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

August 25, 2015

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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 August 25, 2015

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

- Antifungals – updated criteria
- Antiplatelets (formerly called "Platelet Inhibitors") – updated criteria
- Biologicals for RA, Psoriasis and Crohn's Disease – updated criteria
- Codeine – new criteria
- Idiopathic Pulmonary Fibrosis – new criteria
- Intranasal Allergy Drugs (formerly "Nasal Inhalers") – updated criteria
- Ivacaftor – updated criteria
- PDL – Preferred, Non-preferred – updated criteria
- Pulmonary Arterial Hypertension – updated criteria
- Rifaximin – new criteria
- Topical Antipsoriasis Drugs – updated criteria

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 ICD9 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*
Revision(s): *1/1/15. 9/27/14, 1/1/10, 7/1/06, 2/23/06, 11/15/05*
Initiated:

Amylin Analog

Initiative:

- To optimize the correct use of amylin analogs.

Length of Authorization:

Up to 12 months

Requires PA:

- Non-preferred drugs
- Pramlintide

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. Does the patient have a diagnosis of Type1 diabetes and is taking mealtime insulin?	Yes: Approve for 12 months.	No: Go to #2
2. Does the patient have Type 2 diabetes and is taking mealtime insulin?	Yes: Go to #3	No: Pass to RPh; Deny based on appropriateness of therapy.
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 & safety by the Health Resources Commission (HRC).	Yes: Inform provider 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? • Contraindications include: • Renal disease or renal dysfunction • Known hypersensitivity to metformin and/or sulfonylureas • Acute or chronic metabolic acidosis • Patients at increased risk of lactic acidosis (CHF, advanced age, impaired hepatic function)	Yes: Approve for up to 12 months.	No: Deny. Recommend trial of metformin or sulfonylurea. See below for metformin titration schedule.

Initiating Metformin

1. Begin with low-dose metformin (500 mg) taken once or twice per day with meals (breakfast and/or dinner) or 850 mg once per day.
2. After 5-7 days, if gastrointestinal side effects have not occurred, advance dose to 850 mg, or two 500 mg tablets, twice per day (medication to be taken before breakfast and/or dinner).
3. If gastrointestinal side effects appear 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 31; 1-11, 2008.

P&T / DUR Action: *4/26/12 (KS), 3/17/11(KS)*
Revision(s):
Initiated: *7/23/12, 1/1/12*

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 ICD9 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*
Revision(s): *1/1/15, 1/1/14, 5/14/12, 1/1/10*
Initiated:

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 ICD9 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*
Revision(s): *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,*
Initiated: *4/1/03*

Antifungals

Goal(s):

- Approve use of antifungals only for OHP-funded diagnoses. Minor fungal infections of skin, such as dermatophytosis and candidiasis are only funded when complicated by an immunocompromised host.

Length of Authorization:

See criteria

Requires PA:

- Non-preferred drugs

Covered Alternatives:

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

Table 1: Examples of FUNDED indications (1/1/15)

ICD-9	Description
112.1	Candidiasis of vulva and vagina
112.4	Candidiasis of the lung
112.5	Disseminated Candidiasis
112.8x	Candidiasis of other specified sites
114.0-114.9	Coccidiomycosis various sites
115.00-115.99	Histoplamosis
116.0-116.2	Blastomycosis
117.xx	Rhinosporidosis, Sporotrichosis, Chromoblastomycosis, Aspergillosis, Mycotis Mycetomas, Cryptococcosis, Allescheriosis, Zygomycosis, Dematiacious Fungal Infection, Mycoses Nec and Nos
118.xx	Mycosis, Opportinistic
518.6	Bronchopulmonary Aspergillus, Allergic
616.xx (except 616.0)	Inflammatory disease of cervix vagina and vulva
681.xx	Cellulitis and abscess of finger and toe
771.7	Neonatal Candida infection

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

ICD-9	Description
690.10 – 690.8	Erythematosquamous dermatosis
691.0	Diaper or napkin rash
691.8	Other atopic dermatitis and related conditions
692.0 – 692.70, 692.74, 692.79-692.9	Contact dermatitis and other eczema
695.0,695.10, 695.11, 695.19, 695.2-695.4, 695.50-695.59, 695.89-695.9	ERYTHEMATOUS CONDITIONS
697.0-697.9	Lichen Planus
706.0,706.1	ROSACEA; ACNE
110.1	Dermatophytosis of nail (onychomycosis)

111.0	Pityriasis versicolor
111.2	Tinea blanca
111.3	Black piedra
111.8	Dermatomycoses nec
111.9	Dermatomycosis nos
112.3	Cutaneous candidiasis
112.9	Candidiasis site nos
782.1	Nonspecif skin erupt nec

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

ICD-9	Description
110.0	Dermatophytosis of scalp and beard (tinea capitis/ tinea barbae)
110.2	Dermatophytosis of hand (tinea manuum)
110.3	Dermatophytosis of groin and perianal area (tinea cruris)
110.4	Dermatophytosis of foot (tinea pedis)
110.5	Dermatophytosis of body (tinea corporis / tinea imbricate)
110.6	Deep seated dermatophytosis
110.8-110.9	Dermatophytosis of other specified sites - unspecified site
111.1	Tinea nigra
112.0	Candidiasis of mouth
112.2	Candidiasis of other urogenital sites

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 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-9 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 *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 ICD9 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? (372.14, 472.x, 477.x)	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 (493.xx)?	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 (376.00-376.10) • Chronic Sinusitis (473.xx) • Acute Sinusitis (461.xx) • Sleep apnea (327.20,327.21,327.23, 327.27, 327.29, 780.51, 780.53, 780.57) • Wegener's Granulomatosis (446.4)	Yes: Document ICD-9 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 (491.20-491.22)?	Yes: Pass to RPH; Deny, (Medical Appropriateness). Antihistamine not indicated.	No: Go to #9.
9. Is the diagnosis Chronic Bronchitis (491.0, 491.1, 491.8, 491.9)?	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 (465.9) or urticaria (708.0, 708.1. 708.5, 708.8, and 708.9 should be denied).		

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

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 ICD9 code.	
2. Does patient have diagnosis of migraine, ICD-9 346.0-346.9?	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*
Revision(s): *3/23/10, 1/1/10, 7/1/06, 5/31/05*
Initiation: *6/30/04*

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 ICD9 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 (ICD9-333.94)?	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)*
Revision(s): *1/1/14 (MH/BL)*
Initiated: *1/1/11*

Antiplatelets

Goal:

- Approve antiplatelet drugs for funded diagnoses which are supported by medical literature.

Length of Authorization:

- Up to 12 months.

Requires PA:

- Non-preferred drugs

Covered Alternatives:

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

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 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)

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

P&T / DUR Review: 7/15 (KK); 11/11
Implementation: 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 ICD9 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)*
Revision(s):
Initiated: *1/1/11*

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.

Initiative:

- Initiative

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 ICD9 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 ICD9: 054.2, 054.6, 054.73, and 054.9?	Yes: Go to #4.	No: Pass to RPH; Go to #7.

Approval Criteria		
4. Is the patient immune compromised? Document ICD9 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-9 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)*
Revision(s):
Initiated: *1/1/11*

Asthma Controller Drugs

Goal(s):

- The purpose of this prior authorization policy is to ensure that non-preferred asthma controller drugs are used for an above the line condition.

Length of Authorization:

Up to 12 months

Requires PA:

- Non-preferred drugs

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. Is the requested drug montelukast (Singular)?	Yes: Go to Leukotriene Inhibitor Criteria	No: Go to #2.
2. Is the request for a LABA/ICS combination product?	Yes: Go to LABA/ICS criteria	No: Go to #3
3. What diagnosis is being treated?	Record ICD9 code.	
4. Is this an OHP covered diagnosis?	Yes: Go to #5.	No: Pass to RPH; Deny, (Not Covered by the OHP).
5. 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. Approve for 1 year.	No: Go to #6.
6. Will the prescriber consider a change to a preferred product? Message: • Preferred products do not require PA. • Preferred products are evidence-based reviewed for comparative effectiveness & safety by the Drug Use Review (DUR / Pharmacy & 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: *5/31/12, 9/24/09(DO), 5/21/09*
Revision(s): *8/20/12, 1/1/10*
Initiated: *1/1/10*

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 ICD9 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.
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? (592.1, 595.1, 596.0, 596.3-596.5, 596.54, 596.7-596.9, 598, 599.82-599.89)	Yes: Go to #5.	No: Go to #6.

Approval Criteria		
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? (600.01, 600.11, 600.21, and 600.91; 788.2 + 600.xx 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? (599.6, 600.00, 600.10, 600.20, and 600.90)	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. • 788.2 (retention of urine, obstructive); Ask for more specific diagnosis. If along with 600.01, 600.11, 600.21 or 600.91, 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? (592.1, 595.1, 596.0, 596.3-596.5, 596.54, 596.7-596.9, 598, 599.82-599.89)	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? (600.01, 600.11, 600.21, and 600.91; 788.2 + 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? (599.6, 600.00, 600.10, 600.20, and 600.90)	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. • 788.2 (retention of urine, obstructive); Ask for more specific diagnosis. If along with 600.01, 600.11, 600.21 or 600.91, 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*
Revision(s): *2/21/13, 1/1/11, 4/20/10, 5/22/08 (Aebi), 7/1/06, 9/30/05*
Initiated: *10/14/04 (previously excluded)*

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 ICD9 code.	
2. Does the client have a malignant neoplasm (ICD9: 190.00-199.00) or other end of life diagnosis?	**Yes:** Approve for 12 months	**No:** Go to #3
3. Does client have diagnosis of epilepsy, ICD9: 345.9?	**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)

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 ICD9 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-9: 696.1-696.2, 696.8) 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 (690.XX), keroderma (701.1-701.3) or other hypertrophic and atrophic conditions of skin (701.8, 701.9) 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-9 720) 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-9 714.xx) or psoriatic arthropathy (ICD-9 696.0) and the product requested FDA approved for rheumatoid arthritis (see table above)?	**Yes:** Go to #9	**No:** Go to #12
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.

Approval Criteria		
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-9 555) or ulcerative colitis (ICD-9 556.0-556.9) 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: *TBD; 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 ICD9 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)*
Revision(s):
Initiated: *1/1/11*

Botulinum Toxins (BoNT)

Goal(s):

- Approve BoNT only for funded OHP diagnosis which are supported by the medical literature (e.g. various dystonias and spasticity associated with certain neurological diseases).

Length of Authorization:

90 days up to lifetime

Requires PA:

Use of BoNT without associated dystonia or neurological disease diagnosis in last 12 months (i.e. 333.6x, 333.7x, 333.81, 333.83, 333.89, 340.xx, 341.0, 342.xx, 343.xx, 344.0x, 344.1, 344.2, 344.4x, 344.5, or 378.73)

HSN	Generic Drug Name
004867	ONABOTULINUMTOXINA (BOTOX, BOTOX COSMETIC)
036477	ABOBOTULINUMTOXINA (DYSPORT)
021869	RIMABOTULINUMTOXINB (MYOBLOC)
036687	INCOBULINUMTOXINA (XEOMIN)

ProcCode	Descriptions
J0585	Injection, onabotulinumtoxinA, 1 unit
J0586	Injection, abobotulinumtoxinA, 5 units
J0587	Injection, rimabotulinumtoxinB, 100 units
J0588	Injection, incobotulinumtoxinA, 1 unit

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

Approval Criteria	
1. What diagnosis is being treated?	Record ICD9 code.

Approval Criteria		
2. Does client have diagnosis of certain dystonias or spasticity associated with other neurological diseases that make BoNT a first-line treatment option? Examples: 333.6x (genetic torsion dystonia) 333.7x (acquired torsion dystonia), 333.81 (blepharospasm) 333.83 (spasmodic torticollis) 333.89 (other fragments of torsion dystonia) 438.2x – 432.5x (paralysis associated with CVD) 340.xx (multiple sclerosis) 341.0 (neuromyelitis optica) 342.xx (spastic hemiplegia, other specifiedhemiplegia), 343.xx (cerebral palsy), 344.0x (quadriplegia and quadraparesis), 344.1 (parapalegia), 344.2 (diplegia of upper limbs) 344.3x (monoplegia of lower limb) 344.4x (monoplegia of upper limb) 344.5 (unspecified monoplegia) 344.89 (other specified paralytic syndrome) 359.0x – 359.2x (muscular dystrophies) 378.73 (strabismus in other neuromuscular disorders)	**Yes:** Approve for lifetime (until 12/31/2036).	**No:** Go to #3.
3. Does client have diagnosis of chronic migraine based on clinical symptoms; at least 15 headache days per month, of which, at least 8 of those days are considered migraine days?	**Yes:** Go to #6.	**No:** Go to #4.
4. Does client have diagnosis of detrusor over-actitivity (596.5x) e.g. idiopathic detrusor over-activity (IDO) also called “overactive bladder syndrome” Or Neurogenic detrusor over-activity (NDO)?	**Yes:** Go to #7.	**No:** Go to #5.

Approval Criteria		
5. Does client have any of the following diagnoses? Insufficient evidence of benefit: 787.2x (dysphagia) 333.xx (other extrapyramidal disease and abnormal movement disorders excluding 333.6x, 333.7x, 333.81, 333.83, 333.89 and 333.82, 333. 84, 333.94-333.99) 378 excluding 378.73 (other disorders of binocular eye movements (e.g. esotropia, exotropia, mechanical strabismus, sixth nerve palsy) 307.2x (tics) 478.75 (laryngeal spasm), 723.0 and 723.4 (Spinal stenosis in cervical region or Brachial neuritis or radiculitis NOS) 728.85 (spasm of muscle [in absence of neurological diagnoses]), 727.81 (contracture of tendon – sheath [in absence of neurological diagnoses]) 335.20 (amyotrophic sclerosis), 724.00-724.09, 724.4 (clinically significant spinal deformity or disorders of spine with neurological impairment) 600.xx (hyperplasia of prostate),	**Yes:** Pass to RPH; Deny for medical appropriateness.	**No:** Go to #8.
Unfunded OHP condition: 333.82, 333. 84, 333.94-333.99 (neurologic conditions with no or minimally effective treatment or not treatment is necessary) 351.xx (facial nerve disorders), 478.79 (spastic dysphonia) 565.0 (anal fissure), 705.xx (disorders of sweat glands e.g. focal hyperhidrosis), 723.xx except 723.4 (other disorders of cervical region), 705.0-705.1,705.21-705.9,780.8 (disorders of sweat glands) 724.1, 724.2, 724.4-724.6, 727.70-724.9 (acute and chronic disorders of the spine without neurologic impairment) 729.0-729.2 (disorders of soft tissue) 307.81,339.10-339.89,784. (tension headaches) 536.3 (gastroparesis),	(Condition not funded by OHP)	

Approval Criteria		
6. Has the client not responded or are they contraindicated to at least one drug in three of the following drug classes? • B-blocker (metoprolol, atenolol, nadolol, propranolol, timolol) • Tricyclic antidepressant (nortriptyline, amitriptyline) • Anticonvulsant (valproic acid, divalproate, carbamazepine, topiramate, gabapentin) • Calcium Channel Blocker (verapamil, diltiazem, nimodipine)	**Yes:** Approve for 180 days with subsequent approvals dependent on documented* positive response for annual approval. *Documented response means that follow-up and response is noted in client's chart by clinic staff.	**No:** Pass to RPH; Deny for medical appropriateness and recommend trial of preferred alternatives www.orpdl.org.
7. Has the client tried or are they contraindicated to at least two of the following urinary incontinence antimuscarinic therapies? (e.g. fesoterodine, oxybutynin, solifenacin, darifenacin, tolterodine, trospium)	**Yes:** Approve for 90 days with subsequent approvals dependent on documented* positive response for annual approval. *Documented response means that follow-up and response is noted in client's chart by clinic staff.	**No:** Pass or RPH; Deny for medical appropriateness.

P&T / DUR Action: 9/23/14 (KK), 7/31/14(KK)
Revision(s): 9/27/14 (KK)
Initiated:

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 ICD9 code.	
2. Is diagnosis one of the following? • 304.00 Opioid type dependence unspecified use • 304.01 Opioid type dependence continuous use • 304.70 Opioid type dependence continuous use • 304.70 Combinations of opioid type drug with other drug dependence unspecified use • 304.71 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*
Revision(s): *2/3/15, 9/1/13*
Initiated: *1/1/10*

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 ICD9 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*
Revision(s):
Initiated: *8/12*

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 ICD9 code.	
2. Does client have diagnosis of insomnia with sleep apnea, ICD9: 780.51?	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*
Revision(s): *1/1/15, 7/1/14; 1/1/07, 7/1/06, 11/15/05*
Initiated: *11/15/02*

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.

Initiative:

- Initiative

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 ICD9 code.	
2. Does client have diagnosis of insomnia with sleep apnea, ICD9: 780.51?	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.

Approval Criteria		
4. Is the client being treated for co-morbid depression, bipolar disorder (296.xx) OR panic disorder (300.0x) 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.
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): *7/1/14, 1/1/07, 7/1/06, 11/15/05*
Initiated: *11/15/02*

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, ICD9 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)

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 ICD9 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: *7/15 (AG)*
Implementation: *TBD*

Conjugated Estrogens/Bazedoxifene (Duavee®)

Goal(s):

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

Initiative:

- Prior Authorization

Length of Authorization:

- 6-12 months

Requires PA:

- Conjugated estrogens/bazedoxifene

Covered Alternatives:

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 ICD9 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).

Approval Criteria		
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
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*
Revision(s):
Initiated: *1/15*

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
000271	Guaifenesin
000206	Guaifenesin/Codeine PHOS
000223	Guaifenesin/D-methorphan HB
002091	Pseudoephedrine HCL

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 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: 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.

Initiative:

- Prior Authorization

Length of Authorization:

Up to 6 months

Requires PA:

- Non-preferred medications

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 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)*
Revision(s):
Initiated:

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.

Initiative:

- Initiative

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 ICD9 code.	
2. Does the patient have a diagnosis of Multiple Sclerosis (ICD-9 340)?	**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 (ICD-9 345.00-345.51, 345.80, 345.81, 780.33-780.39)?	**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*
Revision(s):
Initiated: *9/1/13*

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

Brand Name and Multi-Source

Goal(s):

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

Length of Authorization:

Up to 12 months

Requires PA:

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

Covered Alternatives:

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

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

Approval Criteria

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)*
Revision(s): *7/1/06, 9/08, 7/1/09 (KK), 1/1/10 (KK)*
Initiated: *6/16/03*

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 ICD9 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*
Revision(s): *7/1/06, 5/31/05*
Effective: *4/1/03*

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 ICD9 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 (ICD9 458.0) due to primary autonomic failure (Parkinson's disease, multiple system atrophy or pure autonomic failure), dopamine beta-hydroxylase deficiency, or nondiabetic autonomic neuropathy? (ICD9 332.0; 333.0; 270.0-270.8; 337.0-337.9)	**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.
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)
Revision(s):
Initiated:

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-9: 536.0-536.3, 536.8-536.9, 537.1-537.2, 537.5-537.6, 537.89-537.9, 564.0-564.6, 564.89-564.9, 787.60, 787.61, 787.63, 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 ICD9 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*
Revisions: *4/18/15*
Initiated: *7/09*

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 ICD9 code.	
2. Is the drug requested pregabalin AND does client have a diagnosis of epilepsy? (ICD-9 code 345.0-345.9, 780.39, or 907.0)	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-9 codes not found in the Table to the Lead Pharmacist. These codes will be forwarded to DMAP for consideration.**

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Table

Not-Funded Diagnoses	ICD9
DISORDERS OF SOFT TISSUE	
Myalgia and myositis, unspecified (includes fibromyalgia syndromes)	7291x
Neuralgia, neuritis, and radiculitis, unspecified	7292x
ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT	
Syringomyelia and syringobulbia	3360x
Disorders of meninges, not elsewhere classified	3492x
Sacroiliitis, not elsewhere classified	7202x
Inflammatory spondylopathies in diseases classified elsewhere	72081
Cervical spondylosis without myelopathy	7210x
Thoracic spondylosis without myelopathy	7212x
Lumbosacral spondylosis without myelopath	7213x
Traumatic spondylopathy	7217x
Other allied disorders of spine	7218x
Spondylosis of unspecified site, without mention of myelopathy	72190
Intervertebral disc disorders	722xx
Cervicalgia	7231x
Brachial neuritis or radiculitis NOS	7234x
Other disorders of cervical region	7236x - 7239x
Pain in thoracic spine/Lumbago	7241x-7242x
Backache, unspecified	7244x-7249x
Nonallopathic lesions not elsewhere classified	739xx
Other specified congenital anomalies of spinal cord	74259
Congenital musculoskeletal deformities of sternocleidomastoid muscle	7541x
Closed dislocation thoracic and lumbar vertebra	8392x
Sprains and strains of other and unspecified parts of back	847xx
CHRONIC PAIN (EXCLUDED DIAGNOSES)	
Chronic pain d/t trauma	33820-33821
Other chronic pain	33829
Chronic pain syndrome	3384x
Funded Diagnoses	ICD9
Hereditary and idiopathic peripheral neuropathy	356xx
Diabetes with neurological manifestations	2506x
Herpes zoster with nervous system complications	0531x

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P&T / DUR Action: 3/26/15; 5/09; 9/07; 11/07
Revision(s): 4/18/15; 1/11; 1/10
Initiated: 4/08

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 ICD9 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)*
Revision(s): *1/1/13, 9/24/12, 5/14/12*
Initiated: *1/1/11*

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 ICD9 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*
Revision(s): *9/1/06; 1/1/12*
Initiated: *10/01/04*

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 ICD9 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: *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 ICD9 code.	
2. Does the patient have a diagnosis of *Clostridium difficile*-associated infection (CDI)? (ICD-9 008.45)?	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: *7/12*

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 ICD9 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*
Revision(s): *5/29/2014 (MH), 1/1/13(HK)*
Initiated: *7/23/12*

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 ICD9 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: *4/15, 1/15; 9/14; 7/14; 3/14*

Hormones – Growth Hormone (Somatropin®)

Goal(s):

- Cover drugs only for covered diagnoses and those where there is medical evidence of effectiveness and safety.

NOTE: Growth Hormone treatment is no longer covered by OHP for adult diagnoses, including isolated deficiency of human growth hormone, AIDS wasting in adults or other conditions in adults.

Initiative:

- Initiative

Length of Authorization:

Up to 12 months

Requires PA:

- Non-preferred drugs
- All drugs in HIC3 = P1A

Covered Alternatives:

- All medications require a PA for OHP Coverage. GH for adults is not covered by OHP. For preferred products for children see:
- Preferred alternatives listed at www.orpdl.org

Note: Criteria is divided by: **Pediatric (<18 years old)**

- New therapy
- Renewal therapy

Approval Criteria		
1. Is the patient an adult (>18 years old)?	**Yes:** Pass to RPH; Deny, (Not Covered by the OHP).	**No:** Go to #2.
2. Is this a request for initiation of growth hormone?	**Yes:** Go to question #3.	**No:** Go to renewal therapy.
3. Is the prescriber a pediatric endocrinologist or pediatric nephrologist?	**Yes:** Go to #4.	**No:** Pass to RPH; Deny (Medical Appropriateness)
4. Is the diagnosis promotion of growth delay in a child with 3rd degree burns (ICD-9 codes 941.3-949.3)?	**Yes:** Document and send to DHS Medical Director for review and pending approval	**No:** Go to #5.

Approval Criteria		
5. Is the diagnosis one of the following? • Turner's Syndrome (758.6) • Noonan Syndrome (759.89) • Pre-transplant chronic renal insufficiency (CRI) (593.9) • Prader - Willi Syndrome(PWS) (759.81) • Neonatal Hypoglycemia associated with Growth Hormone Deficiency (775.6) • X-linked Hypophosphotemia • Pituitary Dwarfism (253.3) • SHOX (Short stature homeobox gene)(783.43)	**Yes:** Document and go to #6.	**No:** Pass to RPH; Deny (Not Covered by the OHP).
6. If male, is bone age <16 years? If female, is bone age <14 years?	**Yes:** Go to #7.	**No:** Pass to RPH; Deny (Medical Appropriateness)
7. Is there evidence of non-closure of epiphyseal plate?	**Yes:** Go to #8.	**No:** Pass to RPH; Deny (Medical Appropriateness)
8. Is the product requested preferred?	**Yes:** Approve for 1 year.	**No:** Go to #9.
9. Will the prescriber consider a change to a preferred product? Message: Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&T) Committee. Reports are available at: http://pharmacy.oregonstate.edu/drug-policy/oregon-pharmacy-therapeutics-committee/about-committee	**Yes:** Inform provider of covered alternatives in class. www.orpdl.org Approve for 1 year.	**No:** Approve for 1 year.

Pediatric Approval Criteria (<18 years old) – Renewal Therapy		
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)

Approval Criteria		
3. Is male bone age <16 years and Is 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 1 year.	**No:** Go to #5.
5. 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://pharmacy.oregonstate.edu/drug-policy/oregon-pharmacy-therapeutics-committee/about-committee	**Yes:** Inform provider of covered alternatives in class. www.orpdl.org Approve for 1 year.	**No:** Approve for 1 year.

P&T / DUR Action: *9/23/14, 9/16/10(KS), 5/27/10(KS), 9/18/08ca, 2/23/06, 11/18/03, 9/9/03,*
Revision(s) *1/1/11, 7/1/10, 4/15/09, 10/1/03, 9/1/06*
Initiated: *10/1/03*

Leuprolide Hormone Therapy

Goal:

- Approve for OHP-funded conditions in children and adolescents up to 16 years of age.

Length of Authorization:

Precocious puberty: through age 12 years in females, age 13 years in males.
Gender dysphoria: through age 16 years.

Requires PA:

- Leuprolide in children and adolescents through 16 years of age.

Approval Criteria		
1. What diagnosis is being treated and what is the age and gender of the patient?	Record ICD9 code and age/gender.	
2. Is the patient female and aged <13 years or male and aged <14 years?	Yes: Go to #3	No: Go to #4
3. Is the diagnosis central precocious puberty (CPP)? [precocious sexual development and puberty, ICD-9 259.1] • Note CPP is often associated with hydrocephalus, cranial irradiation, Silver-Russell syndrome, hypothalamic tumor, or hamartoma. • All above diagnoses and conditions are rare in children and adolescents.	Yes: Approve through: • Age 12 years for females • Age 13 years for males	No: Go to #4
4. Is the diagnosis gender dysphoria (ICD-9 302.6, 302.85)?	Yes: Go to #5	No: Pass to RPH; deny for medical appropriateness

Approval Criteria		
5. Does the request meet all of the following criteria? • Diagnosis of gender dysphoria made by a mental health professional with experience treating gender dysphoria. • At least 6 months of counseling and psychometric testing for gender dysphoria. • Prescribed by a pediatric endocrinologist. • Confirmation of puberty (physical changes and hormone levels) no earlier than Tanner Stages 2-3 (bilateral breast budding or doubling to tripling testicular volume).	Yes: Approve through • Age 16 years	No: Pass to RPH; deny for medical appropriateness
RPH only: All other indications need to be evaluated as to whether it is an OHP-funded condition. Refer unique situations to Medical Director of DMAP.		

P&T / DUR Review: *7/15; 5/15; 9/07*
Implementation: *7/1/15; 11/07; 7/09*

Hormones – Testosterone (Androgens)

Goal(s):

- Cover only for covered diagnosis and for medically appropriate conditions.
- Use for body building is not covered.
- Use for sexual dysfunction is not covered.

Initiative:

- Initiative

Length of Authorization:

Up to 6 months

Requires PA:

- Topical and non-preferred injectable testosterone products require PA for coverage verification

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Does the diagnosis for the medication requested include any of the following? • Testicular Hypofunction (257.2) • Hypopituitarism and related disorders (253.2, 253.4, 253.7, 253.8) • AIDS-related cachexia (253.2)	**Yes:** Go to #3.	**No:** Pass to RPH. RPH go to #4.
3. Will the prescriber consider a change to a preferred product? Message: • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Health Resource Commission (HRC).	**Yes:** Inform provider of covered alternatives in class. Approve for 6 months.	**No:** Approve for 6 months.
4. RPH only All other indications need to be evaluated to see if they are above the line or below the line.	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: *2/23/12 (TDW), 9/16/10 (KS), 2/23/06, 2/21/01, 9/6/00*
Revision(s): *7/31/14 (BL), 5/14/12, 1/24/12, 1/1/11, 9/1/06*
Initiated:

Hydroxyprogesterone caproate (Makena®)

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 ICD9 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)*
Revision(s):
Initiated: *1/1/14*

Idiopathic Pulmonary Fibrosis (IPF) Agents

Goal:

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

Length of Authorization:

- Up to 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-9 516.31)?	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.

Incretin Enhancers

Initiative:

- Optimize correct use of incretin enhancers that corresponds to National Guidelines.

Length of Authorization:

Up to 12 months

Covered Alternatives:

- Sitagliptin (Januvia®)
- Sitagliptin (Januvia®)
- Sitagliptin/metformin ER (Janumet XR ®)
- Saxagliptin (Onglyza®)
- Saxagliptin/metformin (Kombiglyze XR®)
- Linagliptin (Tradjenta®)
- Linagliptin/metformin (Jentadueto®)

Approval Criteria		
1. Does the patient have a diagnosis of Type 2 diabetes?	**Yes:** Go to #2.	**No:** Deny based on appropriateness of therapy.
2. Has the patient tried and failed metformin and sulfonylurea therapy or have contraindications to these treatments? Contraindications include: • Renal disease or renal dysfunction • Known hypersensitivity to therapies • Acute or chronic metabolic acidosis • Patients at increased risk of lactic acidosis (CHF, advanced age, impaired hepatic function) • Increased risk of hypoglycemia	**Yes:** Go to #4.	**No:** Recommend trial of metformin or sulfonylurea. See below for metformin titration schedule.
3. Is the request for sitagliptin (Januvia®) or sitagliptin/metformin (Janumet®)?	Yes: Approve for up to 12 months.	No: Recommend trial of preferred incretin enhancers (sitagliptin or sitagliptin/metformin).

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 31;1-11, 2008.

P&T / DUR Action: *9/23/14 (MH/KS), 9/26/13 (HM/KS), 4/26/12 (KS), 3/17/11 (KS)*
Revision(s): *9/27/14, 1/1/14, 2/21/13*
Initiated: *7/23/12, 1/1/12*

Incretin Mimetics (GLP-1 Analogs)

Initiative:

- To optimize the correct use of insulin mimetics.

Length of Authorization:

Up to 12 months

Requires PA:

- Non-preferred drugs

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. Does the patient have a diagnosis of Type 2 diabetes?	**Yes:** Go to #2.	**No:** Pass to RPH; Deny for medical appropriateness.
2. 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. www.orpdl.org	**No:** Go to #3.
3. Has the patient tried and failed metformin **and** sulfonylurea therapy or have contraindications to these treatments? Contraindications to metformin: • Renal disease or renal dysfunction • Known hypersensitivity • Acute or chronic metabolic acidosis • Increased risk of lactic acidosis (CHF, advanced age, impaired hepatic function) Contraindications to sulfonylureas: • Known hypersensitivity • Increased risk of hypoglycemia	**Yes:** Go to #4.	**No:** Pass to RPH; Deny for medical appropriateness. Recommend trial of metformin or sulfonylurea. See below for metformin titration schedule.
4. Is the patient currently taking insulin?	**Yes:** Go to #5.	**No:** Approve for up to 12 months.

Approval Criteria		
5. Is the patient requesting exenatide (Byetta®), liraglutide (Victoza®) or albiglutide (Tanzeum®) and is using basal insulin?	**Yes:** Approve for up to 12 months.	**No:** Go to #6.
6. Is the patient requesting dulaglutide (Trulicity®) and is using prandial insulin?	**Yes:** Approve for up to 12 months.	**No:** Pass to RPH; Deny for 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 31;1-11, 2008.

P&T / DUR Action: *1/29/15 (KS), 9/23/14 (KS), 9/26/13 (KS), 4/26/12 (KS), 3/17/11 (KS)*
Revision(s): *1/1/14*
Initiated: *7/23/12, 1/1/12*

Indacaterol (LABA)

Goal(s):

- Promote preferred drugs that are selected based on evidence based reviews.
- To ensure appropriate drug use.

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 ICD9 code.	
2. Does patient have COPD (ICD-9 496)?	Yes: Go to #3.	No: Deny (medical inappropriateness)
3. Will the prescriber consider a change to a preferred product? • Preferred products do not require PA	Yes: Inform provider of covered alternatives in class.	No: Go to #4.
4. Does patient have a documented previous trial of salmeterol AND formoterol?	Yes: Approve for one year	No: Pass to RPh, Deny for OHP Coverage.

P&T & DUR Board Action: *2/23/12 (MH)*
Revision(s):
Initiated: *5/14/12*

Insulins

Goal(s):

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

Initiative:

- Initiative

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 ICD9 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 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: • Does the patient have physical dexterity problems/vision impairment • Comprehension related issues • Dosing errors with use of vials • The patient is on a low dose of insulin (≤40 units/day) • Is the request for a child <18 years old?	Yes: Go to #5.	No: Pass to RPh; go to #6.

Approval Criteria
5. Will the prescriber consider a change to a preferred product? Message: 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. www.oregon.gov/DHS/healthplan/tools_prov/dl.shtml. For insulin pens approve for 1 year (other preferred products covered without a PA) • No: Approve for 1 year
6. RPh only • Requests for insulin pens and cartridges on a client-specific basis. • Refer to the PDL for the preferred pens. AND/OR • If the above criteria are met and the request is NOT for convenience issues alone then approve insulin pen or cartridge use.

P&T / DUR Action: *9/16/10 (KS)*
Revision(s): *12/16/10*
Initiated: *1/1/11*

Intranasal Allergy Drugs

Goals:

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

Length of Authorization:

6 months

Requires PA:

- 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 ICD9 code.	
2. Will the prescriber consider switching to a preferred product? *Note: preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics (P&T) Committee.*	Yes: Inform provider of preferred alternatives.	No: Go to #3
3. Is the prescribed drug an intranasal corticosteroid?	Yes: Go to #4	No: Pass to RPh; deny for medical appropriateness or not funded by OHP.
4. Does the patient have asthma or reactive airway disease exacerbated by chronic/allergic rhinitis (493.xx)?	Yes: Go to #5	No: Go to #6

Approval Criteria		
5. Does the drug profile show the patient is currently receiving an orally inhaled corticosteroid (ICS)?	Yes: Pass to RPh; deny for medical appropriateness. Note: asthma-related outcomes are not improved by the addition of an intranasal corticosteroid to an orally inhaled corticosteroid.	No: Approve for 6 months.
6. Does patient have other co-morbid conditions or complications that are funded by the OHP? • Chronic Sinusitis (473.xx) • Acute Sinusitis (461.xx) • Sleep Apnea (327.20; 327.21; 327.23; 327.29; 780.51; 780.53; 780.57)	Yes: Document ICD-9 code(s) and approve for 6 months.	No: Go to #7
7. RPh only: Is the diagnosis funded by the OHP?	Funded: Deny for medical appropriateness. (e.g., COPD, Obstructive Chronic Bronchitis, or other Chronic Bronchitis [496; 490; 491.0; 491.1; 491.2x; 491.8; 491.9]) 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. (e.g., allergic rhinitis (477.x), chronic rhinitis (472.0), allergic conjunctivitis (372.14), upper respiratory infection (465.9), acute nasopharyngitis (common cold) (460), urticaria (708.x), etc.)

P&T / DUR Review: *7/15 (AG); 9/08; 2/06; 9/04; 5/04; 5/02*
Implementation: *8/15; 8/09; 9/06; 3/06; 5/05; 10/04; 8/02*

Ivacaftor (Kalydeco®)

Goal:

- To ensure appropriate drug use and limit to patient populations in which ivacaftor has demonstrated to be effective and safe.

Length of Authorization:

- 60 days to 6 months

Requires PA:

- Ivacaftor

Preferred Alternatives:

- No preferred alternatives at this time

Approval Criteria		
1. Is this a request for continuation of therapy (patient already on ivacaftor)?	Yes: Go to **Renewal Criteria**	No: Go to #2
2. What is the diagnosis?	Record ICD10 code	
3. Does the client have a diagnosis of cystic fibrosis and is 2 years of age or older?	**Yes:** Go to #4	**No:** Pass to RPH; Deny (medical appropriateness)
4. Is the request from a practitioner at an accredited Cystic Fibrosis Center or a pulmonologist?	**Yes:** Go to #5	**No:** Pass to RPH; Deny (medical appropriateness)
5. Does the patient have a baseline sweat chloride level? Note: if yes, document baseline level.	**Yes:** Document baseline level; go to #6	**No:** Pass to RPH; Deny (medical appropriateness). Request a baseline level before approving therapy
6. 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 #8	**No:** Go to #7 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)

7. 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)
8. Is the patient on ALL the following drugs, or has had an adequate trial of each drug, unless contraindicated **or** not appropriate based on age (<6 y/o) and normal lung function: • Dornase alfa, AND • Hypertonic saline, AND • Inhaled or oral antibiotics (if appropriate)	**Yes:** Go to #9	**No:** Pass to RPH; Deny (medical appropriateness)
9. Is the patient on concomitant therapy with a strong CYP3A4 inducer (see Table 1)?	**Yes:** Pass to RPH; Deny (medical appropriateness)	**No:** Go to #10
10. Does the patient have decreased liver function, defined as elevated levels (ie, ≥3x the upper limit of normal) in ≥3 of the following levels: ALT, AST, AP, GGT, total bilirubin? Note: This was an additional exclusion criteria from the trials	**Yes:** Pass to RPH; Deny (medical appropriateness)	**No:** Go to #11
11. Is ivacaftor dosed appropriately based on age, weight, and co-administered drugs (see dosing and administration below)?	**Yes:** Approve for 60 days Note: Approve for 60 days to allow time for patient to have a sweat chloride test done after 30 days of treatment (see **Renewal Criteria**)	**No:** Pass to RPH; Deny (medical appropriateness)

Renewal Criteria		
1. Is this the first time the patient is requesting a renewal?	**Yes:** Go to #2	**No:** Go to #3
2. Does the patient have a documented physiological response to therapy and evidence of adherence after 30 days of treatment as defined as below? • Sweat chloride test has decreased by at least 20 mmol/L	**Yes:** Go to #6	**No:** Pass to RPH; consider patient's adherence to therapy and repeat test in 2 weeks to allow for variability in test. If sodium chloride has still not decreased by 20 mmol/L, deny therapy for medical appropriateness.
3. Does the patient have documented response to therapy as defined as below? For patients ≥ 6 y/o • A 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 2-5 y/o (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 #4	**No:** Pass to RPH; Deny (medical appropriateness)
4. Has the patient been compliant with therapy, as determined by refill claims history?	**Yes:** Go to #5	**No:** Pass to RPH; Deny
5. If within first year of treatment, are liver function tests (AST/ALT) within normal limits in the past 3 months? If after 1 year of treatment, are liver function tests (AST/ALT) within normal limits in past 1 year? Note: Monitoring LFTs is recommended every 3 months for the	**Yes:** Go to #6	**No:** Pass to RPH; Deny (medical appropriateness)

first year, followed by once a year.		
6. Is ivacaftor 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)

Limitations of Use:
• Ivacaftor is not effective in patients with Cystic Fibrosis who are homozygous for the *F508del* mutation in the *CFTR* gene.

Dosage and Administration:

- Adults and pediatrics ≥6 y/o: 150 mg orally every 12 hours with fat-containing foods
- Children 2 to < 6 y/o:
  - < 14 kg: 50 mg packet every 12 hours
  - ≥ 14 kg: 75 mg packet every 12 hours
- Hepatic Impairment
  - Moderate Impairment (Child-Pugh class B):
    - ≥6 y/o: one 150 mg tablet once daily
    - 2 to < 6 y/o 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 Clofazamine	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	CYP3A4 strong inducers	Concurrent use is **NOT** recommended

LABA/ICS Inhalers

Goal(s):

- Approve LABA/ICS only for covered diagnosis (e.g. COPD or Asthma and on concurrent controller medication).
- LABA are only indicated for use in clients with Asthma already receiving treatment with an asthma controller medication (e.g. Inhaled corticosteroids or leukotriene receptor antagonists,).

Initiative:

- LABA/ICS Step Therapy

Length of Authorization:

6-12 months

Requires PA:

- All combination inhaled corticosteroid/long-acting beta-agonist inhalers, except when prescribed by emergency department clinicians

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

Step Therapy Required Prior to Coverage:

Asthma: oral corticosteroid inhalers (see preferred drug list options at (www.orpdl.org)

COPD: short and long-acting beta-agonist inhalers, anticholinergics and inhaled corticosteroids (see preferred drug list options at www.orpdl.org), DO NOT require prior authorization.

Approval Criteria		
1. Does patient have asthma or reactive airway disease (ICD-9: 493, 493.0-493.93)?	**Yes:** Go to #2.	**No:** Go to #4.
2. Is the medication for Breo Ellipta™ (fluticasone furoate / vilanterol)?	**Yes:** Pass to RPH; Deny for medical appropriateness.	**No:** Go to #3.

Approval Criteria		
3. Has patient: • failed an inhaled corticosteroid or other controller medication OR • Had ≥2 exacerbations requiring oral systemic corticosteroids in the past year, OR • Is there documentation of step 3 asthma or higher OR • Is there a hospital admission or ER visit related to asthma or reactive airway disease within last 365 days?	**Yes:** Document the following: Date of trial, drug, reason(s) for failure or contraindications OR chart notes of asthma severity in the PA record Approve for 1 year if this is patient's first prescription for a combination inhaler or if this is a continuation of therapy and patient is well controlled on current dose.	**No:** Pass to RPH; Deny, (Medical Appropriateness).
4. Does patient have COPD (ICD-9 496) or Chronic bronchitis (491.1-2.) and/or emphysema (492.xx)?	**Yes:** Approve for 12 months.	**NO:** Pass to RPH. Deny (Medical Appropriateness). Need a supporting diagnosis. If prescriber believes diagnosis appropriate inform them of the provider reconsideration process for Medical Director Review.

P&T / DUR Action: *11/20/14 KK, 11/21/13, 5/31/12, 9/24/09 (DO/KK), 2/23/06*
Revision(s): *1/1/15, 1/1/14, 9/26/12, 1/1/10*

Leukotriene Inhibitors

Goal(s):

- Approve montelukast only for covered diagnosis.
- 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 medical evidence.

Length of Authorization:

6 months or 2 years (diagnosis specific)

Requires PA:

- Non-preferred drugs
- Montelukast (Singulair®)

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org
- Allergic Rhinitis: Certirizine, chlorpheniramine, diphenhydramine, loratidine & hydroxyzine DO NOT require prior authorization.
- Asthma: Oral corticosteroid inhalers. Long-acting beta-agonist inhalers and zarfirlukast (Accolate®) DO NOT require prior authorization.

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Does client have asthma or reactive airway disease (ICD-9: 493.xx)?	Yes: Approve for 2 years	No: Go to #3.
3. Does client have diagnosis allergic rhinitis, allergic conjunctivitis, or chronic rhinitis/pharyngitis/nasopharyngitis? (ICD-9: 472.xx, 372.01-05, 372.14, 372.54, 372.56, 477.xx, 995.3, V07.1	Yes: Go to #4.	No: Go to #6.
4. Does client have other co-morbid conditions or complications that are above the line? • Acute or chronic inflammation of the orbit (376.0 – 376.12) • Chronic Sinusitis (473.xx) • Acute Sinusitis (461.xx) • Sleep apnea (327.20,327.21,327.23-327.29,780.51, 780.53, 780.57) • Wegener's Granulomatosis (ICD-446.4)	Yes: Go to #5.	No: Pass to RPH; Deny, (Not Covered by the OHP).

Approval Criteria		
5. Does client have contraindications (e.g. Pregnant) or had insufficient response to at least 2 available alternatives? Document.	Yes: Approve 6 months	No: Pass to RPH; Deny, (Cost-Effectiveness)
6. Is the diagnosis COPD (496) or Obstructive Chronic Bronchitis? (491.1-491.2)	Yes: Pass to RPH; Deny, (Medical Appropriateness). Leukotriene not indicated	No: Pass to RPH; Go to #7.
7. Is the diagnosis Chronic Bronchitis? (491.0, 491.8, 491.9)	Yes: Pass to RPH; Deny, (Not Covered by the OHP)	No: Pass to RPH Go to #8.
8. RPH only: Is the diagnosis above the line or below the line?	Above: Deny with yesterday's date (Medically Appropriateness) 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) "The treatment for your condition is not a covered service on the Oregon Health Plan." (e.g. URI - 465.9 or Uticaria – 708.0, 708.1, 708.5, 708.8, 995.7 should be denied)

Refer questions regarding coverage to DMAP.

P&T / DUR Action: *5/31/12, 9/18/08reh, 2/23/06, 9/14/04, 5/25/04*
Revision(s): *8/20/12, 7/1/09, 9/1/06, 7/1/06, 5/31/05, 4/1/05 Re-established,*
Suspended *12/17/04*
Initiated: *11/18/04*

Low-Dose quetiapine (Seroquel® and Seroquel XR®)

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:

- Require Prior Authorization for quetiapine doses <150 mg/day for greater than 90 days. HSN = 14015

Length of Authorization:

Up to 12 months (criteria specific)

Requires PA:

- Non-preferred drugs

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org
- zolpidem
- benzodiazepine sedatives are available for short-term (15 doses/30days) without PA.
- mirtazapine (Off-label use)

Table 1 - Adult (>18 years old) FDA-approved indications for quetiapine

Bipolar Disorder	296.0, 296.4, 296.6-296.8,296.89	
Major Depressive Disorder	296.2, 296.24, 296.3, 296.23, 296.33, 296.34, 296.5, 296.53, 296.54	For Seroquel XR® only, Adjunctive therapy with antidepressants for Major Depressive Disorder
Schizophrenia	295, 295.4, 295.44, 295.45, 295.6,295.62, 295.64, 295.85, 295.95, 295.80-295.82,295.40-295.42, 295.90-295.92	
Bipolar Mania	296.1, 296.3, 296.4, 296.43, 296.44	
Bipolar Depression	296.5	

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 ICD9 code. Do not proceed and deny if diagnosis is not listed in Table. 1 or Table 2 above. (Medically Appropriate)	
2. Is the prescription for quetiapine less than 150 mg/day? (Verify that day's supply entry is accurate)	Yes: Go to #3.	No: Trouble-shoot claim processing with the pharmacy.
3. Is planned duration of therapy greater than 90 days?	Yes: Go to #4.	No: Approve for titration up to maintenance dose (60days).
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?	Yes: Approve for up to 1 year.	No: Deny, (Medically Appropriate). • Provide tapering schedule if needed. See below. • Approve up to 6 months to allow taper.

Suggested tapering strategies for quetiapine:

According to the manufacturer, downward dosage adjustments may be made dependent upon the clinical response and tolerance of the patient. Several other references which include:
The Journal of Family Practice; the Texas Medication Algorithm Project Procedural Manual on Bipolar Disorder Algorithms, and the State of Connecticut Department of Developmental Services Neuroleptic Taper Protocol recommend reducing the antipsychotic dose by 10 to 25 % of the current regimen every 1 to 2 weeks, with the exception of the State of Connecticut Protocol recommendation of additional decreases every 3 to 6 months as tolerated.

References:

1. Prescribing information for Seroquel®. AstraZeneca Pharmaceuticals LP. Wilmington, DE 19850. November 2009.
2. Prescribing information for Seroquel XR®. AstraZeneca Pharmaceuticals LP. Wilmington, DE 19850. November 2009.
3. Ramaswamy S, Malik S, Dewan V. Tips to manage and prevent discontinuation syndromes. J Fam Pract 2005; 4(9): 1-7.
4. Texas Department of State Health Services. Texas Medication Algorithm Project Procedural Manual: Bipolar disorder algorithms. http://www.pbhcare.org/pubdocs/upload/documents/TIMABDman2007.pdf (Accessed 2010 June 4).
5. State of Connecticut Department of Developmental Services Neuroleptic Taper Protocol. http://www.ct.gov/dds/cwp/view.asp?a=2042&q=391462. (Accessed 2010 June 4).

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 ICD9 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)*
Revision(s)
Initiated: *4/9/12*

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 ICD9 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)*
Revision(s): *1/1/14, 11/21/2013*
Initiated: *1/1/14*

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 ICD9 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)*
Revision(s):
Initiated:

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 ICD9 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)*
Revision(s): *1/1/15*
Initiated:

New Drug Policy

Goal(s):

- Restrict coverage of selected new drugs until the DUR Board can review 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-covered condition on the Oregon Health Plan List of prioritized services.

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Is the diagnosis an OHP (DMAP) above the line diagnosis?	Yes: Go to #3.	No: Pass to RPH; Deny (Not Covered by the OHP).
3. Client has documented therapeutic failure, adverse event or contraindication to 2 covered alternatives (CONSULT WITH PHARMACIST for appropriate covered alternatives). Document the drugs tried or contraindications.	Yes: Approve for 6 months or anticipated length of therapy; whichever is shorter.	No: Pass to RPH; Deny (Cost Effectiveness)

P&T / DUR Action: *12/3/2009 (klk)*
Revision(s):
Initiated: *7/1/2010*

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 ICD9 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 ICD9 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*
Revision(s): *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 ICD9 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)
Revision(s):
Initiated:

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 (ICD9 = 190xx – 199xx) 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:*	ICD9 Codes
Disorders of soft tissue (including Fibromyalgia)	*729.0-729.2, 729.31-729.39, 729.4-729.9, V53.02*
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	*721-724, except 723.3* *739, 839.2, 847*

*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 ICD9	

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-9 338.3) 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:** Approve 30-90 days; 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*
Revision(s): *6/12; 5/12; 1/12; 1/10*
Initiated: *7/09*

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 ICD9 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: *7/15; 9/05; 5/05; 12/03; 5/03*

Oral MS Drugs

Goal(s):

- To ensure appropriate and safe drug use drugs
- Promote preferred drugs

Length of Authorization:

Up to 12 months

Requires PA:

- Fingolimod (Gilenya®)
- Teriflunomide (Augabio®)
- Dimethyl Fumarate (Tecfidera®)

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Does the patient have a diagnosis of relapsing remitting Multiple Sclerosis (ICD-9 340)?	**Yes:** Go to #3.	**No:** Pass to RPH; Deny (medical appropriateness).
3. Will the prescriber consider a change to a Preferred MS product? • 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. www.orpdl.org.	**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.
8. Is the patient of childbearing potential?	**Yes:** Go to #9.	**No:** Approve for up to one year.

Approval Criteria		
9. Is the patient currently on a documented use of reliable contraception?	**Yes:** Approve for up to one 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 (ICD-9 362.07)?	**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 antiarrhythmics, beta-blockers, or calcium channel blockers?	**Yes:** Go to #13.	**No:** Approve up to one year.
13. Has the patient had a cardiology consultation before initiation (see clinical notes)?	**Yes:** Approve up to one year.	**No:** Pass to RPH; Deny (medical appropriateness).
14. Is the prescription for dimethyl fumarate?	**Yes:** Approve up to one 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.

P&T / DUR Action: *9/26/13 (MH), 5/30/13, 3/29/2012*
Revision(s): *1/1/14 (MH)*
Initiated: *6/21/2012*

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 ICD9 code.	
2. Does the patient have an active infection with suspected or documented MRSA (e.g. 041.11-041.12, 482.42) or VRE (e.g. V09.8x) or other multi-drug resistant gram-positive cocci (e.g. V09.9x)?	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 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 ICD9 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 ICD9 7485x or 7486x **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 746xx or 747xx 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)*
Revision(s): *3/30/12 (KS)*
Initiated: *8/20/12*

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.

Initiative:

- PDL: Preferred Drug List

Length of Authorization:

Up to 6 months

Requires PA:

- Non-preferred drugs

Covered Alternatives:

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

Note:

A complete list of PDL classes is available at http://www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
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: *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.

Initiative:

- Initiative

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 ICD9 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)*
Revision(s):
Initiated: *9/23/14*

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 ICD9 code: (571.40; 571.41; 571.49)	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).

Continuation of Therapy- HCV		
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?	**Yes:** Approve as follows: Approval for beyond quantity and duration limits requires approval from the medical director. **Geno-type** / **Approve for:** / **Apply** 1 or 4 / **An additional 36 weeks** or for up to a total of 48 weeks of therapy (whichever is the lesser of the two). / Ribavirin quantity limit of 200 mg tablets QS# 180 / 25 days (for max daily dose =1200 mg). 2 or 3 / **An additional 12 weeks** or for up to a total of 24 weeks of therapy (whichever is the lesser of the two). / Ribavirin quantity limit of 200 mg tab QS# 120 / 25 days (for max daily dose = 800 mg). For all genotypes and HIV co-infection / **An additional 36 weeks** or for up to a total of 48 weeks of therapy (whichever is the lesser of the two) / Ribavirin quantity limit of 200 mg tablets QS# 180 / 25 days (for max daily dose = 1200 mg).	**No:** DENY (Medical Appropriateness) Treatment with pegylated interferon-ribarvirin does not meet medical necessity criteria because there is poor chance of achieving an SVR.

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*
Revision(s): *5/14/12, 1/1/10, 5/22/08 (Koder)*
Initiated: *1/1/07*

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 ICD9 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)*
Revision(s):
Initiated: *2/21/13*

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 ICD9 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 (53081), esophagitis (53010 – 53019)] or • *H. pylori* infection (04186)?	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 (53081) Esophagitis (5301x)	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 (04186)	2 weeks	Dexlansoprazole 60 mg Esomeprazole 40 mg Lansoprazole 60 mg Omeprazole 40 mg Pantoprazole 80 mg Rabeprazole 40 mg
Achalasia and cardiospasm (5300x) Stricture & Stenosis of Esophagus (5303x) Perforation of Esophagus (5304x) Dyskinesia of esophagus (5305x) Gastroesophageal laceration-hemorrhage syndrome (5307x) Esophageal hemorrhage (53082) Gastric Ulcer (5310x – 53191) Duodenal Ulcer (5320x – 53291) Peptic ulcer site unspecified (5330x – 53391) Gastrojejunal ulcer (5340x – 53491) Gastritis and duodenitis (5350x – 53571) Zollinger-Ellison (2515x) Neoplasm of uncertain behavior of other and unspecified endocrine glands (2374x) Malignant mast cell tumors (2026x) Multiple endocrine neoplasia [MEN] type I (25801)	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: *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 ICD9 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)*
Revision(s):
Initiated: *1/1/13*

Oral/Inhalation Pulmonary Arterial Hypertension 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/drugs/

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 (see Table 1)?	**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)

Table 1. 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
Revision(s):	5/12, 1/12
Initiated:	1/11

Regranex

Wound Healing Agent

Goal(s):

- To cover agents only for above-the-line diagnosis and those indicated by medical evidence, i.e. Restrict diabetic neuropathic ulcers.

Length of Authorization:

Up to 6 months

Requires PA:

HSN	Generic	Brand
017028	Becaplermin	Regranex

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Is the diagnosis stated as Diabetic neuropathic ulcers?	Yes: Go to #3.	No: Pass to RPH; Deny, (Medical Appropriateness).
3. Does the client take any oral anti-diabetic meds/insulin OR has office faxed documentation of diabetic status?	Yes: Approve ONLY 15 grams of Regranex at a time x 6 mos	No: Pass to RPH; Deny, (Medical Appropriateness).

P&T / DUR Board Action:
Revision(s)
Effective:

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 ICD9 code.	
2. Is the diagnosis monotherapy for infantile spasms in infants and children under 2 years of age (ICD-9 345.6)?	**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-9 340)?	**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-9 696.0, 714, 714.3, 720.0, 710.0)? **OR** • The following collagen diseases: systemic lupus erythematosus, systemic deramtomyositis (ICD-9 710.0, 710.3, 710.4)?, **OR** • Dermatologic diseases such as erythema multiforme, Stevens-Johnson syndrome (ICD-9 695.1, 695.13, 695.14)?, **OR** • Ophthalmic diseases such as keratitis, iritis, uveitis, optic neuritis, or chorioretinitis (ICD-9 970, 364.0-364.3, 377.3, 363.2)?, **OR** • For the treatment of respiratory diseases including Symptomatic Sarcoidosis (ICD-9 For treatment of an edematous state (ICD-9 782.3)?	**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)*
Revision(s):
Initiated: *1/1/2014*

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 ICD9 code.	
2. Is the treating diagnosis prevention or treatment of hepatic encephalopathy (572.2)?	**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 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:
Revision(s): *05/31/05*
Effective: *11/18/04*

Roflumilast

Goal(s):

- Decrease the number of COPD exacerbations in patients with severe COPD and chronic bronchitis and a history of prior exacerbations.

Length of Authorization:

Up to 12 months

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Is the diagnosis an OHP covered diagnosis?	Yes: Go to #3.	No: Pass to RPh, Deny for OHP Coverage.
3. Does the patient have documented severe or very severe (Stage III or Stage IV) COPD?	Yes: Go to #4	No: Deny (medical inappropriateness)
4. Does the patient have a history of chronic bronchitis AND Prior COPD exacerbations?	Yes: Go to #5	No: Deny (medical inappropriateness)
5. Is the patient currently on a long-acting bronchodilator?	Yes: Go to #6	No: Deny. Recommend trial of preferred long-acting bronchodilators
6. Has the patient tried an inhaled corticosteroid (ICS), and ICS combination, or tiotropium (LAMA)?	Yes: Approve up to 1 year	No: Deny. Recommend trial of preferred long-acting ICS or LAMA

P&T & DUR Board Action: *5/23/13, 2/23/12 (AB)*
Revision(s): *1/1/14,*
Initiated: *5/14/12*

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 ICD9 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

References:
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)*
Revision(s): *1/1/14 (MH)*
Initiated:

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

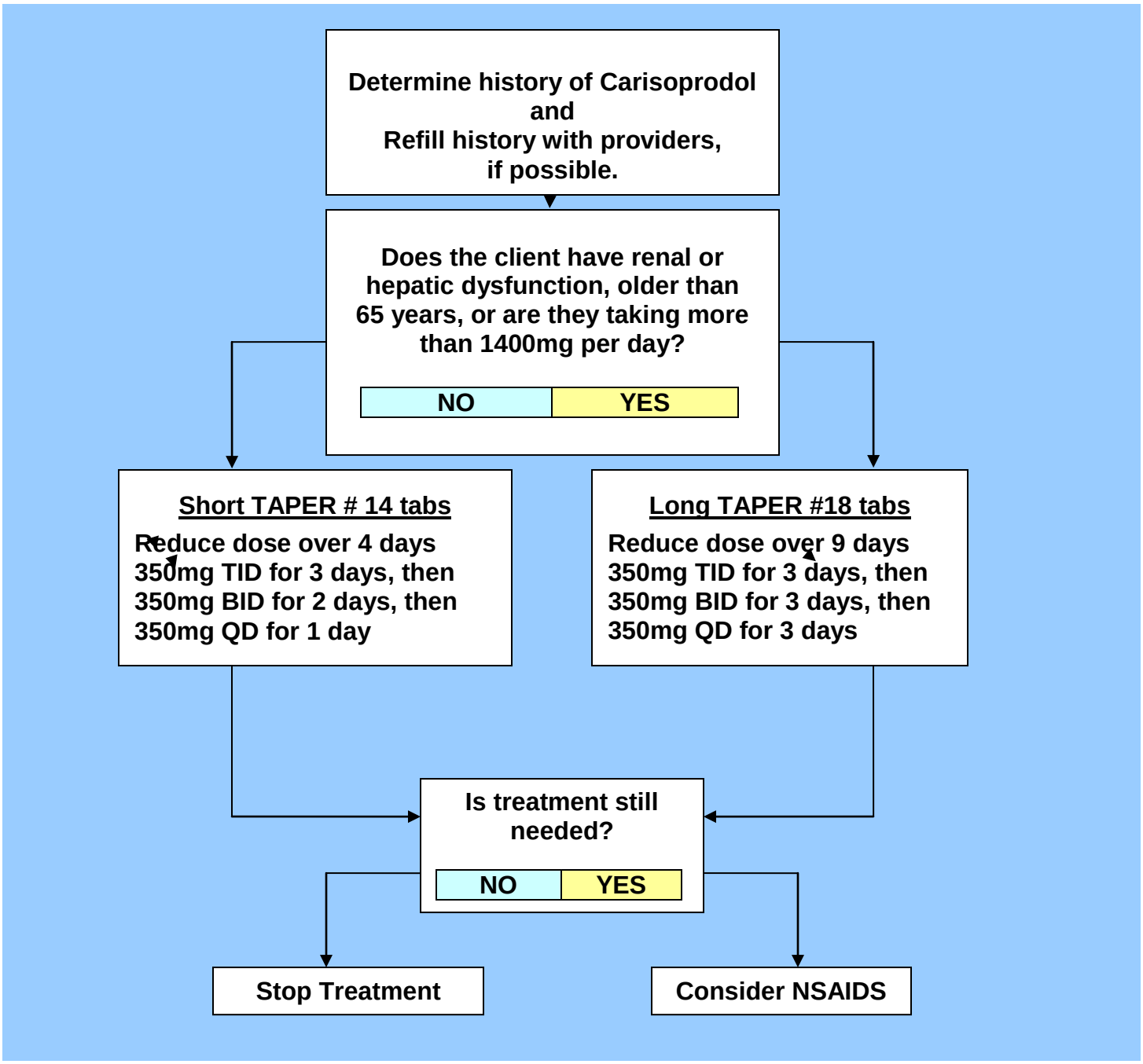
Covered Alternatives:

- 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 ICD9 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*
Revision(s): *1/1/15, 1/1/14, 1/1/10, 11/18/04*
Initiated: *12/6/02*

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 ICD9 code.	
2. Is the diagnosis for tobacco dependence? (ICD-9 305.1)?	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*
Revision(s):
Initiated: *7/23/12*

Sodium-Glucose Co-Transporter 2 (SGLT2)

Initiative:

- Optimize appropriate prescribing of SGLT2.

Length of Authorization:

Up to 12 months

Requires PA:

- Non-preferred drugs

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. Does the patient have a diagnosis of Type 2 diabetes?	**Yes:** Go to #2.	**No:** Deny based on appropriateness of therapy.
2. Has the patient tried and failed metformin and sulfonylurea therapy or have contraindications to these treatments? Contraindications include: • Renal disease or renal dysfunction • Known hypersensitivity to therapies • Acute or chronic metabolic acidosis • Patients at increased risk of lactic acidosis (CHF, advanced age, impaired hepatic function) • Increased risk of hypoglycemia	**Yes:** Go to #3.	**No:** Recommend trial of metformin or sulfonylurea. See below for metformin titration schedule.
3. Is the patient requesting 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:** Deny based on appropriateness of therapy.	**No:** Go to #4.
4. Has the patient tried and failed third-line* treatments for type 2 diabetes or have contraindications to third-line* treatments? *Insulins, thiazolidinediones, incretin enhancers (DPP-4 inhibitors), incretin mimetics (GLP-1 agonists) or amylin analogs.	**Yes:** Approve for up to 12 months.	**No:** Deny. Require a trial of third-line agents.

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 31;1-11, 2008.

P&T / DUR Action: *1/29/15 (KS), 9/23/14 (KS), 9/26/13 (KS)*
Revision(s):
Initiated: *1/1/14 (KS)*

Tesamorelin (Egrifta®)

Goal(s):

- Cover for only OHP covered diagnoses
- Restrict to indications supported by medical literature

Requires PA:

- Tesamorelin (Egrifta®)

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Is the diagnosis an OHP covered diagnosis?	Yes: Go to #3	No: Pass to RPH; Deny, (Not covered by the OHP).
3. Is the diagnosis a reduction of excess abdominal fat in HIV-infected patients with lipodystrophy?	Yes: Pass to RPH; Deny, (Not covered by the OHP).	No: Pass to RPH; Deny (medical appropriateness).

P&T / DUR Action: *4/26/12*
Revision(s):
Initiated: *7/23/12*

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 (696.1-696.2, 696.8), seborrheic dermatitis (690.XX), keroderma (701.1-701.3) and other hypertrophic and atrophic conditions of skin (701.8, 701.9) 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 ICD9 code.	
2. Is the diagnosis for seborrheic dermatitis (690.XX), keroderma (701.1-701.3) or other hypertrophic and atrophic conditions of skin (701.8, 701.9)?	**Yes:** Pass to RPh; deny, not funded by the OHP.	**No:** Go to #3
3. Is the diagnosis Psoriasis? (ICD-9: 696.1-696.2, 696.8)	**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
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.

Approval Criteria		
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: *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 ICD9 code.	
2. Does patient have diagnosis of epilepsy (ICD-9 code 345.0-345.9, 780.39, or 907.0)?	Yes: Approve for lifetime (until 12-31-2036)	No: Go to #3.
3. Does the patient have a diagnosis of migraine (ICD9 346)?	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-9 296 and subsets • ICD-9 295 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.
6. Is the patient using the medication for weight loss? (Obesity ICD9 278.0, 278.01)?	Yes: Pass to RPH; Deny, (Not covered by the OHP)	No: Go to #7.

Approval Criteria	
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*
Revision(s): *4/18/15; 5/12, 1/12*
Initiated: *1/11*