-TID; upward titration by 2.5 mg q8h no sooner than weekly

Approval Criteria		
4. Is the total Morphine Equivalent Dose per Day < 200mg? Dose Calculator at:		**Yes:** Pass to RPH; Deny (Medical Appropriateness) Recommend initiate methadone @ 2.5mg - 5 mg q8h; upward titration by 2.5 mg q8h no sooner than weekly and use short-acting opioids for break-through pain
5. Is this patient terminal (<6 months) or admitted to hospice?	**Yes:** Approve for up to 6 months.	**No:** Go to #6.
6. Is patient being treated for oncology pain?	**Yes:** Approve for up to 6 months.	**No:** Pass to RPH; Deny (Medical Appropriateness)

P&T / DUR Action: *1/26/12 (KK), 5/19/11(KK), 3/17/11(KK)*
Implementation: *10/15*

Mipomersen (Kynamro®) and Lomitapide (Juxtapid®)

Goal(s):

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

Length of Authorization:

- Up to 6 months

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org

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 (see Clinical Notes below)?	**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 to them?	**Yes:** Approve for 1 year	**No:** Pass to RPH; Deny (medical appropriateness)

Clinical Notes:

Mipomersen and lomitapide are approved only for HoFH, a rare but serious disorder associated with premature cardiovascular morbidity and mortality with few effective treatment options. Both are proven effective in reducing LDL-C levels, but there is uncertainty about whether this equates to reduced cardiovascular morbidity and mortality. It is not feasible to do an outcomes study due to the low prevalence of the disease. However, the current safety data does not support the use of mipomersen and lomitapide in patients with lower CHD risk.[1, 2]

Few patients with homozygous FH achieve adequate LDL-C lowering even with 4-drug therapy. Maximum lipid lowering therapy is defined as reaching the highest tolerated statin dose or maximum FDA recommended high potency statin dose defined as follows:

Atorvastatin 80mg daily[3]
Rosuvastatin 40mg daily[3]
Simvastatin 40mg daily[3]
Pitavastatin 4 mg daily[3]

PLUS

Combination therapy with ezetimibe 10 mg per day, colesevelam, and/or niacin. Niacin and bile acid sequestrants should both be used unless they do not produce significant LDL-C lowering (< 5%) and/or if significant side-effects are occurring.[4, 5]

OR

If statins are contraindicated or not tolerated then, combination therapy with ezetimibe 10mg per day, colesevelam and/or niacin is recommended.[4, 5] Statin intolerance includes but is not limited to: evidence of new-onset muscle pain, significant gastrointestinal disturbance or alterations of liver function tests.[4, 5]

1. FDA Summary Review. Reference ID 3252189. 2013. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/203568Orig1s000SumR.pdf. Accessed April 1, 2013.

2. FDA. Lomitapide Summary Review - Reference ID 3236195. 2012. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/203858Orig1s000SumR.pdf. Accessed April 3, 2013.

3. Berglund L, Brunzell JD, Goldberg AC, et al. Evaluation and Treatment of Hypertriglyceridemia: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2012;97(9):2969–2989. doi:10.1210/jc.2011-3213.

4. NICE. Identification and management of familial hypercholesterolaemia. 2008. Available at: http://www.nice.org.uk/nicemedia/live/12048/41697/41697.pdf. Accessed April 1, 2013.

5. Ito MK, McGowan MP, Moriarty PM. Management of Familial Hypercholesterolemias in adult patients: Recommendations from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. J Clin Lipidol. 2011;5(3):S38–S45. doi:10.1016/j.jacl.2011.04.001.

P&T Action:	*9/26/2013 (KK); 7/25/2013(MH); 5/30/2013 (KK/MH)*
Implementation:	*10/15; 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:

- Preferred alternatives 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 this a funded diagnosis? Non-funded diagnoses: - Shift work disorder (ICD10 G4720-4729; G4750-4769; G478) - Unspecified hypersomnia (ICD10 G4710)	**Yes:** Go to #3	**No:** Pass to RPh; Deny, not funded by OHP
3. Will prescriber consider a preferred alternative?	**Yes:** Inform prescriber of options (eg, preferred methylphenidate)	**No:** Go to #4
4. Is the request for continuation of current therapy?	**Yes:** Pass to RPh; Go to #12	**No:** Go to #5
5. Is the prescribed daily dose higher than recommended in Table 2?	**Yes:** Pass to RPh; Deny for medical appropriateness.	**No:** Go to #6
6. 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 #7
7. Is the request for armodafinil?	**Yes:** Pass to RPh; Deny for medical appropriateness. There is insufficient evidence for any off-label use.	**No:** Go to #8
8. 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 #9

Approval Criteria		
9. 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 #10
10. Is the diagnosis ADHD?	**Yes:** Pass to RPh; Deny for medical appropriateness. There is insufficient evidence for benefit for ADHD. See available options at www.orpdl.org/drugs/	**No:** Go to #11
11. 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.		
12. 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 / DUR Review: *09/15 (kk)*
Implementation: *10/15*

Multivitamins and Antioxidant Multivitamin Combinations

Goal(s):

- Approve only 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 = C6Z, C6I and C6G

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 covered diagnosis?	**Yes:** Go to #3.	**No:** Pass to RPh; Deny, (not covered by 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 difficulties (e.g. Crohns 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 for medical appropriateness.

P&T / DUR Action: *3/27/2014 (MH/ KK)*
Implementation: *10/15*

Naltrexone Extended Release Inj. (Vivitrol®)

Goal(s):

- Promote safe and cost effective therapy for the treatment of alcohol and opioid dependence.

Length of Authorization:

- Initial – 3 months; Renewal – 1 year

Covered Alternatives:

- Acamprosate, naltrexone tablets, disulfiram. Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Does the member have a diagnosis of alcohol dependence (DSM-IV-TR) or alcohol use disorder (AUD: DSM5)?	**Yes:** Go to #3.	**No:** Go to #4.
3. Has the requesting prescriber provided documentation and/or confirmation of abstinence from alcohol as assessed by the provider and/or objective testing?	**Yes:** Go to #6	**No:** Pass to RPH. Deny for medical appropriateness. Patients must have demonstrated alcohol abstinence prior to administration.
4. Does the member have a diagnosis of opioid dependence (DSM-IV-TR) or opioid use disorder (OUD: DSM5)?	**Yes:** Go to #5	**No:** Pass to RPH. Deny for medical appropriateness. Naltrexone extended release injection is only approved for alcohol and opioid dependence.
5. Has the patient tried and failed other oral agents for the treatment of opioid dependency (buprenorphine, methadone) **OR** Is the patient unable to take oral therapy or does the patient require injectable therapy due to adherence issues?	**Yes:** Go to #6	**No:** Pass to RPH. Deny for medical appropriateness.

Approval Criteria		
6. Is the member part of a comprehensive treatment program for substance abuse that includes a psychosocial support system?	**Yes:** Go to #7	**No:** Pass to RPH. Deny for medical appropriateness. Naltrexone extended release injection therapy must be part of a comprehensive treatment program including psychosocial support.
7. Has the patient received any opioid prescription within the last 30 days from a prescriber other than the requesting provider based on prescription claims history?	**Yes:** Notify requesting provider of the opioid prescriber, drug, dose, prescription date and the day supply; Go to #8.	**No:** Go to #8.
8. Has the patient abstained from the use of any opioids for at least 7 to 10 days, including street opioids such as heroin or prescription opioids as assessed by the provider and/ or objective testing?	**Yes:** Approve for 3 months for initial therapy, 12 months for continuation therapy.	**No:** Pass to RPH. Deny for medical appropriateness. Patient must be opioid free for 7 to 10 days prior to administration to minimize risk of acute opioid withdrawal syndrome.

P&T / DUR Action: *1/29/15 (AG), 5/29/14 BBL, 11/21/2013 (TW / MH)*
Implementation: *10/15; 1/1/15*

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*

Nutritional Supplements (Oral Administration Only)

Goal(s):

- Restrict use to clients 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.

Please 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. However, the equipment does 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) Clients 6 years or older
2) Clients under 6 years

Not Covered:

- Supplements and herbal remedies such as Acidophilis, Chlorophyll, Coenzyme and Q-10 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:

- Preferred alternatives listed at www.orpdl.org

CLIENTS 6 YEARS or 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 (g-tube)?	**Yes:** Go to #10.	**No:** Go to #4.
4. All indications need to be evaluated as to whether they are above the line or below the line.	Above the line: Go to #5.	Below the line: Pass to RPH; Deny, (Not Covered by the OHP).
5. Is this request for a client that is currently on supplemental nutrition?	**Yes:** Go to #6.	**No:** Go to #7.
6. Has there been an annual assessment by MD for continued use of nutritional supplement? Document assessment date.	**Yes:** Approve up to 1 year	**No:** Request documentation of assessment OR Pass to RPH; Deny, (Medical Appropriateness)
7. Client must have a nutritional deficiency identified by one of the following: • Has there been a recent (within year) Registered Dietician assessment indicating adequate intake is not obtainable through regular/liquefied or pureed foods? (Supplement cannot be approved for convenience of client or caregiver.) **OR** • Is there a recent serum protein level < 6?	**Yes:** Go to #9.	**No:** Go to #8.

Approval Criteria		
8. Does the client have a prolonged history (>1 year) of malnutrition and cachexia OR reside in a LTC facility or chronic home care facility? Document: • Residence • Current weight • Normal weight	**Yes:** Go to #9.	**No:** Request more documentation OR Pass to RPH; Deny, (Medical Appropriateness)
9. Does the client have a recent unplanned weight loss of at least 10%, plus one of the following: • An increased metabolic need resulting from severe trauma (e.g. Severe burn, major bone fracture, etc.)? OR • Malabsorption difficulties (e.g. Crohns Disease, Cystic Fibrosis, bowel resection/ removal, Short Gut Syndrome, gastric bypass, renal dialysis, dysphagia, achalasia, etc)? OR • A diagnosis that requires additional calories and/or protein intake (e.g. Cancer, AIDS, pulmonary insufficiency, MS, ALS, Parkinson's, Cerebral Palsy, Alzheimers, etc.)	**Yes:** Approve for up to 1 year	**No:** Request more documentation **OR** Pass to RPH; Deny, (Medical Appropriateness)
10. Is this request for a client that is currently on supplemental nutrition? • Yes: Approve for 1 month and reply: Nutritional formulas, when administered by enteral tube, are no longer available through the point of sale system. For future use, service providers should use the CMS form 1500 or the 837P electronic claim form and not bill through POS. A one-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 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. 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		

CLIENTS AGED 5 YEARS and UNDER

Document:

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

Approval Criteria		
1. What is the diagnosis being treated that is responsible for needing nutritional support?	Record the ICD10 codes.	
2. Is the product to be administered by enteral tube feeding (g-tube)?	**Yes:** Go to #9.	**No:** Go to #3.
3. All indications need to be evaluated as to whether they are above or below the line.	Above the line: Go to #4.	Below the line: Pass to RPH; Deny (Not covered by the OHP).
4. Is this request for a client that is currently on supplemental nutrition?	**Yes:** Go to #5.	**No:** Go to #6.
5. Has there been an annual assessment by MD for continued use of nutritional supplement? (No recent weight loss, serum protein level or dietitian assessment required if body weight being maintained by supplements due to clients medical condition). Document assessment date.	**Yes:** Approve up to 1 year	**No:** Request more documentation OR Pass to RPH; Deny, (Medical Appropriateness)
6. Is the diagnosis failure to thrive (FTT)? (783.4)	**Yes:** Approve for up to 1 year.	**No:** Go to #7.
7. Does the client have: • An increased metabolic need resulting from severe trauma (e.g. Severe burn, major bone fracture, etc.)? OR • Malabsorption difficulties (e.g. Crohns Disease, Cystic Fibrosis, bowel resection/ removal, Short Gut Syndrome, gastric bypass, renal dialysis, dysphagia, achalasia, etc.)? OR • A diagnosis that would requires additional calories and/or protein intake (e.g. Cancer, AIDS, pulmonary insufficiency, Cerebral Palsy, etc.)	**Yes:** Approve for up to 1 year.	**No:** Go to #8.

8. Client must have a nutritional deficiency identified by one of the following: • Has there been a recent (within year) Registered Dietician assessment indicating adequate intake is not obtainable through regular/liquefied or pureed foods? (Supplement cannot be approved for convenience of client or caregiver.) OR • Is there a recent serum protein level <6?	**Yes:** Approve for up to 1 year.	**No:** Request more documentation OR Pass to RPH; Deny, (Medical Appropriateness)

9. Is this request for a client that is currently on supplemental nutrition?

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

Please visit: 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 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. 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 3.2 – 5.0 g/dl

P&T / DUR Action: *2/23/06, 11/20/14*
Implementation: *10/15; 9/1/06, 7/1/06, 4/1/03, 6/22/07, 1/1/15*

Omega-3 Fatty Acids

Goal(s):

- Promote safe and effective therapies for lipid lowering agent.

Length of Authorization:

- Up to 12 months

Requires PA:

- Omega-3-Acid Ethyl Esters (Lovaza®)
- Icosapent Ethyl (Vascepa®)

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the diagnosis an OHP covered diagnosis?	**Yes:** Go to #3.	**No:** Pass to RPh; Deny for OHP coverage.
3. Will the prescriber consider a change to a preferred product? Message: • Preferred products do not require PA. • Preferred products have received evidence-based reviews for comparative effectiveness and safety by the Pharmacy & Therapeutics Committee	**Yes:** Inform provider of covered alternatives in class. www.ordpl.org	**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 for medical appropriateness.

Approval Criteria		
5. Has the patient failed or have a contraindication to an adequate trial (at least 8 weeks) of a fibric acid derivitave (fenofibrate or gemfibrozil) at maximum tolerable dose (as seen in dosing table below). **AND** niacin 1-2 mg/day **OR** Is patient taking a statin and is unable to take a fibric acid derivative or niacin due to an increased risk of myopathy.	**Yes:** Approve up to 1 year.	**No:** Deny for medical appropriateness. Recommend untried agent(s).

Table 1: Dosing of fenofibrate and derivatives for hypertriglyceridemia

Drug	Recommended dose	Maximum dose
Antara (micronized)	43-130 mg once daily	130 mg once daily
Fenoglide	40-120 once daily	120 mg once daily
Fibricor	25-105 mg once daily	105 mg once daily
Lipofen	50-150 mg once daily	150 mg once daily
Lofibra (micronized)	67-200 mg once daily	200 mg once daily
Lofibra (tablets_	54-160 mg once daily	160 mg once daily
TriCor	48-145 mg once daily	145 mg once daily
Triglide	50-160 mg once daily	160 mg once daily
Trilipix	45-135 mg once daily	135 mg once daily
Gemfibrozil	600 mg twice daily	600 mg twice daily

P&T / DUR Action: *3/27/14 (MH / KK)*
Implementation: *10/15*

Opioid Analgesics – High Dose

Goal(s):

- Limit the use of high dose opioid therapy to above-the-line diagnoses that are supported by the medical literature
- Limit the use of non-preferred products
- Promote the safe use of opioids.
  - Opioids have been associated with an increasing proportion of deaths in Oregon and the US.
  - Opioid deaths in Oregon are often associated with concurrent use of other drugs (e.g. other opioids, benzodiazepines, skeletal muscle relaxants)
  - Opioid deaths in Oregon are often associated with patients with a history of drug abuse.
  - Buprenorphine, Fentanyl and Methadone carry FDA Black Box Warnings and have been associated with adverse cardiac effects associated with QTc prolongation and/or life-threatening hypoventilation.
    - This risk is increased with concurrent use of other drugs prolonging the QTc interval or other drugs affecting metabolism of methadone or fentanyl.
  - See Oregon DUR Board newsletter at:
    - http://pharmacy.oregonstate.edu/drug_policy/sites/default/files/pages/dur_board/newsletter/articles/volume11/durv11i2.pdf
    - http://pharmacy.oregonstate.edu/drug_policy/sites/default/files/pages/dur_board/newsletter/articles/volume5/durv5i5.pdf

Initiative:

Long and Short Acting Opioid quantity and dose limits: preferred agents, approved indications, and dose limits.

Length of Authorization:

Up to 6 months

Covered Alternatives:

A list of preferred opioids is available at www.orpdl.org

Requires a PA:

- All non-preferred opioids and preferred opioids exceeding the dose threshold in the table below, not to exceed a Morphine Equivalent Dose (MED) of 120 mg per day.
- Patient with terminal diagnosis, hospice, and metastatic neoplasm (ICD10: C6900-C799; C800-C802) are exempt from the PA requirements.

Approved Prior Authorizations may be subject to quantity limits.

Dosing Threshold adapted from Washington State Agency Medical Directors Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain 2010 (www.agencymeddirectors.wa.gov)

Opioid	Dose threshold	Recommended starting dose for opioid-naïve patients	Considerations
Buprenorphine Transdermal	20 mcg/hour (q 7 days)	5 mcg/hr patch q 7 days	May increase dose q72 hours patients up to a max of 20 mcg/hr q7 days. Doses >20 mcg/hr q7days increases risk of QTc prolongation.
Fentanyl Transdermal	50 mcg/hour (q72 hr)	Use only in opioid-tolerant patients who have been taking ≥ 60 mg MED daily for a week or longer	
Hydromorphone	30 mg per 24 hours	2 mg q4–6 hours	

Dosing Threshold adapted from Washington State Agency Medical Directors Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain 2010 (www.agencymeddirectors.wa.gov)			
Opioid	**Dose threshold**	**Recommended starting dose for opioid-naïve patients**	**Considerations**
Methadone	40 mg per 24 hours	2.5-5 mg BID – TID	Methadone is difficult to titrate due to its half-life variability. It may take a long time to reach a stable level in the body. Methadone dose should not be increased more frequently than every 7 days. Do not use as PRN or combine with other long-acting opioids.
Morphine	120 mg per 24 hours	Immediate-release: 10 mg q4 hours Sustained-release: 15 mg q12 hours	Adjust dose for renal impairment.
Oxycodone	80 mg per 24 hours	Immediate-release: 5 mg q4–6 hours Sustained Release: 10 mg q12 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing acetaminophen (maximum dose = 4000 mg/day x <10 days or 2500 mg/day for 10 days or more)
Oxymorphone	40 mg per 24 hours	Immediate-release: 5–10 mg q4–6 hours Sustained Release: 10 mg q12 hours	**Use with extreme caution due to potential fatal interaction with alcohol or medications containing alcohol**.

Dosing Threshold for select short acting opioids		
Opioid	**Dose threshold**	**Considerations**
Codeine	800 mg/day	
Hydrocodone	120 mg/day	Dosing limits based on combinations (e.g. acetaminophen, ibuprofen) may lower the maximum daily dose

Common indications OHP does not cover:*	**ICD10 Codes**
Disorders of soft tissue (including Fibromyalgia)	*M79.0,M60.9,M79.1,M79.7,M54.10,M79.2,M79.4,M79.3 ,M72.9,M79.609,M79.5,M79.A19,M79.A29,M79.A3,M79.A9,M79.89,R 25.2* *Z45.42*
Acute and chronic disorders of spine without one of the following neurologic impairments: a. Reflex loss b. Dermatomal muscle weakness c. Dermatomal sensory loss d. EMG or NCV evidence of nerve root impingement e. Cauda equina syndrome f. Neurogenic bowel or bladder See Prioritized List of Health Services Guideline Notes 37 and 41	*M47.812,M47.12,M47.814,M47.817,M47.14,M47.16,M48.20,M48.10, M48.30,M48.9,M47.819,M47.10,M50.20,M51.26,M51.27,M51.24,M51. 25,M51.9,M51.9,M51.44,M51.45,M51.46,M51.47,M51.9,M50.30,M51. 34,M51.35,M51.36,M51.37,M51.9,M50.00,M51.04,M51.05,M51.06,M5 1.07,M96.1,M46.40,M51.9,M50.80,M50.90,M46.45,M51.84,M51.85,M 46.47,M51.86,M51.87,M48.02,M54.2,M53.0,M54.12,M54.13,M43.6,M 54.02,M67.88,M53.82,M48.00,M48.04,M48.06,M48.08,M54.6,M54.5, M54.30,M54.14,M54.15,M54.16,M54.17,M54.89,M54.9,M43.27,M43.2 8,M53.2X7,M53.3,M53.2X8,M53.3,M54.08,M43.8X9,M53.9, except M53.1* *M99.01,M99.02,M99.03,M99.04,M99.05,M99.06,M99.07,M99.08,M99 0.9,, S33.101A,S23.101A,,* *S13.4XXA,S13.8XXA,S23.3XXA,S23.8XXA,S33.5XXA,S33.8XXA,S23 .9XXA*

*Covered diagnoses are dependent on funding levels. A list of currently funded diagnoses can be found at www.oregon.gov/OHA/herc/pages/prioritizedlist.aspx

Approval Criteria		
1. What is the patient's diagnosis?	Record ICD10	
2. Is the request for methadone >100 mg?	**Yes:** Go to 3	**No:** Go to 5
3. Does the patient have any of the following QTc Risk Factors? • Family history of "long QTc syndrome", syncope, sudden death • Potassium depletion primary or secondary to drug use (i.e. diuretics) • Concurrent use of C34 inhibitors or QTc prolonging drugs (see table below) • Structural heart disease, arrhythmias, syncope	**Yes:** Go to 4	**No:** Go to 5
4. Is this new therapy (i.e. no previous prescription for the same drug last month)?	**Yes:** Pass to RPH; Deny, (Medical Appropriateness) Go over black box warning and offer alternatives (e.g. Fentanyl transdermal, morphine extended release).	**No:** Pass to RPH; approve for 30-60 days to allow time to taper or transition to alternative. Direct to DUR Newsletter for assistance. Refer to Rx "Lock-in" Program for evaluation and monitoring.
5. Is the patient being treated for any of the following: a. Oncology pain (ICD-10,G893) b. Terminal diagnosis (<6 months) c. Hospice care	**Yes**: Go to #6	**No**: Go to #8
6. Is the requested medication a preferred agent?	**Yes:** Approve for up to 6 months	**No**: Go to #7
7. Will the prescriber consider a change to a preferred product?	**Yes**: Inform provider of covered alternatives in class.	**No**: Approve for up to 6 months
8. Will the prescriber consider a change to a preferred product not to exceed 120 mg MED?	**Yes**: Inform provider of covered alternatives in class.	**No:** Go to #9

9. Is the diagnosis covered by the OHP?	**Yes**: Go to #10	**No:** Pass to RPh, Deny (Not Covered by the OHP) May approve for 30-60 days to allow for tapering
10. Is this new therapy (i.e. no previous prescription for the same drug, same dose last month)?	**Yes**: Go to #11	**No**: Go To #12
11. Does the total daily opioid dose exceed 120 mg MED?	**Yes: Pass to RPh, Deny** (Medical Appropriateness) In general, the total dose of opioid should not exceed 120 mg MED Risks substantially increase at doses at or above 100 mg MED. Alternatives: Preferred NSAIDs or LAOs @ doses < 120 mg MED.	**No**: Go to #12
12. Has the patient had a recent urinary drug screen (within the past 90 days)?	**Yes**: Go to #13	**No:** Pass to RPH: Deny (Medical Appropriateness) Recommend Urine Drug Screen
13. Is the patient seeing a single prescribing practice & pharmacy for pain treatment (short and long acting opioids)?	**Yes**: Go To #14	**No:** <u>Approve 30-90 days;</u> Refer to Rx Lock-In program for evaluation. Further approvals pending RetroDUR / Medical Director review of case.
14. Does the total daily opioid dose exceed 120 mg MED?	**Yes**: Go to #15	**No:** Go to #16

15. Can the prescriber provide documentation of sustained improvement in both function and pain AND is prescriber aware of additional risk factors (e.g. concurrent benzodiazepines, skeletal muscle relaxants, other LAO or history of drug abuse)?	**Yes: Approve up to 6 months.** **Quantity Limits Apply, e.g.:** Avinza: 1 dose / day Butrans: 1 patch / week Embeda: 2 doses / day Exalgo: 1 dose / day Fentanyl: 1 patch / 72 hours Kadian: 2 doses / day Opana XR: 2 doses / day Oxycodone ER: 2 doses / day	**No:** Approve 30-90 days to allow for potential tapering of dose. Refer to Rx Lock-In program for evaluation. Further approvals pending RetroDUR / Medical Director review of case.
16. Is the patient concurrently on other long-acting opioids (e.g. fentanyl patches, methadone, or long-acting morphine, long-acting oxycodone, and long-acting oxymorphone)?	**Yes**: Go to #17	**No**: Approve for up to 6 months
17. Is the duplication due to tapering or switching products? The concurrent use of multiple long-acting opioids is not recommended unless tapering and switching products. Consider a higher daily dose of a single long-acting opioid combined with an immediate release product for breakthrough pain.	**Yes**: Approve for 30-90 days at which time duplication LAO therapy will no longer be approved.	**No: Deny** (Medical Appropriateness) **May approve for taper only.** Refer to Rx Lock-In program for evaluation. If necessary, inform prescriber of provider reconsideration process.

P&T or DUR Board Action: *3/15 (AM); 2/12; 11/11; 12/09; 9/09; 3/09; 12/08*
Implementation: *10/15; 6/12; 5/12; 1/12; 1/10*

Opioid/non-narcotic Combinations and Excessive Dose Limits

Goal(s):

- Decrease risk for adverse events attributed to high doses of acetaminophen (APAP) or aspirin (ASA) when combined with an opioid product.
- Pay only for conditions funded on the OHP list of prioritized services.

Requires PA:

- Non-preferred drugs.
- Prescriptions exceeding FDA recommendations of 4000 mg/day of APAP or ASA.
- All codeine-containing products for patients under 13 years of age.

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org/drugs/
- Pharmacy may need to adjust day's supply entry.
- Prescriber may choose a product with a higher ratio of narcotic to keep APAP or ASA within maximum limits or use a single-ingredient opioid.

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Does daily dose of APAP or ASA exceed the maximum daily dose?	**Yes:** Go to #3	**No:** Instruct pharmacy to correct day's supply entry
3. Is the diagnosis funded on the OHP list of prioritized services?	**Yes**: Pass to RPh; deny (medical appropriateness). Review FDA maximum dose and provide alternatives.	**No:** Pass to RPh; deny (not covered by the OHP). Review FDA maximum dose and provide alternatives

Examples of products containing ASA:

Aspirin Combinations			
Drug	**Maximum quantity per day**	**Drug**	**Maximum quantity per day**
Codeine/ASA/Caffeine/ Butalbital 30/325/40/50 mg	12 tablets	Oxycodone/ASA 4.8355/325 mg	12 tablets
Codeine/ASA/Carisoprodol 16/325/200 mg	12 tablets	Dihydrocodeine/ASA/Caffeine 16/356.4/30 mg	11 capsules

Examples of products containing APAP:

Hydrocodone/APAP combinations			
Drug	**Maximum quantity per day**	**Drug**	**Maximum quantity per day**
Hydrocodone/APAP 5/300 mg	13 tablets	Hydrocodone/APAP 2.5/108 mg per 5 mL	185 mL
Hydrocodone/APAP 7.5/300 mg	13 tablets	Hydrocodone/APAP 5/217 mg per 10 mL	184 mL
Hydrocodone/APAP 10/300 mg	13 tablets	Hydrocodone/APAP 7.5/325 mg per 15 mL	184.5 mL
Hydrocodone/APAP 2.5/325 mg	12 tablets	Hydrocodone/APAP 7.5/500 mg per 15 mL	120 mL
Hydrocodone/APAP 5/325 mg	12 tablets	Hydrocodone/APAP 10/325 mg per 15 mL	184.5 mL
Hydrocodone/APAP 7.5/325 mg	12 tablets		
Hydrocodone/APAP 10/325 mg	12 tablets		

Oxycodone/APAP combinations	
Oxycodone/APAP 5/300 mg	13 tablets
Oxycodone/APAP 7.5/300 mg	13 tablets
Oxycodone/APAP 10/300 mg	13 tablets
Oxycodone/APAP 2.5/325 mg	12 tablets
Oxycodone/APAP 5/325 mg	12 tablets
Oxycodone/APAP 7.5/325 mg	12 tablets
Oxycodone/APAP 10/325 mg	12 tablets
Oxycodone/APAP 5/325 per 5 mL	61.5 mL

Codeine/APAP combinations	
Codeine/APAP 12/120 mg per 5 mL	166.5 mL
Codeine /APAP 15/300 mg	13 tablets
Codeine /APAP 30/300 mg	13 tablets
Codeine /APAP 60/300 mg	13 tablets

Other Combinations	
Tramadol/APAP 37.5/325 mg	12 tablets
Dihydrocodeine/APAP/caffeine 16/320.5/30 mg	12 tablets

P&T/DUR Review: *5/15; 2/06; 11/99; 2/99*
Implementation: *10/15; 7/15; 9/05; 5/05; 12/03; 5/03*

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:

- No preferred alternatives at this time

Approval Criteria		
1. Is this a request for continuation of therapy (patient already on ivacaftor or lumacaftor/ivacaftor)?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #2
2. What is the diagnosis?	Record ICD-10 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?	Document and go to #5 If no baseline, request a baseline value before approving therapy	
5. Is the request for ivacaftor (Kalydeco)?	**Yes:** Go to #6	**No:** Go to #10
6. What is the patient's baseline sweat chloride level?	Document and go to #7 If no baseline level, Request a baseline level before approving therapy	
7. Does the client 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)
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 cleared 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 cleared 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 (Orkambi)?	**Yes:** Go to #11	**No:** Pass to RPH; Deny (medical appropriateness)
11. Does the client have a diagnosis of cystic fibrosis and is 12 years of age or older?	**Yes:** Go to #12	**No:** Pass to RPH; Deny (medical appropriateness)
12. Does the patient have a documented homozygous Phe508del mutation in the CFTR gene detected by an FDA-cleared CF mutation test?	**Yes:** Go to #13	**No:** Pass to RPH; Deny (medical appropriateness) If unknown, there needs to be a FDA cleared 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?	**Yes:** 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 (age <6 years) and normal lung function?: • Dornase alfa, AND	**Yes:** Go to #15	**No:** Pass to RPH; Deny (medical appropriateness)

• Hypertonic saline, AND • Inhaled or oral antibiotics (if appropriate)		
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 tests (within previous 3 months)?	Document and go to #17. If no baseline, request baseline before approving.	
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 (Kalydeco): • Does the patient have a documented physiological response to therapy and evidence of adherence after 30 days of treatment as defined as a sweat chloride test that has decreased by at least 20 mmol/L from baseline?	**Yes:** Go to #7	**No:** Go to #3
3. If the prescription is for lumacaftor/ivacaftor (Orkambi): • 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; 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.
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 FEV_1 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
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 and go to #7 Note: Therapy should be interrupted in patients with AST or ALT >5 x the upper limit of normal, or ALT or AST >3 x upper limit of normal with bilirubin > 2 x the upper limit of normal.	
7. Is the CFTR modulator dosed appropriately based on age, weight, and co-administered drugs (See dosing and administration below)?	**Yes:** Approve for additional 4 months (total of 6 months since start of therapy)	**No:** Pass to RPH; Deny (medical appropriateness)

Dosage and Administration:

Ivacaftor:

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

Lumacaftor/ivacaftor:

- Adults and pediatrics age ≥12 years: 2 tablets (lumacaftor 200 mg/ivacaftor 125 mg) every 12 hours
- Hepatic Impairment
  - Moderate Impairment (Child-Pugh class B):
    - Two 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.

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:
- Preferred alternatives 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 (MS) (ICD10 G35)?	**Yes:** Go to #3	**No:** Pass to RPh; Deny, not funded under the OHP per Guideline NOTE 95.
3. Will the prescriber consider a change to a preferred MS product? Message: • Preferred products do not require a PA or a copay. • 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. Has the patient failed or cannot tolerate a full course 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?	**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 (ICD10 E11311)?	**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-arrhythmics, 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:** Approve 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 six hours after initial dose in a clinically appropriate area.
- Patients on antiarrhythmics, beta-blockers or calcium channel blockers or with bradycardia risk factors (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 and cardiology evaluation should be done 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 Terinflunomide, screen patients for latent tuberculosis infection with a TB skin test, exclude pregnancy, confirm use of reliable contraception in women of childbearing potential, check BP, obtain a complete blood cell count within the 6 months prior to starting therapy, instruct patients receiving Terinflunomide to report symptoms of infections, and obtain serum transaminase and bilirubin levels within the 6 months prior to starting therapy.
- After starting Terinfluomide, monitor ALT levels at least monthly for 6 months after, consider additional ALT monitoring when Terinflunomide is given with other potentially hepatotoxic drugs, consider stopping Teriflunomide if serum transaminase levels increase (>3 times the ULN), monitor serum transaminase and bilirubin particularly in patients who develop symptoms suggestive of hepatic dysfunction, stop TER and start accelerated elimination in those with suspected TER-induced liver injury and monitor liver tests weekly until normalized, check BP periodically and manage elevated BP, check serum potassium level in TER-treated patients with hyperkalemia symptoms or acute renal failure, monitor for signs and symptoms of infection.
- Monitor for hematologic toxicity when switching from TER to another agent with a known potential for hematologic suppression, because systemic exposure to both agents will overlap.

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 faicium* (VRE)

Length of Authorization:

- 6 days

Requires PA:

- Non-preferred Oxazolidinone antibiotics

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org

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 *10/15; 7/15*

Palivizumab (Synagis®)

Goal(s):

- Promote safe and effective use of Synagis®.

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 is 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) **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	**Yes:** Go to #5.	**No:** Pass to RPH: DENY for 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 for medical appropriateness. Synagis not recommended for patients ≥24 months old.

Approval Criteria		
6. **GROUP A** Does the patient have the CLD (chronic lung disease) of prematurity ICD10 Q331through Q339 **and** in the past 6 months has required medical treatment with at least one of the following: a. diuretics b. chronic corticosteroid therapy c. supplemental oxygen therapy	**Yes:** Go to #18.	**No:** Go to #7.
7. **GROUP B** Has the patient received a cardiac transplant during the RSV season?	**Yes:** Go to #18.	**No:** Go to #8.
8. **GROUP C** Is the child profoundly immunocompromised during the RSV season (i.e. solid organ transplant or hematopoietic stem cell transplantation)?	**Yes:** Go to #18.	**No:** Go to #9.
9. **GROUP D** Does the infant have cystic fibrosis and manifestations of severe lung disease or weight or length less than the 10th percentile?	**Yes:** Go to #18.	**No:** Go to #10.
10. **GROUP E** Is the request for a second season of palivizumab prophylaxis for a child born <32 weeks, 0 days gestation who required at least 28 days of oxygen, chronic systemic corticosteroid therapy, or bronchodilator therapy within 6 months of start of second RSV season?	**Yes:** Go to #18.	**No:** Go to #11.
11. Will the patient be <12 months at start of RSV season?	**Yes:** Go to #12	**No:** Pass to RPH. DENY for medical appropriateness.
12. **GROUP F** Was the infant born before 29 weeks, 0 days gestation?	**Yes:** Go to #18.	**No:** Go to #13.
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.

Approval Criteria		
14. **GROUP H** Does the patient have hemodynamically significant congenital heart disease (CHD) ICD9 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 for 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 for medical appropriateness. Prophylaxis is indicated for 5 months maxiumum 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 15mg/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:_____		

Table 1. Maximum number of doses to approve for RSV prophylaxis (Based on Criteria Group from Above) – Beginning **NOVEMBER 1st**

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 to approve for RSV prophylaxis (Based on Criteria Group from Above) – Beginning **OCTOBER 1-31**

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 five doses.
- Approval for more than five doses or additional doses after March 31 is considered on a case-by-case basis. Results from clinical trials indicate that Synagis trough concentrations greater than 30 days after the 5th dose will be well above the protective concentration therefore five doses will provide more than 20 weeks of protection.

DUR/P&T Action: *9/23/14 (KS), 5/17/11 (DO/KK), 5/24/12 (KS)*
Implementation: *10/15; 3/30/12 (KS)*

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:

- Preferred alternatives 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 cardiovascular disease, defined as documented history of ≥1 of the following: • Myocardial infarction • Unstable angina • Coronary revascularization procedure (PCI or CABG) • 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 #8

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

Renewal Criteria		
1. What is the most recent LDL-C (within last 12 weeks)?	Recent LDL-C _____ mg/dL Date:_____ ; go to #2	
2. Is the patient adherent with PCSK9 inhibitor therapy?	**Yes:** Approve for up to 12 months Note: pharmacy profile may be reviewed to verify >80% adherence (PCSK9 inhibitor prescription refilled 10 months' supply in last 12 months)	**No:** Pass to RPh; deny for medical appropriateness

High- and Moderate-intensity Statins. 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: cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular 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 Cardiovascular 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: *11/15 (AG)*
Implementation: *1/1/16*

Preferred Drug List (PDL) – Non-Preferred Drugs in Select PDL Classes

Goal(s):

- The purpose of this prior authorization policy is to ensure that non-preferred drugs are used appropriately for an OHP-funded condition.

Length of Authorization:

- Up to 6 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 ICD10code.	
2. Is this an FDA approved indication?	**Yes**: Go to #3	**No:** Pass to RPh. Deny for 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 provider 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: *10/15; 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:

- Preferred alternatives listed at www.orpdl.org

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:** Deny; Pass to RPH (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? (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:** Deny; Pass to RPH (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:** Deny; Pass to RPH 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:** Deny; Pass to RPH 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:** Deny; Pass to RPH Medical Appropriateness
11. Is the request for Pegasys and the treatment of confirmed, compensated Chronic Hepatitis B?	**Yes:** Go to #11	**No:** Deny; Pass to RPH 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:** Deny; Pass to RPH Medical Appropriateness	**No:** Go to #12
13. Has the member received previous treatment with pegylated interferon?	**Yes:** Deny; Pass to RPH 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="3">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>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: 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 percent 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 / DUR Board Action: *2/23/12(KK), 9/9/09 (DO), 9/15/05, 11/30/04, 5/25/04*
Implementation: *10/15; 5/14/12, 1/1/10, 5/22/08 (Koder)*

Phosphate Binders

Goal(s):

- Promote preferred drugs.
- Reserve non-calcium acetate binders for second-line therapy

Length of Authorization:

- Up to 12 months

Requires PA:

- Non-preferred phosphate binders and all non-calcium acetate phosphate binders

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is this an OHP-covered diagnosis?	**Yes:** Go to #3.	**No:** Go to #5.
3. Has the patient tried or contraindicated to calcium acetate?	**Yes:** Go to #4. Document trial dates and/or intolerance	**No:** Pass to RPH, Deny, Medical Appropriateness Recommend trial of preferred calcium acetate.
4. Will the prescriber consider a change to a preferred non-calcium acetate product?	**Yes:** Approve for 1 year and inform provider 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 they are above the line or below the line diagnosis. • If above the line and clinic provides supporting literature: Approve for length of treatment. • If below the line: Deny, (Not Covered by the OHP).		

P&T / DUR Action: *11/29/2012 (kk); 9/27/2012 (mh); 9/10/2010 (kk)*
Implementation: *10/15*

Proton Pump Inhibitors (PPIs)

Goals:

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

Requires PA:

- Preferred PPIs beyond 60 days' duration
- Non-preferred PPIs

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org
- 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 evidence-based 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: • GERD [esophageal reflux (K219), esophagitis (K200 - K210)] or • *H. pylori* infection (B9681)?	**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:** Pass to RPh; not funded by OHP. 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.

7. Does the patient have a history of gastrointestinal ulcer or bleed and have one or more of the following risk factors? • Age 65 years or older • 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.

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 Esomeprazole 20 mg Lansoprazole 15 mg Omeprazole 20 mg Pantoprazole 40 mg Rabeprazole 20 mg
H. pylori Infection (B9681)	2 weeks	Dexlansoprazole 60 mg Esomeprazole 40 mg Lansoprazole 60 mg Omeprazole 40 mg Pantoprazole 80 mg Rabeprazole 40 mg
Achalasia and cardiospasm (K220) Stricture & Stenosis of Esophagus (K222) Perforation of Esophagus (K223) Dyskinesia of esophagus (K224) Gastroesophageal laceration-hemorrhage syndrome (K226) Esophageal hemorrhage (K228) Gastric Ulcer (K250 – K259) Duodenal Ulcer (K260 – K269) Peptic ulcer site unspecified (K270 – K279) Gastrojejunal ulcer (K280 – K289) Gastritis and duodenitis (K2900 – K2901; K5281) Zollinger-Ellison (E164) Neoplasm of uncertain behavior of other and unspecified endocrine glands (D440,D442,D449) Malignant mast cell tumors (C962) Multiple endocrine neoplasia [MEN] type I (E3121)	1 year	

*A current list of funded conditions is available at: http://www.oregon.gov/oha/herc/Pages/PrioritizedList.aspx

P&T / DUR Review: *5/15 (AG); 3/15; 1/13; 2/12; 9/10; 3/10; 12/09; 5/09; 5/02; 2/02; 9/01, 9/98*
Implementation: *10/15; 7/15; 4/15; 5/13; 5/12; 1/11; 4/10; 1/10; 9/06, 7/06, 10/04, 3/04*

Pulmonary Arterial Hypertension Agents IV/SQ

Goal(s):

- To ensure appropriate drug use and limit to patient populations in which agents for pulmonary arterial hypertension (PAH) has been shown to be effective and safe.

Length of Authorization:

- Up to 12 months

Requires PA:

- Non-preferred drugs
- Epoprostenol (Flolan®, Veletri®)
- Treprostinil (Remodulin®)

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Does the client have a diagnosis of pulmonary arterial hypertension (PAH) classified as World Health Organization (WHO) Group 1 (see table 1 below)?	**Yes:** Go to #3.	**No:** Pass to RPH; Deny (medical appropriateness)
3. Does the client have WHO or New York Heart Association (NYHA) Functional Class III-IV symptoms (see table 2 below)?	**Yes:** Go to #4	**No:** Pass to RPH; Deny (medical appropriateness)
4. Is the drug being prescribed by a PAH specialist (pulmonologist or cardiologist)?	**Yes:** Approve for 12 months	**No:** Pass to RPH; Deny (medical appropriateness)

Table 1. Updated Clinical Classification of Pulmonary Hypertension (Data Point, 2008)

WHO Group I: Pulmonary Arterial Hypertension	
1. Pulmonary arterial Hypertension	1.5 Associated with
1.2 Idiopathic PAH (IPAH)	1.4.1 Connective tissue disease
1.2 Heritable	1.4.2 HIV infection
1.2.1 Bone morphogenetic protein receptor (BMPR) type 2	1.4.3 Portal hypertension
1.2.2 Activin receptor-like kinase 1 (ALK1) endoglin (with or without hereditary hemorrhagic telangiectasia)	1.4.4 Congenital heart disease
	1.4.5 Schistosomiasis

1.2.3 Unknown	1.4.6 Chronic hemolytic anemia
1.3 Drug induced	1.5 Persistent pulmonary hypertension of the newborn
	1'. Pulmonary veno-occulsive disease (PVOD) and/or pulmonary capillary hemangiomatosis (PCH)

** Simonneau, G, et al. Updated Clinical Classification of Pulmonary Hypertension. J AM Coll Cardiol 2009; 54:S43-S54.*

Table 2. World Health Organization (WHO) Functional Classification of Pulmonary Hypertension

Class	Description
I	Patients with pulmonary hypertension (PH) with no limitation in physical ability
II	Patients with PH with slight limitations in physical activity; ordinary physical activity produces dyspnea, fatigue, chest pain or near-syncope
III	Patients with PH with marked limitation of physical activity; less than ordinary physical activity produces dyspnea, fatigue, chest pain or near-syncope
IV	Patients with PH unable to perform any physical activity without symptoms; dyspnea and/or fatigue present at rest

** Rubin, Lewis. Diagnosis and Management of Pulmonary Arterial Hypertension: ACCP Evidende-Based Clinical Practice Guidelines. CHEST 2004; 126:7S-10S)*

P&T / DUR Action: *9/27/12 (KS)*
Implementation: *10/15*

Pulmonary Arterial Hypertension Oral/Inhalation Agents

Goal(s):

- Approve therapy for covered diagnoses which are supported by the medical literature.
  - Erectile dysfunction is not covered by OHP

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 is the diagnosis?	Record ICD10 code**.**	
2. Is this an OHP covered diagnosis?	**Yes:** Go to #3	**No**: Pass to RPH. Deny, (Not covered by the OHP)
3. Does the patient have a diagnosis of WHO Group 1 pulmonary arterial hypertension (PAH)?	**Yes:** Go to #8	**No:** Go to #4.
4. Does the patient have a diagnosis of WHO Group 4 PAH?	**Yes**: Go to #5	**No:** Pass to RPH. Deny (Medical Appropriateness)
5. Is the request for riociguat (Adempas®)?	**Yes**: Go to #6	**No:** Pass to RPH. Deny (Medical Appropriateness)
6. Is the drug being prescribed by a pulmonologist or cardiologist?	**Yes**: Go to #7	**No:** Pass to RPH. Deny (Medical Appropriateness)
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 provider of alternatives in class.	**No**: Go to #9
9. Is the patient classified as having World Health Organization (WHO) Functional Class II-IV symptoms?	**Yes:** Go to #10	**No:** Pass to RPH. Deny (Medical Appropriateness)
10. Is the drug being prescribed by a pulmonologist or a cardiologist?	**Yes:** Approve for 12 months.	**No:** Go to #11
11. RPH Only: Is the diagnosis above the line and has the clinic provided supporting literature for use?	**Yes:** Approve for length of treatment.	**No:** Deny (not covered by the OHP)

WHO Functional Classification of Pulmonary Hypertension*

Class I
- Patients with pulmonary hypertension but without resulting limitation of physical activity.
- Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or syncope.

Class II
- Patients with pulmonary hypertension resulting in slight limitation of physical activity.
- They are comfortable at rest.
- Ordinary physical activity causes undue dyspnea or fatigue, chest pain, or syncope.

Class III
- Patients with pulmonary hypertension resulting in marked limitation of physical activity.
- They are comfortable at rest.
- Less than ordinary activity causes undue dyspnea or fatigue, chest pain, or syncope.

Class IV
- Patients with pulmonary hypertension with inability to carry out any physical activity without symptoms.
- These patients manifest signs of right heart failure.
- Dyspnea and/or fatigue may even be present at rest.
- Discomfort is increased by any physical activity.

*Table adapted from "Classification of Pulmonary Hypertension.
" Libby: Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine, 8th ed. Peter Libby et al. 2007.web. 21 Oct 2010.

P&T/DUR Review: 7/14 (KS), 3/14, 2/12, 9/10
Implementation: 10/15; 5/12, 1/12

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.

Initiative:

- Step Therapy

Length of Authorization:

- 4 weeks

Requires PA:

- Repository Corticotropin Injection (Acthar Gel®)

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org

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 (ICD-10 G40821-G40824)?	**Yes:** Approve up to 4 weeks (2 weeks of treatment, and 2 weeks of taper)	**No:** Go to #3.
3. Is the diagnosis for acute axacerbation or relapse of multiple sclerosis (ICD-10 G35)?	**Yes:** To to #4.	**No:** Pass to RPH; Deny for medical appropriateness.
4. Has the patient tried and unable to tolerate IV methylprednisolone or oral administration of high-dose methylprednisolone?	**Yes:** Approve up to 5 weeks (3 weeks of treatment, followed by 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, ankylosing spondylitis.(ICD-10 L4054, L4059, M069, M0800,, M459, M3210)? **OR** • The following collagen diseases: systemic lupus erythematosus, systemic deramtomyositis (ICD-10 M3210, M3390, M3320)?, **OR** • Dermatologic diseases such as erythema multiforme, Stevens-Johnson syndrome (ICD-10 L510, L519, L511, L513)?, **OR** • Ophthalmic diseases such as keratitis, iritis, uveitis, optic neuritis, or chorioretinitis (ICD-10, 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 (ICD-10 For treatment of an edematous state (ICD-10 R600, R601, R609)?	**Yes:** Go to #6.	**No:** Go to #6.
6. Are there contraindications or intolerance to any, or therapeutic failure with at least one intravenous corticosteroid?	**Yes:** Approve for 6 months.	**No:** Pass to RPH; Deny for medical appropriateness.

P&T / DUR Action: *5/30/13 (MH)*
Implementation: *10/15*

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.

Length of Authorization:

- Date of service OR 12 months, depending on criteria

Requires PA:

- Risperdal Consta

This is a quantity initiative, **not a clinical initiative**. The syringe is 2 ml size. The pharmacy must submit the dispensing quantity as 1 syringe not 2 ml.

Approval Criteria		
1. Is the quantity being submitted by the pharmacy expressed correctly as # syringes?	**Yes**: Go to #2.	**No:** Have pharmacy correct to the number of syringes instead of ml's.
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)	Please Note: This medication should NOT be denied for clinical reasons.

P&T / DUR Action:
Implementation: *10/15; 05/31/05*

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:
- Preferred alternatives listed at http://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.	
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 for 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 for 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 for 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: *09/15 (AG)*
Implementation: *10/15*

Saproterin (Kuvan®)

Goal(s):

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

Length of Authorization:

Initial – 1 to 2 months; Renewal – one year

Covered Alternatives:

NA

Approval Criteria - Initial		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the drug prescribed by or in consultation with a specialist in metabolic disorders?	**Yes:** Go to #3	**No:** Pass to RPH, Deny (medical appropriateness)
3. Is the diagnosis tetrahydrobiopterin- (BH4-) responsive phenylketonuria?	**Yes:** Go to #4	**No:** Pass to RPH, Deny (medical appropriateness)
4. Is member currently compliant in a Phe-restricted diet and unable to achieve target blood phenylalanine level?	**Yes:** Go to #5	**No:** Deny and recommend Phe-restricted diet.
5. Is member'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). 1 month if initial dose is 20 mg/kg/day (Adults and children).	**No:** Request information from provider.
Approval Criteria – Renewal		
1. Did the patient meet the target phenylalanine level set by the specialist (see Clinical Notes)? **AND** 2. Is the patient remaining compliant with the Phe-restricted diet?	**Yes:** Approve for 12 months	**No:** Deny for lack of treatment response.

Clinical Notes:
The National Institutes of Health Consensus Development Conference on PKU recommend maintaining the following blood concentration[1]:

• Neonates through 12 years of age:	2 to 6 mg/dl (120 to 360 µmol/L)
• After 12 years of age:	2 to 15 mg/dl (120 to 900 µmol/L) or 2 to 10 mg/dl (120 to 600 µmol/L)*
• During Pregnancy	2-6 mg/dl (120-360 µmol/L)
*However, although data are limited, higher blood Phe concentrations appear to adversely affect brain function, even in adults. Thus, maintenance of lower levels (2 to 10 mg/dl, or 120 to 600 µmol/L) is strongly encouraged during adolescence or even beyond.	

In addition to the recommended Phe concentrations, often, a 30% or more reduction in blood Phe is 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 Kuvan therapy.

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

<u>References:</u>

1) National Institutes of Health Consensus Development Conference Statement: Phenylketonuria: Screening and Management, October 16-18, 2000. *Pediatrics* 2001;108;972.
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 Action: *11/21/13 (MH), 9/26/2013 (MH); 7/25/2013(BL/MH)*
Implementation: *10/15; 1/1/14 (MH)*

Sodium-Glucose Co-Transporter-2 Inhibitors (SGLT-2 Inhibitors)

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

Length of Authorization:
- Up to 12 months

Requires PA:
- All SGLT-2 inhibitors

Covered Alternatives:
- Preferred alternatives 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 Type 2 diabetes mellitus?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Has the patient tried and failed metformin and sulfonylurea therapy or have contraindications to these treatments? (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
6. Has the patient tried and failed all of the following drugs, or have contraindications to these drugs? • Insulin • Thiazolidinedione • DPP-4 inhibitor • GLP-1 agonist • 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		
1. 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/DUR Review: *9/15 (KS); 1/15; 9/14; 9/13*
Implementation: *10/15; 2/15*

Skeletal Muscle Relaxants

Goal(s):

- Cover non-preferred drugs only for above-line-line diagnosis.
- Restrict carisoprodol to short-term use per medical evidence.
  - There are no long-term studies of efficacy or safety for carisoprodol.
  - Case reports suggest it is often abused and can be fatal when used in association with opioids, benzodiazepines, alcohol or illicit drugs.
  - Carisoprodol is metabolized to meprobamate.

Length of Authorization:

- Up to 6 months

Requires PA:

- Non-preferred agents

Covered Alternatives:

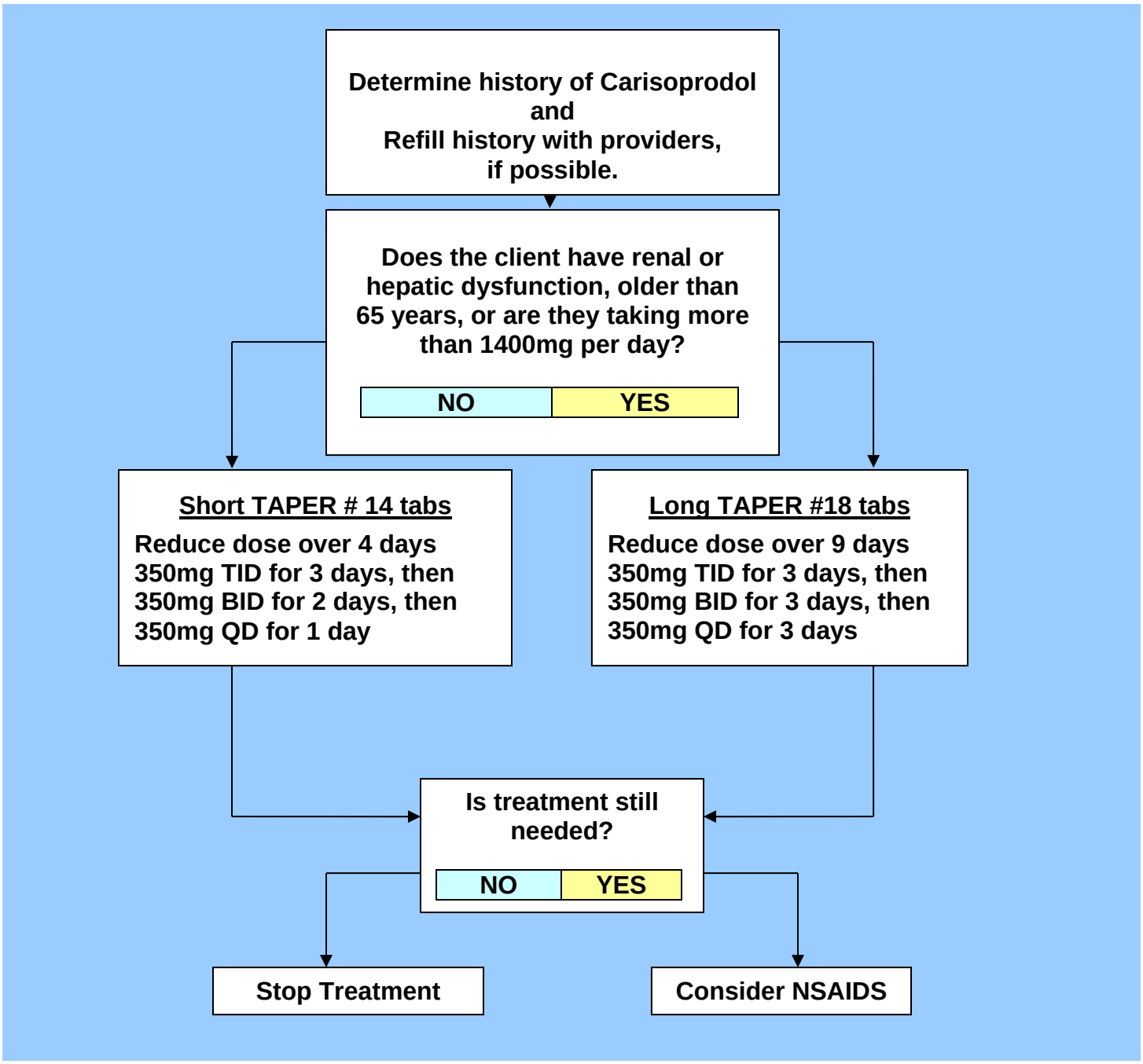
- Preferred alternatives listed at www.orpdl.org
- Cyclobenzaprine (similar to tricyclic antidepressants – TCAs) has the largest body of evidence supporting long-term use and is the preferred product in the muscle relaxant class. For patients that have contraindications to TCAs, NSAIDs, benzodiazepines or opioids are other alternatives. OHP does not cover pain clinic treatment.

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is diagnosis covered by the Oregon Health Plan?	Yes: Go to #3.	**No:** Pass to RPH; Deny, (Not Covered 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 provider of covered alternatives in class	**No:** Go to #4
4. Is drug requested carisoprodol (Soma®)?	**Yes:** Go to #5	**No:** Approve for up to 6 months

Approval Criteria		
5. Does total quantity of carisoprodol (Soma®) products exceed 56 tablets within 90 days? From claims, document product, dose, directions, and amount used during last 90 days:	**Yes:** Go to #6	**No:** Approve for up to 6 months
6. Does patient have a terminal illness (e.g. metastatic CA, end stage HIV, ALS)?	**Yes:** Approve for 6 months.	**No:** Pass to RPH. Go to #7

7. 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 Soma (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?:
  o >65 years old
  o Renal Failure
  o Hepatic failure
 	
Take > 1400mg per day (>3.5 tablets)
	Yes: Document reason and approve long taper:
	
	• Authorize 18 tablets
	• Reduce dose over 9 days
	• 350mg TID X 3 days, then
	• 350mg BID X 3 days, then
	• 350mg QD 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 QD x 1 day, then evaluate

Tapering Carisoprodol



P&T / DUR Action: *11/20/14 (MH), 9/24/09(DO), 2/23/06, 2/24/04, 11/14/01, 2/21/01, 9/6/00, 5/10/00, 2/9/00*
Implementation: *10/15; 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
- NRT beyond 6 months in the absence of behavioral counseling
- Varenicline beyond 12 weeks

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the diagnosis for tobacco dependence? (ICD-10 F17200)?	**Yes**: Go to #3	**No:** Pass to RPH; Deny (medical appropriateness)
3. Is the request for a preferred NRT?	**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 x 6 additional months or Approve varenicline x 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 x 6 additional months or Approve varenicline x 12 additional weeks	**No:** Pass to RPH; Deny (medical appropriateness)

Approval Criteria		
7. Will the prescriber consider a 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. Reports are available at: http://pharmacy.oregonstate.edu/drug-policy/ohp-drug-list/drug-class-reviews	**Yes:** Inform provider of covered alternatives in class	**No:** Approve treatment for up to 6 months

DUR/P&T Action: *4/26/12*
Implementation: *10/15*

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:

- Preferred alternatives 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 for medical appropriateness

Approval Criteria		
5. Will the prescriber consider a change to a preferred product? Message: • Preferred products to 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 non-funded: Deny (not funded by the OHP)

P&T / DUR Review: 11/15 (KS); 2/12; 9/10; 2/06; 2/01; 9/00
Implementation: 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 covered diagnoses (above the line) 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:

- Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Does patient have diagnosis of epilepsy (ICD-10code G40101-G40311, G40401-G40509, G40802, G40804, G40901-G40919-, R569, or S069X9S)?	**Yes:** Approve for lifetime (until 12-31-2036)	**No:** Go to #3.
3. Does the patient have a diagnosis of migraine (ICD10 G43001-G43919, G43A0, G43B0, G43C0, G43D0, G43A1, G43B1,G43C1,G43D1)?	**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? • ICD-10 F30.10-F33.9 and subsets • ICD-10 F259 and subsets	**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) and recommend trial of covered alternative.

Approval Criteria		
6. Is the patient using the medication for weight loss? (Obesity ICD10 E669, E6601,)?	**Yes:** Pass to RPH; Deny, (Not covered by the OHP)	**No:** Go to #7.
7. Pass to RPH. 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. Below the line diagnoses: Deny, (Not covered by the OHP) If clinically warranted: Deny, yesterday's date (Medical 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."	

P&T / DUR Action: *3/15 (AG), 2/12, 9/07, 11/07*
Implementation: *10/15; 4/18/15; 5/12, 1/12*