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

July 15, 2014

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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.dhs.state.or.us/policy/healthplan/guides/pharmacy/main.html.

Update information

Effective July 15, 2014

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

- Central Nervous System (CNS) Sedatives – Non Benzodiazepines – updated criteria
- Central Nervous System (CNS) Sedatives – Quantity Limit – updated criteria
- Central Nervous System (CNS) Sedatives – Therapy duplication – updated criteria
- Hepatitis B Antivirals – updated criteria
- Ivacaftor (Kalydeco®) – updated criteria
- Multi-Vitamins & Antioxidant Multivitamin combinations – new criteria (effective August 1, 2014)

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 410-121-0400 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.dhs.state.or.us/policy/healthplan/guides/genrules/main.html.

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 Authority

For Internal Use Only: PA Number

Prior Authorization Request for Prescriptions & 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
Supporting Justification for Urgent/Immediate Processing: ☐ Urgent
☐ Immediate

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

* ☐ Pharmacy ☐ Home EPIV ☐ Other _____

III Client Information

* Client ID _____ DOB ___ / ___ / _____
* Last Name _____ * First Name, MI _____

IV Service Information

Estimated length of treatment _____ Frequency _____
Primary diagnosis _____ * Primary ICD-9 diagnosis code _____
Other pertinent diagnosis
(For prescriptions and oral nutritional supplements, list all applicable ICD-9 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 ___ / ___ / _____

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

Line Item	Procedure Code	Modifier	Description	Units	U&C	MSRP	Total Dollars
1							
2							
3							
4							
5							
			Total Units	0			$0

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, etc)? _____	☐	☐
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: _____

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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://pharmacy.oregonstate.edu/drug-use-research-and-management/oregon-pharmacy-therapeutics-committee/about-committee.
- For summaries of P&T Committee recommendations approved by OHA for policy implementation, view the OHA Recommendations posted at www.oregon.gov/OHA/pharmacy/Pages/therapeutics/index.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

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 drugs
- 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.

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 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: *9/21/13, 2/23/12 (TW), 9/24/09 (DO/KK), 2/23/06*
Revision(s): *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

Generic	Brand	Quantity Limit
Aprepitant	Emend	3 doses / 7 days
Dolasetron	Anzemet	9 doses / 7 days
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 have received evidence-based reviews 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: *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): *1/1/14, 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 covered diagnoses. Minor fungal infections of skin, such as dermatophytosis of nail and skin are only covered 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

Table 1 – Examples of COVERED indications (1/1/06)

ICD-9	Description
112.1	Candidiasis of vulva and vagina
112.2	Candidiasis of other urogenital sites
112.4	Candidiasis of the lung
112.5	Disseminated Candidiasis
112.81	Candidal Endocarditis
112.82-112.89	Candidal Otitis Externa - Other Candidiasis site
114.0-114.9	Coccidiomycosis various sites
115.00-115.99	Histoplamosis
116.0-116.2	Blastomycosis
117 & subsets	Rhinosporidosis, Sporotrichosis, Chromoblastomycosis, Aspergillosis, Mycotis Mycetomas, Cryptococcosis, Allescheriosis, Zygomycosis, Dematiacious Fungal Infection, Mycoses Nec and Nos
118	Mycosis, Opportinistic
518.6	Bronchopulmonary Aspergillus, Allergic
616 & subsets	Inflammatory disease of cervix vagina and vulva
681 & subsets	Cellulitis and abscess of finger and toe
771.7	Neonatal Candida infection

Table 2 – Examples of NON-COVERED indications (1/1/06)

ICD-9	Description
690 & subsets	Erythematosquamous dermatosis
691	Atopic dermatitis and related conditions
691.0	Diaper or napkin rash
691.8	Other atopic dermatitis and related conditions
692 & subsets	Contact dermatitis and other eczema
695.2-695.4	Erythema nodosum, rosacea, lupus erythematosus
695.8-695.9	Other specified erythematous conditions, erythematous cond nec, unspecified erythematous condition
697 & subsets	Lichen
706 & subsets	Diseases of sebaceous glands

111	Dermatomycosis nec/nos
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 (1/1/06)

ICD-9	Description
110	Dermatophytosis
110.0	Dermatophytosis of scalp and beard (tinea capitis/ tinea barbae)
110.1	Dermatophytosis of nail (onychomycosis)
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	Dermatophytosis of other specified sites
110.9	Dermatophytosis site of unspecified site
111.1	Tinea nigra
112.0	Candidosis of mouth

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Is this an OHP covered diagnosis? See Table 1, Examples of COVERED indications (1/1/06)?	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 & safety by the Health Resources Commission (HRC).	Yes: Inform provider of covered alternatives in class.	No: Approve for 3 months or course of treatment.
4. Is the diagnosis in Table 2? See Examples of NOT-COVERED indications (1/1/06)	Yes: Pass to RPH: Deny, (Not Covered by the OHP).	No: Got to #5.

<table>
<tr><th colspan="3">Approval Criteria</th></tr>
<tr><td>5. Is the diagnosis in Table 3, Criteria driven diagnoses (1/1/06)?</td><td>Yes: Go to #6.</td><td>No: Go to #8.</td></tr>
<tr><td>6. Is the client immunocompromised?
• Does the client 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 client have a diagnosis of HIV/AIDS? OR
• Does client have diagnosis of diabetes that requires anti-diabetic medications e.g. Insulin, metformin, glyburide, or any drug in the therapeutic class of Diabetic Therapy? Document medication(s). OR
• Does client have sickle cell anemia?</td><td>Yes: Record ICD-9 code. Approve as follows: (Immunocompromised client)
ORAL
• Toenails = 12 weeks. Max 1 course per year.
• Fingernails = 6 weeks. Max 1 course every 6 months.
ORAL & TOPICAL
• All other diagnosis = course of treatment only with PRN renewals.
• If length of therapy is unknown, approve for 3 months.</td><td>No: Go to #7.</td></tr>
<tr><td>7. Is client currently taking an immunosuppressive drug? Document drug. Pass to RPH for evaluation if drug not in list.

Immunosuppressive drugs include but are not limited to:
<table>
<tr><th>Generic</th><th>Brand</th></tr>
<tr><td>azathioprine</td><td>Imuran</td></tr>
<tr><td>basiliximab</td><td>Simulect</td></tr>
<tr><td>cyclosporine</td><td>Sandimmune, Neoral</td></tr>
<tr><td>sirolimus</td><td>Rapamune</td></tr>
<tr><td>tacrolimus</td><td>Prograf</td></tr>
<tr><td>methotrexate (Mtx)</td><td>Rheumatrex</td></tr>
<tr><td>hydroxychloriquin</td><td>Plaquenil</td></tr>
<tr><td>etanercept</td><td>Enbrel</td></tr>
<tr><td>leflunomide</td><td>Arava</td></tr>
</table></td><td>Yes: Approve as follows: (Immunocompromised client)
ORAL
• Toenails = 12 weeks. Max 1 course per year.
• Fingernails = 6 weeks. Max 1 course every 6 months.
ORAL & TOPICAL
• All other diagnosis = course of treatment only with PRN renewals.
• If length of therapy is unknown, approve for 3 months.</td><td>No: Pass to RPH; Deny, (Not Covered by the OHP)</td></tr>
</table>

Approval Criteria

8. RPH only: All other indications need to be evaluated to see if they are above or below the line diagnosis:
 	
• If above the line fungal code, then it may be approved for treatment course with prn renewals. If length of therapy is unknown, approve for 3 months intervals only.
 	
• If below the line: Deny, (Not Covered by the OHP).
  o Deny Non-fungal diagnosis (Medical Appropriateness)
  o Deny Fungal ICD-9 codes that do not appear on the OHP list pending a more specific diagnosis code (Not Covered by the OHP).
  o 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 Action: *09/16/10 (KS/DO); 2/23/06; 11/10/0; 9/15/05; 5/12/05*
Revision(s): *1/1/11; 7/1/06; 11/1/0; 9/1/0*
Initiated:

Antihistamines

Goal(s):

- Approve antihistamines 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 Oregon Asthma Guidelines and medical evidence. Http://www.oregon.gov/DHS/ph/asthma/pubs.shtml#oregon

Initiative:

- Initiative

Length of Authorization:

6 months

Requires PA:

- All drugs (antihistamines and combinations) in TC = 14, except preferred alternatives

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/nasophrynigitis? (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 #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 steroid, leukotriene antagonist, etc.) And/or 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 steroids).*
6. 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 (327.20,327.21,327.23327.29,780.51, 780.53, 780.57) • Wegener's Granulomatosis (ICD-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 (491.1-491.2)?	Yes: Pass to RPH; Deny, (Medical Appropriateness). Antihistamine not indicated.	No: Go to #9.
9. 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 #10.
10. RPH only: Is the diagnosis above the line or below the line? • Above: Deny, yesterday's date (Medical Appropriateness) • Below: Deny, (Not Covered by the OHP). (e.g., URI-465.9 or Uticaria-708.0, 708.1. 708.5, 708.8, and 995.7 should be denied)		

Refer questions regarding coverage to DMAP.

P&T / DUR Action: *9/16/2010 (KK), 9/18/08 reh, 2/23/06, 9/14/04, 5/25/04, 2/10/02, 5/7/02*
Last Revision(s): *1/1/11 (KK), 7/1/09, 7/1/06, 3/20/06, 10/14/04, 8/1/02, 9/1/06*
Initiation:

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*

Antipsoriatics

Goal(s):

- Cover topical antipsoriatics only for covered OHP diagnoses. Moderate/Severe psoriasis treatments are covered 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 covered.

Length of Authorization:

Up to 12 months

Requires PA:

- Non-preferred drugs
- TC = 92 and HIC = L1A, L5F, L9D, T0A
- After OHP coverage verified these products are preferred:

ANTHRALIN	CREAM(GM)
CALCIPOTRIENE	SOLUTION
DOVONEX	CREAM(GM)
TACLONEX	OINT.(GM)
TAZORAC	CREAM(GM)

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 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 Covered 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 #6
4. Is the Psoriasis Moderate/Severe? Defined as: At least 10% body surface area involved or with functional impairment?	**Yes:** Go to #5	**No:** PASS TO RPH Deny (Not Covered by the OHP)
5. Is the product requested a non-preferred biologic agent approved for plaque psoriasis?	**Yes:** Go to #6	**No:** Go to #7

Approval Criteria		
6. Has the patient tried and not had an adequate response to standard systemic therapies, including cyclosporine or methotrexate or acitretin, or the person is intolerant of or has a contraindication to these treatments?	**Yes**: Approve for length of treatment; maximum 1 year.	**No:** PASS TO RPH Deny (medical appropriateness)
7. Is the product requested preferred?	**Yes:** Approve for length of treatment ; maximum 1 year.	**No:** Go to #8
8. 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. Reports are available at: http://pharmacy.oregonstate.edu/drug_policy/index.php	**Yes:** Inform provider of covered alternatives in class. http://www.oregon.gov/DHS/healthplan/tools_prov/pdl.shtml . Approve for length of treatment or 1year.	**No:** Approve for length of treatment; maximum 1 year.
9. 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 or clinic provides supporting literature:** approve for length of treatment.	**If below the line:** Deny, (Not Covered by the OHP).

P&T / DUR Action: *09/16/2010 (DO),9/24/09 (klk), 3/19/09(klk), 2/26/06, 5/24/07*
Revision(s): *09/16/2010 (DO),1/1/10, 7/1/09, 6/1/07, 6/28/12 (MH), 9/1/13*
Initiated: *9-1-06*

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).

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)*

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*

Buprenorphine Sublingual

Goal(s):

- Expand access to opioid addiction treatment
- Treatment of pain remains a priority, including e.g. addicts with injury & illness. Buprenorphine would need to be held during opioid treatment, exp. Long-acting opioids.
- Clinical Guidelines for the Use of Buprenorphine n the Treatment of Opioid Addiction, TIP 40, available at http://www.samhsa.gov or http://www.ncbi.nlm/nih.gov/books/bv.fcgi?rid=hstat5

Initiative: Opioid Addiction Therapies

Length of Authorization: up to 6 months; 2 months if MD prescribing for immediate need pending certification.

Requires PA:

Brand	Generic
Suboxone	buprenorphine/naloxone
Subutex	buprenorphine

Covered Alternatives: See PDL list at http://www.orpdly.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 MD meets criteria SAMHSA may take 45 days to process.) *Note: Physicians do not have to list their license on the SAMHSA Buprenorphine Physician Locator we site, 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 MD 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/hosto.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) Levodromoran Long-acting morphine (e.g. MS Contin, Oramorph SR, Kadian, Avinza) Long-acting oxycodone (e.g. OxyContin) Fentanyl patches (e.g. Duragesic) Opana XR	**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 = 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 MD 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, i.e. 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 x 2 months. **b)** If prescriber is certified: Approve for anticipation length of treatment or months, whichever is shorter.	

P&T / DUR Action: *9/24/09 (REH), 5/21/09, 9/24/09*
Revision(s): *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: *5/31/12 (MH)*
Revision(s):
Initiated: *8/20/12*

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

GSN	Generic Name	Brand Name	Form
66591	doxepin	Silenor	Tablet
66592	doxepin	Silenor	Tablet
58482	eszopiclone	Lunesta	Tablet
58483	eszopiclone	Lunesta	Tablet
58484	eszopiclone	Lunesta	Tablet
59509	ramelteon	Rozerem	Tablet
42993	zaleplon	Sonata	Capsule
42994	zaleplon	Sonata	Capsule
59696	zolpidem	Ambien CR	Tab M-Phase
59697	zolpidem	Ambien CR	Tab M-Phase
65334	zolpidem	Edular	Tab Sublingual
65335	zolpidem	Edular	Tab Sublingual
68726	zolpidem	Intermezzo	Tab Sublingual
68727	zolpidem	Intermezzo	Tab Sublingual
66941	zolpidem	Zolpimist	Spray

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

• Zolpidem (NDC's priced as generic) • Trazodone • Mirtazapine • Diphenhydramine • 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). Sedative/hypnotics, due to depressant effect, are contraindicated for this diagnosis and are not approvable.
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)

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)

Central Nervous System (CNS) - Stimulants

Goal(s):

- Cover stimulants only for OHP covered diagnoses (e.g. ADHD, narcolepsy).
- Restrict to doses supported by medical literature and promote preferred drugs in class.
- The long-term effects of stimulants are unknown. Adverse events are more frequently associated with high doses. However, effectiveness is not linearly associated with dose and promote preferred drugs in class.

Initiative:

- CNS Stimulants (Non-PDL & Excessive Dose)

Length of Authorization:

Up to 12 months (criteria specific)

Requires PA:

- Non-preferred drugs

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org
- PA does NOT concern drugs in STC 07 or 11; however, these drugs are not to be encouraged. The State is prohibited from prior authorizing Class 11 drugs by statute. These include:
  - armodafinil (Nuvigil)
  - atomoxetine (Strattera)
  - modafanil (Provigil)

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Is diagnosis one of the following?: ADHD (ICD9 314-314.01); Narcolepsy (ICD9 341); Drug-induced sedation (ICD9 292.89)?	Yes: Go to #4.	No: Go to #3.
3. Is the diagnosis above the line? Unspecified hypersomnia (ICD9 780.54) and Obesity treatment (278.0 - 278.1) are below the line.	No: Pass to RPH; Deny, (Not Covered by the OHP)	Yes: Go to #4.
4. Is drug requested preferred?	Yes: Go to #7.	No: Go to #5.
5. Is this continuation of therapy (claim indicating prescription filled within prior 90 days)?	Yes: Document prior prescription drug & date in PA record. Go to #7.	No: Go to #6.

Approval Criteria		
6. Will the prescriber consider a change to a preferred product? Message: • Preferred products do not require PA for FDAapproved doses. • 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 #7.
7. Is dose greater than limits in table below?	Yes: Go to #8.	No. Approve for up to 1 year.
8. Is the prescriber a psychiatrist?	Yes: Approve for up to 1 year	No: Go to #9.
9. Is the patient < 18 years old?	Yes: Go to #10.	No: Pass to RPH; Deny, (Medical Appropriateness) Dose exceeds maximum recommended dose
10. How much does the patient weigh?	Document patient's weight and continue to #11.	
11. Is the patient receiving an accumulative dose that EXCEEDS 2mg/kg/day of methylphenidate products or EXCEEDS 0.5mg/kg/day of amphetamine products?	Yes: Pass to RPH; Deny. (Medical Appropriateness) - Dose exceeds maximum recommended dose. Consider switching to an alternative stimulant drug class or assessing compliance with the current therapy.	No: Approve for up to 1 year.

Additional Criteria for Pharmacists:

If a client does not meet criteria and has been established on high doses (long term use), then:

1. A 1-month PA may be entered to allow time for the provider to collect the necessary information (i.e. patient's weight).
2. A 2-month PA may be entered to allow the physician to taper the patient down to acceptable doses.
3. If neither #1 nor #2 is acceptable to the prescriber, a 1-month PA may be entered; refer them for provider reconsideration and Medical Director review.

Maximum Recommended Dose Limits for Stimulants

HICL 001682 Methylphenidate (>90mg)		
Brand	Strength	Daily Limit
Methylin/Ritalin	5mg tab	18
Methylin/Ritalin	10mg tab	9
Methylin/Ritalin	20mg tab	4
Metadate ER, Methylin ER, Ritalin SR	20mg ER/SR tab	4
Metadate ER, Methylin ER	10mg ER tab	9
Metadate CD	10mg CD cap	9
Metadate CD	20mg CD cap	4
Metadate CD	30mg CD cap	3
Metadate CD	40mg CD cap	2
Metadate CD	50mg CD cap	1
Metadate CD	60mg CD cap	1
Ritalin LA	10mg LA cap	9
Ritalin LA	20mg LA cap	4
Ritalin LA	30mg LA cap	3
Ritalin LA	40mg LA cap	2
Concerta	18mg tab	5
Concerta	27mg tab	3
Concerta	36mg tab	2
Concerta	54mg tab	1
Methylin	2.5mg chew tab	36
Methylin	5mg chewable tab	18
Methylin	10mg chewable tab	9
Methylin	5mg/5ml soln.	90mls
Methylin	10mg/5ml soln.	45mls

HICL 022987 Dexmethylphenidate (>20mg		
Brand	Strength	Daily Limit
Focalin	2.5 mg tab	8
Focalin	5mg tab	4
Focalin	10mg tab	2
Focalin XR	5mg XR cap	4
Focalin XR	10mg XR cap	2
Focalin XR	20mg XR cap	1

HICL 002067 Methamphetamine (>60mg)		
Brand	Strength	Daily Limit
Desoxyn	5mg tab	12
Desoxyn	10mg tab	6
Desoxyn	5mg SA tab	12
Desoxyn	10mg SA tab	6
Desoxyn	15mg SA tab	4

HICL 013449 Mixed Amphetamine Salts (>60mg)		
Brand	Strength	Daily Limit
Adderall	5 mg tab	12
Adderall	10mg tab	6
Adderall	20mg tab	3
Adderall	30mg tab	2
Adderall	7.5mg tab	8
Adderall	12.5mg tab	5
Adderall	15mg tab	4
Adderall XR	10mg XR cap	6
Adderall XR	20mg XR cap	3
Adderall XR	30mg XR cap	2
Adderall XR	5 mg XR cap	12
Adderall XR	15mg XR cap	4
Adderall XR	25mg XR cap	2

HICL 002065 Dexroamphetamine (>40mg)		
Brand	Strength	Daily Limit
Dexedrine Spansule	5mg SA cap	8
Dexedrine Spansule	10mg SA cap	4
Dexedrine Spansule	15mg SA cap	2
Dexedrine	5mg/5ml elixir	40mls
Dextrostat/Dexedrine	5mg tab	8
Dextrostat	10mg tab	4
Dextrostat	15mg tab	2

HICL 034486 Lisdexamfetaimine (>70mg)		
Brand	Strength	Daily Limit
Vyvanse	20mg	2
Vyvanse	30mg	2
Vyvanse	40mg	1
Vyvanse	50mg	1
Vyvanse	60mg	1
Vyvanse	70mg	1

HICL 033556 Methylphenidate Transdermal (>30mg)		
Brand	Strength	Daily Limit
Daytrana	10mg	1
Daytrana	15mg	1
Daytrana	20mg	1
Daytrana	30mg	1

P&T / DUR Action: *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): *1/1/10, 7/1/06, 2/23/06, 11/15/05*
Initiated:

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.

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

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 Action: *2/23/06*
Last Revision(s):
Initiated: *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 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 State Maximum Allowable Cost (SMAC) or Federal Upper Limits (FUL) reimbursement rates.
- SMAC and/or FUL are applied only when two or more A-rated generics are available from a manufacturer that participates in the Federal rebate program. SMAC and FUL prices and dispute forms are listed at: https://aix-xweb1p.state.or.us/es_xweb/FORMS/

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

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

P&T / DUR Action: *2/23/06, 3/19/09, 12/3/09 (KK)*
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*

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.
4. Rizzo JD, Brouwers M, Hurley P, et al. American Society of Hematology/American Society of Clinical Oncology clinical practice guideline update on the use of opoetin and darbepoetin in adult patients with cancer. *Blood*. 2010:116(20):4045-4059.
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: http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/main.html

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	Trgaserod	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	Clindaminycin 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	Rosac	Acne Not Covered on OHP List
TC = 93; Except HSN = 002363 (dextranomer) 002361 (zno)	Emmolients/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 Transmucosal, Buccal, and Sprays

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 warning:

- Short acting fentanylis indicated only for the management of breakthrough cancer pain in clients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.
- Clients considered opioid tolerant are those who are taking at least 60 mg morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Because life-threatening hypoventilation could occur at any dose in clients not taking chronic opiates, transmucosal and buccal fentanyl is contraindicated in the management of acute or postoperative pain.
- This product must not be used in opioid non-tolerant clients. Short acting (SA) fentanyl is intended to be used only in the care of cancer clients and only by oncologists and pain specialists who are knowledgeable of 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 could 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."

Initiative:

- MAP: Actiq/Fentora

Length of Authorization:

Up to 6 months (w/qty limit)

Requires PA:

- Non-preferred drugs

GENERIC	BRAND
Fentanyl Citrate lozenge	Actiq
Fentanyl Citrate buccal tablet	Fentora
Fentanyl Citrate buccal film	Onsolis
Fentanyl Citrate nasal spray	Lazanda
Fentanyl Citrate sublingual spray	Subsys
Fentanyl Citrate sublingual tablet	Abstral

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).
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."*

Approval Criteria		
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 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 Action: *6/25/13 (MH); 3/18/10 (DO); 12-3-09 (KS), 9-15-05, 5-12-05*
Revision(s): *1/1/14 (MH), 4/26/10 (DO); 4/1/08, 6/1/08, 1/1/10,*
Initiated: *9-1-06,*

Fidaxomicin (Dificid®)

Goal(s):

- To optimize appropriate treatment of Clostridium difficile associated diarrhea

Length of Authorization:

10 days

Requires PA:

- Non-preferred drugs
- Fixaxomicin (Dificid®)

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 Diarrhea (CDAD)? (ICD-9 008.45)?	Yes: Go to #3.	No: Pass to RPH; Deny (medical appropriateness)
3. Will the prescriber consider a change 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 CDAD (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 Action: 4/26/12
Revision(s):
Initiated: 7/23/12

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 Oral Protease Inhibitors/Triple Therapy

Goal(s):

- Approve treatments of chronic hepatitis C which are supported by the medical literature

Length of Authorization:

- Initial trial 8-12 weeks (depending on regimen)
- Continuation of therapy up to 48 weeks of total therapy

Requires PA:

- Telaprevir
- Boceprevir
- Simeprevir
- Sofosbuvir (see dedicated criteria)

Approval Criteria		
1. Is the request for treatment of Chronic Hepatitis C? Document appropriate ICD-9 code:	**Yes:** Go to #2	**No:** Pass to RPh; Deny for medical appropriateness.
2. Does the patient have documented HCV genotype 1? Record Genotype:	**Yes:** Go to #3.	**No:** Pass to RPh; Deny for medical appropriateness.
3. Is the request for continuation of therapy? (Patient has been on triple therapy with an oral antiviral agent in preceding 6 weeks.)	**Yes:** Go to "Continuation of Therapy".	**No:** Go to #4
4. Is the prescription for simeprevir?	**Yes:** Go to #5.	**No:** Go to #8.
5. Is the request for combination therapy of sofosbuvir (Solvaldi®) and simeprevir (Olysio®)?	**Yes:** Use sofosbuvir PA criteria.	**No:** Go to #6.
6. Has the patient been screened for the presence of virus with the NS3 Q80K polymorphism at baseline?	**Yes:** Go to #7.	**No:** Pass to RPh; Deny for medical appropriateness.
7. Does the patient have the genotype 1 Q80K polymorphism virus?	**Yes:** Pass to RPh; Deny for appropriateness.	**No:** Go to #8.

Approval Criteria		
8. Does the patient have a biopsy or other non-invasive technology (Fibroscan), including serum tests (Fibrosure, Fibrotest) to indicate severe fibrosis (stage 3 or greater) OR radiologic, laboratory, or clinical evidence of cirrhosis? OR has extrahepatic manifestations (vasculitis, glomerulonephritis, cryoglobulins). Note: Occasional patients with HCV and hepatocellular carcinoma who do not have advanced fibrosis (Stage 3-4) should be included for treatment. Discuss with physician to confirm these particular cases.	**Yes:** Go to #9.	**No:** Pass to RPh; Deny for medical appropriateness.
9. Is the patient also being prescribed peginterferon alfa-2a or -2b and ribavirin and has been granted prior authorization or meets criteria for pegylated interferon-alfa and ribavirin?	**Yes:** Go to #10.	**No:** Pass to RPh; Deny for appropriateness.
10. Is the medication being prescribed by or in consultation with a specialist in the field of gastroenterology, infectious disease, or hepatitis C?	**Yes:** Go to #11.	**No:** Pass to RPh; Deny for medical appropriateness.
11. If the patient has been treated with peginterferon and ribavirin before, do they have documented compliance/adherence to their previous treatment?	**Yes:** Go to #12.	**No:** Pass to RPh; Deny for medical appropriateness.
12. Does the patient have a HIV coinfection?	**Yes:** Go to #13.	**No:** Go to #14.
13. Is the patient under the supervision of an HIV specialist?	**Yes:** Go to #14.	**No:** Pass to RPh; Deny for medical appropriateness.
14. Has the patient previously been treated with boceprevir, telaprevir, or simeprevir?	**Yes:** Pass to RPh, Deny for appropriateness.	**No:** Go to #15.
15. Does the patient have a Child-Pugh score < 7 (compensated liver disease)?	**Yes:** Go to #16.	**No:** Pass to RPh; Deny for appropriateness.

Approval Criteria		
16. Is the request for telaprevir 750mg (two tabs) TID or 1125 mg (three tabs) BID for 12 weeks?	**Yes:** Approve for 8 weeks to allow for 4 week viral load check to continue for a maximum of 12 weeks.	**No:** Go to #17 (If dose is different pass to RPh for appropriateness.)
17. Is the request for boceprevir 800mg (four tabs) TID and the patient has completed 4 weeks of lead-in treatment with ribavirin and peginterferon?	**Yes:** Approve for 12 weeks to allow for 8 week viral load check to continue for a maximum of 24, 32, or 40 weeks based on response.	**No:** Go to #18. (If dose is different pass to RPh for appropriateness.)
18. Is the request for simeprevir 150 mg once daily for 12 weeks?	**Yes:** Approve for 8 weeks to allow for 4 weeks viral load check to continue for a maximum of 12 weeks.	**No:** Pass to RPh; Deny for medical appropriateness if dose is different.

Continuation of Treatment - Teleprevir		
1. Is the patient treatment-naïve or a prior relapse patient and has undetectable HCV RNA or measured at 4 and 12 weeks?	**Yes:** Approve as follows: • Approve additional 6 weeks of triple therapy with telaprevir, peginterferon, and ribavirin (total 12 weeks), followed by continued dual therapy with peginterferon and ribavarin for 12 weeks (total treatment duration of 24 weeks).	**No:** DENY (Medical Appropriateness) Patients with inadequate viral response are unlikely to achieve SVR, and may develop treatment-emergent resistance substitutions. Discontinuation of therapy is recommended in all patients with (1) HCV-RNA levels of greater than or equal to 1000 IU/mL at Treatment Week 4 or 12; or (2) confirmed detectable HCV-RNA levels at Treatment Week 24.

2. Is the patient treatment-naïve or a prior relapse patient and has detectable (1000 IU/mL or less) at Weeks 4 and/or 12?	**Yes:** Approve as follows: • Approve additional 6 weeks of triple therapy with telaprevir, peginterferon, and ribavirin (total 12 weeks), followed by continued dual therapy with peginterferon and ribavarin for additional 36 weeks (total treatment duration of 48 weeks).	**No:** DENY (Medical Appropriateness) Patients with inadequate viral response are unlikely to achieve SVR, and may develop treatment-emergent resistance substitutions. Discontinuation of therapy is recommended in all patients with (1) HCV-RNA levels of greater than or equal to 1000 IU/mL at Treatment Week 4 or 12; or (2) confirmed detectable HCV-RNA levels at Treatment Week 24.
3. Is the patient a prior partial or null responder?	Yes: Approve as follows: • Approve additional 6 weeks of triple therapy with telaprevir, peginterferon, and ribavirin (total 12 weeks), followed by continued dual therapy with peginterferon and ribavarin for additional 36 weeks (total treatment duration of 48 weeks).	No: DENY (Medical Appropriateness)
4. Is the patient treatment-naïve with documented cirrhosis that has undetectable HCV-RNA at weeks 4 and 12?	Yes: Approve as follows: • Approve additional 6 weeks of triple therapy with telaprevir, peginterferon, and ribavirin (total 12 weeks), followed by continued dual therapy with peginterferon and ribavarin for additional 36 weeks (total treatment duration of 48 weeks).	No: DENY (Medical Appropriateness) Patients with inadequate viral response are unlikely to achieve SVR, and may develop treatment-emergent resistance substitutions. Discontinuation of therapy is recommended in all patients with (1) HCV-RNA levels of greater than or equal to 1000 IU/mL at Treatment Week 4 or 12; or (2) confirmed detectable HCV-RNA levels at Treatment Week 24.
*TREATMENT FUTILITY RULES Week 4 or Week 12: HCV-RNA greater than 1000 IU/mL: Discontinue INCIVEK and peginterferon alfa and ribavirin (INCIVEK treatment complete at 12 weeks) Week 24: Detectable Discontinue peginterferon and ribavirin. If peginterferon alfa or ribavirin is discontinued for any reason, INCIVEK must also be discontinued		

Continuation of Treatment - Boceprevir		
1. Is the patient treatment-naïve and have undetectable HCV RNA at treatment weeks 8 and 24?	**Yes:** Approve as follows: Approve additional 14 weeks of boceprevir for total treatment duration of 28 weeks (4 week lead-in, 24 weeks triple therapy)	**No:** DENY (Medical Appropriateness)
2. Is the patient treatment-naïve and have detectable HCV RNA at treatment week 8 and undetectable at week 24?	**Yes**: Approve as follows: Approve additional 22 weeks of boceprevir followed by continued dual therapy with peginterferon and ribavirin for 16 weeks for total treatment duration of 48 weeks (4 week lead-in, 32 weeks triple therapy, 12 weeks dual therapy)	**No:** DENY (Medical Appropriateness)
3. Is the patient a previous partial responder or relapser and has undetectable HCV RNA at treatment weeks 8 and 24?	**Yes:** Approve as follows: Approve additional 22 weeks of boceprevir for total treatment duration of 36 weeks (4 week lead-in, 32 weeks triple therapy)	No: DENY (Medical Appropriateness)
4. Is the patient a previous partial responder or relapser and has detectable HCV RNA at treatment week 8 and undetectable at week 24?	**Yes:** Approve as follows: Approve additional 22 weeks of boceprevir followed by continued dual therapy with peginterferon and ribavirin for 16 weeks for total treatment duration of 48 weeks (4 week lead-in, 32 weeks triple therapy, 12 weeks dual therapy)	**No:** DENY (Medical Appropriateness)
5. Does the patient have documented cirrhosis or is documented as a null responder and does not meet the futility rules at treatment weeks 8, 12, and 24?	**Yes:** Approve as follows: Continue triple therapy with boceprevir for a total treatment duration of 48 weeks (4 week lead-in, 44 weeks triple therapy).	**No:** DENY (Medical Appropriateness)

***TREATMENT FUTILITY RULES**
If the patient has HCV-RNA results greater than or equal to 100 IU/mL at TW12, then discontinue three-medicine regimen.
If the patient has confirmed, detectable HCV-RNA at TW24, then discontinue three-medicine regimen.

Continuation of Therapy- Simeprevir: Simeprevir in combination with peginterferon alfa and ribavirin should only be given for 12 weeks. No more simeprevir should be approved. The following are the recommended duration of treatments for dual therapy with peginterferon alfa and ribavirin after the initial 12 weeks of triple therapy		
1. Is the patient treatment-naïve or a prior relapse and has undetectable HCV RNA (< 25 IU/ml) at week 4?	**Yes:** Approve as follows: Approve additional 4 weeks of simeprevir for total treatment duration of 12 weeks of triple therapy, followed by continued dual therapy with peginterferon and ribavarin for 12 weeks (total treatment duration of 24 weeks).	**No:** DENY (Medical Appropriateness) It is unlikely that patients with inadequate on-treatment virologic response will achieve a SVR, therefore discontinuation of treatment is recommended in these patients.
2. Is the patient a prior non-responder (including partial and null responders) and has an undetectable HCV RNA (<25 IU/ml) at week 4?	**Yes:** Approve as follows: Approve additional 4 weeks of simeprevir for total treatment duration of 12 weeks of triple therapy, followed by continued dual therapy with peginterferon and ribavarin for 36 weeks (total treatment duration of 48 weeks).	**No:** DENY (Medical Appropriateness) It is unlikely that patients with inadequate on-treatment virologic response will achieve a SVR, therefore discontinuation of treatment is recommended in these patients

***TREATMENT FUTILITY RULES**
If the patient has HCV-RNA results greater than or equal to 25 IU/mL at TW12, then discontinue three-medicine regimen.
If the patient has confirmed, detectable HCV-RNA at TW24, then discontinue two-medicine regimen.

P&T / DUR Action: 9/26/13 (MH), 1/26/12(KS)
Revision(s): 3/27/14 (MH); 1/30/14 (MH); 1/1/14 (MH)
Initiated: 4/9/12 (KS)

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 Health Resource Commission (HRC).	Yes: Inform provider of covered alternatives in class. 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)
3. Is male bone age <16 years and Is female bone age <14 years?	**Yes:** Approve for 1 year.	**No:** Pass to RPH; Deny, (Medical Appropriateness)

P&T / DUR Action:	*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*

Hormones - Leuprolide

Goal(s):

- Approve for above-the-line conditions, such as central precocious puberty, endometriosis or prostate cancer and medically appropriate short-stature treatment.

Initiative:

- MAP: Leuprolide

Length of Authorization:

Through age 12 years in girls, age 13 years in boys

Requires PA:

- Leuprolide in children and adolescents ages 10 through 18 years

GCN	Generic Drug Name	Label Name Description
44964	Leuprolide acetate intramusc 22.5mg disp syrin	Lupron depot 22.5 mg 3mo kit
44967	Leuprolide acetate sub-q 1mg/0.2ml kit	Lupron 2-wk 1 mg/0.2 ml kit
44968	Leuprolide acetate intramusc 30mg kit	Lupron depot-4 month kit
44969	Leuprolide acetate sub-q 1mg/0.2ml vial	Lupron 1 mg/0.2 ml vial
44970	Leuprolide acetate intramusc 7.5mg disp syrin	Lupron depot 7.5 mg kit
44980	Leuprolide acetate intramusc 11.25mg kit	Lupron depot 11.25 mg 3mo kt
45017	Leuprolide acetate intramusc 3.75mg kit	Lupron depot 3.75 mg kit
47665	Leuprolide acetate intramusc 11.25mg kit	Lupron depot-ped 11.25 mg kt
47666	Leuprolide acetate intramusc 7.5mg kit	Lupron depot-ped 7.5 mg kit
47851	Leuprolide acetate intramusc 15mg kit	Lupron depot-ped 15 mg kit
50363	Leuprolide acetate sub-q 7.5mg disp syrin	Eligard 7.5 mg syringe
50857	Leuprolide acetate sub-q 22.5mg disp syrin	Eligard 22.5 mg syringe
51826	Leuprolide acetate sub-q 30mg disp syrin	Eligard 30 mg syringe
58789	Leuprolide acetate sub-q 45mg disp syrin	Eligard 45 mg syringe

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 & < 13 years old or male & < 14 years old?	Yes, Go to #3.	No: Pass to RPH; Go to #3.

Approval Criteria		
3. Is the diagnosis one of the following? • central precocious puberty (CPP) aka precocious sexual development & puberty NOC ICD-9 259.1; • endometriosis ICD-9 617.0-617.9; • prostate cancer ICD-9 185, 189, 198; • uterine fibroids 218.9 • Note that CPP is often associated with hydrocephalus, cranial irradiation, Silver-Russell syndrome, hypothalamic tumor, or hamartoma. • All above diagnosis & conditions are rare in children and adolescents.	Yes: Approve through: • Age 12 for female • Age 13 for male	No: Pass to RPH; 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. If above: Deny, (Medical Appropriateness), e.g. when initial treatment not until age 10 years in girls, or age 12 years in boys; CPP beyond age 12 years in girls, or age 13 years in boys. Refer unique situations to Medical Director of DMAP. If below: Deny, (Not Covered by the OHP), e.g unspecified psychosexual disorder, as sexual deviancy, or chemical castration as sexual disorder NOS, ICD-9 302.9		

P&T / DUR Action: *9/20/07(reh)*
Revision(s):
Initiated: *Via Retro DUR 11/07, 7/1/09 via PA*

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:

- All topical testosterones 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? • Ovarian failure (256.31, 256.39) • 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.

Approval Criteria		
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): *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*

Incretin Enhancers

Initiative:

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

Length of Authorization:

Up to 12 months

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 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: *9/26/13 (HM/KS), 4/26/12 (KS), 3/17/11 (KS)*
Revision(s): *1/1/14, 2/21/13*
Initiated: *7/23/12, 1/1/12*

Incretin Mimetics

Initiative:

- To optimize the correct use of incretin 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 Health Resources Commission (HRC). Reports available at: http://www.oregon.gov/OHPPR/HRC/Evidence_Based_Reports.shtml.	**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.

Approval Criteria		
4. Is the patient currently taking insulin?	**Yes:** Go to #5.	**No:** Approve for up to 12 months.
5. Is the patient requesting exenatide (Byetta®) and is taking insulin glargine?	**Yes:** Approve for up to 12 months.	**No:** Pass to RPH; Deny for medical appropriateness. The safety and efficacy of other insulin formulations 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: *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*

Ivacaftor (Kalydeco®)

Goal(s):

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

Length of Authorization:

Up to 6 months

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Does the client have a diagnosis of cystic fibrosis and is 6 years of age or older?	Yes: Go to #3.	No: Pass to RPH; Deny (medical appropriateness)
3. Does the patient have a documented G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R mutation in the CFTR gene? • If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a mutation.	Yes: Go to #4.	No: Pass to RPH; Deny (medical appropriateness)
4. Is the request from a practioner at an accredited Cystic Fibrosis Center or a pulmonologist?	Yes: Go to #5.	No: Pass to RPH; Deny (medical appropriateness)
5. Is the patient on ALL or has had an adequate trial, if indicated and/or tolerated of the following medications below: - Dornase alfa (Pulmozyme®) AND - Hypertonic saline (Hyper-Sal®) AND - Inhaled or oral antibiotics (if appropriate)	Yes: Go to #6.	No: Pass to RPH; Deny (medical appropriateness)
6. Is the prescription for ivacaftor 150mg twice daily, once daily or twice-a-week?	Yes: Approve for 6 months.	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.

Renewal Criteria		
2. Does the patient have documented response to therapy? Documented response (e.g. improvement in FEV_1, weight gain, reduction in exacerbations or sweat test).	Yes: Go to #3.	No: Pass to RPH; Deny (medical appropriateness)
3. Has the patient been compliant with therapy, as determined by refill claims history or as reported by requestor?	Yes: Go to #4.	No: Pass to RPH; Deny (medical appropriateness)
4. Is the prescription for ivacaftor 150mg twice daily, once daily or twice-a-week?	Yes: Approve for 6 months.	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.
- Ivacaftor has not been studied in other populations of patients with Cystic Fibrosis.

P&T / DUR Action: *6/28/12 (KS), 4/26/12 (MH/KS)*
Revision(s): *5/29/14 (MH)*
Initiated:

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

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 60 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: *11/21/13, 5/31/12, 9/24/09 (DO/KK), 2/23/06*
Revision(s): *1/1/14, 9/26/12, 1/1/10*

Laxatives (Selected Laxatives)

Length of Authorization:

Up to 12 months

Not Covered by OHP:

- Disorders of function of stomach and other functional digestive disorders (ICD-9: 536.0-536.3, 536.8-536.9, 537.1-537.2, 537.5-537.6, 537.89, 537.9, 564.0-564.7, 564.9). This includes chronic constipation and Irritable Bowel Syndrome.

Requires PA:

- Non-preferred drugs

GCN	Brand	Generic
060341, 063946	Amitiza	Lubiprostone
064008, 064011	Relistor	Methylnaltrexone Bromide

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org
- Lactulose, senna, sorbitol, polyethylene glycol (PEG, Miralax, Glycolax) and all other FDA approved laxatives.

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Is request for methylnaltrexone (Relistor)?	Yes: Go to #3.	No: Go to #4.
3. Does the patient average < 3 spontaneous bms per week for at least 4 weeks AND have life expectancy less than 6 months AND continuous opioids for > 60 days?	Yes: Go to #8.	No: Pass to RPH; Deny, Medical Appropriateness (only approvable for late-stage, advanced illness in a chronic condition or cancer, receiving continuous opioids)
4. Is the diagnosis IBS (564.1)?	Yes: Pass to RPH, Deny Not Covered by the OHP.	No: Go to #5.
5. Is the diagnosis constipation (564.0, 564.2-564.7, or 564.9) or gastroparesis (536.3)?	Yes: Pass to RPH, Deny Not Covered by the OHP.	No: Go to #5.

Approval Criteria		
6. Is the constipation or gastroparesis secondary to one of the following?: • Cancer (140-239) • Diabetes (250) • Neurologic disorders (330-337)	Yes: Go to #7.	No: Pass to RPH Go to #9.
7. Is patient >18 years old?	Yes: Go to #8.	No: Pass to RPH; Deny, Medical Appropriateness
8. Has patient failed, or become intolerant to, an adequate trial (2 weeks) of at least 3 of the following categories? **A** Dietary modification—increased dietary fiber (25 g/day) **B** Fiber supplementation/bulk laxatives (Psyllium, Metamucil,Perdiem, Fibercon, etc) **C** Saline laxatives (milk of magnesia, magnesium citrate, Fleet phospho-soda, etc) **D** Stimulant laxative (senna, bisacodyl, cascara sagrada, etc) **E** Lactulose, sorbitol or polyethylene glycol (Miralax, Glycolax, etc)	Yes: Approve for 4 months. Continued coverage will be dependent on documentation to support clinical response and lack of adverse effects to therapy.	No: Pass to RPH. Go to #9.
9. RPH only All other indications need to be evaluated to see if they are above or below the line. • Lubiprostone (Amitiza): IBS not approvable. Chronic constipation secondary to an above the line diagnosis not listed above is approvable if medically appropriate and #7 & #8 are met. • Methylnaltrexone (Relistor) is only approvable for late-stage, advanced illness in a chronic condition or cancer, receiving continuous opioids. Use beyond 4 months has not been studied. No efficacy or safety RCT's beyond 2 weeks have been done to date.		

P&T / DUR Action: 12/4/08klk, 3/19/09
Revision(s):
Initiated: 7/1/09

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 #5.
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*

Milnacipran (Savella®)

Goal(s):

- Cover milnacipran only for above-the-line diagnoses that are supported by the medical literature (e.g., depression).

Initiative:

- Map: milnacipran (Savella)

Length of Authorization:

12 months

Requires PA:

- Milnacipran (Savella®)

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org
- SSRIs, TCAs, other antidepressents

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Does the client have rheumatism, unspecified or fibrositis, fibromyalgia/myalgia or myositis or below-the-line neuralgia/neuritis (729.0, 729.1 or 729.2)?	Yes: Pass to RPH; Deny, (Not covered by the OHP)	No: Go to #3.
3. Does the client have an anxiety disorder or depressive disorder (ICD9 296xx, 300xx, 309xx, 311xx)?	Yes: Approve for one year.	No: Go to #4.
4. Pass to RPH All other indications need to be evaluated to see if diagnosis is supported by the medical literature and above or below the OHP coverage line. For Psychiatric Disorders other than Depression: There is no data to support its use for any psychiatric indication other than depression indication, (Deny Medical Appropriateness) recommend other alternatives as appropriate. Evidence for use as an antidepressant is from European trials. Below the line diagnoses should be **Denied** (not covered by the OHP).		

P&T / DUR Action: *5/21/09*
Revisions:
Initiated: *1/1/10*

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?	**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:** Deny, medical appropriateness. Patients must have demonstrated alcohol abstinence prior to administration.
4. Does the member have a diagnosis of opioid dependence?	**Yes:** Go to #5	**No:** Deny, 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** Does the patient require injectable therapy due to adherence issues?	**Yes:** Go to #6	**No:** Deny, 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:** Deny, 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:** Deny, 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: *11/21/2013 (TW / MH)*
Revision(s):
Initiated: *1/1/2014*

Nasal Inhalers

Goal(s):

- Approve use of nasal inhalers 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 Oregon Asthma Guidelines and medical evidence. http://www.oregon.gov/DHS/ph/asthma/pubs.shtml#oregon

Initiative:

- Initiative

Length of Authorization:

6 months

Requires PA:

- Non-preferred drugs
- Nasal antihistamines
- Nasal cromolyn
- Nasal steroids

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org
- Oral corticosteroid inhalers, first generation antihistamines, and preferred prescription second generation antihistamines DO NOT require prior authorization.

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Does patient have diagnosis allergic rhinitis, allergic conjunctivitis, or chronic rhinitis/pharyngitis/nasopharynigitis? (ICD-9: 472.xx, 372.01-05, 372.14, 372.54, 372.56, 477.xx, 995.3, V07.1	Yes: Go to #3.	No: Go to #7.
3. Does patient also have asthma or reactive airway disease exacerbated by chronic/allergic rhinitis (493.xx)?	Yes: Go to #4.	No: Go to #5.

Approval Criteria		
4. Does the drug profile show an asthma controller medication (e.g. ORAL inhaled steroid, leukotriene antagonist, etc.) &/or 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 patients have access to rescue inhalers and those with persistent disease should use anti-inflammatory medicines daily (preferably orally inhaled steroids).
5. Does patient 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: Document ICD-9 codes and go to #6.	No: If No, Pass to RPH; Deny, (Not Covered by the OHP).
6. Does patient have contraindications (e.g. pregnant), or had insufficient response to available alternatives? If yes, document.	Yes: Approve 6 months.	No. Pass to RPH; Deny, (Cost-Effectiveness)
7. Is the diagnosis COPD(496) or Obstructive Chronic Bronchitis (491.1-491.2)	Yes: Pass to RPH; Deny, (Medical Appropriateness). Nasal steroid not indicated	No: Pass to RPH; Go to #8.
8. 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 #9.

Approval Criteria		
9. RPH only: Is the diagnosis above the line or below the line?	Above: 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."	Below: Deny, (Not Covered by the OHP) (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: *9/18/08reh, 2/23/06, 9/14/04, 5/25/04, 2/10/02, 5/7/02*
Last Revision(s): *8/11/09, 7/1/09, 9/1/06, 7/1/06, 3/20/06, 5/31/05, 10/14/04, 8/1/02,*
Initiation: *??*

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.dhs.state.or.us/policy/healthplan/guides/homeiv/main.html

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 a 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.dhs.state.or.us/policy/healthplan/guides/homeiv/main.html***

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: Approve for up to 1 year	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: • 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.dhs.state.or.us/policy/healthplan/guides/homeiv/main.html • 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.dhs.state.or.us/policy/healthplan/guides/homeiv/main.html		

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. All indications need to be evaluated as to whether they are above or below the line covered diagnoses.	Above the line: Go to #3.	Below the line: Pass to RPH; Deny, (Not Covered by the OHP)
3. Is the product to be administered by enteral tube feeding (g-tube)?	Yes: Go to #9.	No: Go to #4.
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 require 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.dhs.state.or.us/policy/healthplan/guides/homeiv/main.html • 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.dhs.state.or.us/policy/healthplan/guides/homeiv/main.html		

Note: Normal Serum Protein 6 – 8 g/dl
Normal albumin range 3.2 – 5.0 g/dl

P&T / DUR Action: *2/23/06*
Revision(s): *9/1/06, 7/1/06, 4/1/03, 6/22/07*

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. http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/clinical.html	**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 120mg 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	20mcg/hour (q 7 days)	5mcg/hr patch q 7 days	May increase dose q72 hours patients up to a max of 20mcg/hr q 7 days. Doses >20mcg/hr q7days increase risk of QTc prolongation.
Fentanyl Transdermal	50mcg/hour (q 72 hr)	Use only in opioid-tolerant patients who have been taking ≥ 60mg MED daily for a week or longer	
Hydromorphone	30mg per 24 hours	2mg q 4–6 hours	
Methadone	40mg per 24 hours	2.5-5mg 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 (LA) opioids.
Morphine	120mg per 24 hours	Immediate-release: 10mg q 4 hours Sustained-release: 15mg q 12 hours	Adjust dose for renal impairment.
Oxycodone	80mg per 24 hours	Immediate-release: 5mg q 4–6 hours Sustained Release: 10mg q 12 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing acetaminophen (maximum dose = 4000mg/day x <10day or 2500mg/day for 10 days or more)
Oxymorphone	40mg per 24 hours	Immediate-release: 5–10mg q 4–6 hours	**Use with extreme caution due to potential fatal interaction with**

		Sustained Release: 10mg q 12 hours	**alcohol or medications containing alcohol**.

Dosing Threshold for select short acting opioids		
Opioid	**Dose threshold**	**Considerations**
Codeine	800mg/day	
Hydrocodone	120mg/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 http://www.oregon.gov/OHA/OHPR/HSC/current_prior.shtml

Approval Criteria		
1. What is the patient's diagnosis?	Record ICD9	
2. Is the request for methadone >100mg?	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 120mg 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 120mg MED?	**Yes: Pass to RPh, Deny** (Medical Appropriateness) In general, the total dose of opioid should not exceed 120mg MED Risks substantially increase at doses at or above 100mg MED. Alternatives: Preferred NSAIDs or LAOs @ doses < 120mg 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 120mg 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 is 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: *2/23/12 (TDW), 11/17/11(KK); 12/3/09 (KS), 9/9/09(klk), 12/4/08klk, 3/19/09*
Revision(s): *6/21/12, 5/14/12; 1/1/12; 1/1/10*
Initiated: *7/1/09*

Opioids – Narcotic Combination – Excessive Dose Limits

Goal(s):

- Avoid adverse effects due to high dose of combined ingredient by enforcing FDA maximum dose labeling.
- Pay only for treatment of covered OHP diagnoses.

Length of Authorization:

None

Requires PA:

- Non-preferred drugs
- Limits by the maximum dose of the non-narcotic ingredient(s).
- Acetaminophen is not to exceed 4 gms/day.
- Aspirin is not to exceed 8 gms/day.

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org
- 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 exceed the maximum for combination ingredient?	Yes: Go to #3.	No: Instruct pharmacy to correct day's supply entry
3. All indications need to be evaluated as to whether they are above the line or below the line.	Above: Pass to RPH, DENY, (Medical Appropriateness) Review FDA maximum dose and provide alternatives.	Below: Pass to RPH, DENY, (Not Covered by the OHP) Review FDA maximum dose and provide alternatives

Examples of products containing aspirin that is limited to 8 grams per day of ASA

Aspirin Combinations			
Drug	**Maximum quantity per day**	**Drug**	**Maximum quantity per day**
Codeine /ASA 15/325 mg	24.6 tablets	Oxycodone/Oxycodone terp/ASA 2.25/0.19/325 mg	24.6

Codeine/ASA 30/325 mg	24.6 tablets	Oxycodone/Oxycodone terp/ASA 4.5/0.38/325 mg	24.6
Codeine/ASA 60/325 mg	24.6	Propoxyphene/ASA 65/325 mg	24.6
Codeine/ASA/Caffeine/Butalbital - 7.5/325/40/50 mg	24.6	Propoxyphene nap/ASA 100/325 mg	24.6
Codeine/ASA/Caffeine/Butalbital - 15/325/40/50 mg	24.6	Propoxyphene/ASA/Caffeine 32/389/32mg	20.6
		Propoxyphene/ASA/caffeine 65/389/32 mg	20.6
		Pentazocine/ASA 22.5/325 mg	24.6
		Dihydrocodone/ASA/Caffeine 16.2/356.4/	22.4

Examples of products containing acetaminophen that are limited to 4 grams per day of APAP

Hydrocodone/APAP combinations			
Drug	**Maximum quantity per day**	**Drug**	**Maximum quantity per day**
Hydrocodone/APAP 2.5/500mg	8 tablets	Hydromorphone/APAP10/400 mg	10 tablets
Hydrocodone/APAP 5/500mg	8 tablets	Hydrocodone/APAP 10/500mg	8 tablets
Hydrocodone /APAP 5/400 mg	10 tablets	Hydrocodone/APAP 10/650mg	6.2 tablets
Hydrocodone /APAP 7.7/400 mg	10 tablets	Hydrocodone/APAP 10/660mg	6.1 tablets
Hydrocodone/APAP 7.5/500mg	8 tablets	Hydrocodone 7.5mg/APAP 500mg per 15 ml Elixir	120 ml
Hydrocodone/APAP 7.5/650mg	6.2 tablets	Hydrocodone 5 mg/APAP 100mg/5ml	200 ml
Hydrocodone/APAP 7.5/750mg	5.3 tablets	Hydrocodone 5 mg/APAP 120 mg/5 ml	166.5 ml
Hydrocodone/APAP 10/325mg	12.3 tablets	Hydrocodone 2.5 mg/APAP 167 mg/15 ml	359.6 ml

Propoxyphene/APAP combinations	
Propoxyphene /APAP 65/650mg	6.1tablets
Propoxyphene nap100mg/APAP 500mg	8 tablets

Oxycodone/APAP combinations	
Oxycodone/APAP 2.5/325mg	12 tablets
Oxycodone/APAP 5/325mg	12 tablets
Oxycodone/APAP 5/500	8 tablets

Oxycodone/APAP 7.5/325mg	12 tablets
Oxycodone/APAP 7.5/500mg	8 tablets
Oxycodone/APAP 10/325mg	12 tablets
Oxycodone/APAP 10/650mg	6 tablets
Oxycodone/APAP 5/325 per 5 ml	61.5 ml

Codeine/APAP combinations	
Codeine/APAP Elixir 120mg/5ml and 12mg/5ml	500 ml
Codeine /APAP 15/300mg (Tylenol #2)	12.3 tablets
Codeine /APAP 30/300mg (Tylenol #3)	12.3 tablets
Codeine /APAP 60/300mg (Tylenol #4)	12.3 tablets

Tramadol/APAP combinations	
Tramadol/APAP 37.5/325mg	12 tablets

P&T / DUR Action: *2/23/06, 11/5/99, 2/1/-99*
Revision(s) *9/30/05, 5/16/05, 12/1/03, 5/1/03*
Initiated:

Oral Direct Factor Xa Inhibitors (Rivaroxaban and Apixaban)

Goal(s):

- Promote safe and effective use of oral direct factor Xa inhibitors.

Length of Authorization:

Up to 12 months

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. What diagnosis is the factor Xa being prescribed for?	Record ICD9 code.	
2. Does the patient have a diagnosis requiring short-term (<45 days) anticoagulation (i.e. total knee replacement (ICD9 81.54-81.55) or total hip replacement(ICD9 81.51-81.52))?	**Yes:** Go to #3	**No:** Go to #4
3. Is the request for rivaroxaban?	**Yes:** Approve for up to 35 days.	**No:** Deny with the allowance of 14 days of apixaban (or until patient is deemed adequately anticoagulated)*. Recommend a trial of rivaroxaban or preferred LMWH.
4. Does the patient have a diagnosis of nonvalvular atrial fibrillation (ICD9 427.3x)?	**Yes:** Go to #5.	**No:** Go to #8.
5. Will the prescriber consider a change to the preferred oral anticoagulant, warfarin?	**Yes:** Approve. Additional information can be found at http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/clinical.html	**No:** Go to #6.
6. Is the patient unable to tolerate warfarin due to one of the following: • unstable INR • allergy • contraindications to therapy • drug-drug interactions • intolerable side effects	**Yes:** Go to #7.	**No:** Deny with the allowance of a 14 days of rivaroxaban or apixaban (or until patient is deemed adequately anticoagulated)*. Recommend trial of warfarin.

Approval Criteria		
7. Is patient unable to tolerate the second line agent, apixaban?	**Yes:** Approve for one year.	**No:** Deny with the allowance of a 14 days of rivaroxaban (or until patient is deemed adequately anticoagulated)*. Recommend trial of apixaban.
8. Does the patient have a diagnosis requiring acute or chronic DVT or PE treatment?	**Yes:** Go to #9.	**No:** Deny (Medical appropriateness)
9. Will the prescriber consider a change to warfarin or preferred LMWH?	**Yes:** Approve. Additional information can be found at http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/clinical.html	**No:** Got to #10.
10. Is the patient unable to tolerate the warfarin or preferred LMWH due to one of the following: • unstable INR • allergy • contraindications to therapy • drug-drug interactions • intolerable side effects	**Yes:** Go to #11.	**No:** Deny with the allowance of 14 days of rivaroxaban or apixaban (or until patient is deemed adequately anticoagulated)*. Recommend warfarin or preferred LMWH.
11. Is the request for rivaroxaban?	**Yes:** Approve for up to 1 year.	**No:** Deny with the allowance of 14 days rivaroxaban or apixaban (or until patient is deemed adequately anticoagulated)*. Recommend rivaroxaban trial.
* Patients switching from rivaroxaban or apixaban to other anticoagulants have been shown to have an increased risk of thrombotic events. Adequate anticoagulation is recommended during the switch from rivaroxaban or apixaban to another anticoagulant. Rivaroxaban and apixaban effect INR measurements, therefore, the appropriate dose of warfarin based on INR cannot be used. Adding a parenteral anticoagulant, in addition to warfarin at the time the next dose of rivaroxaban or apixaban is due is recommended.		

Oral Direct Thrombin Inhibitors (Dabigatran)

Goal(s):

- Promote safe and effective therapies for oral direct thrombin inhibitors.

Length of Authorization:

Up to 12 months

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. Does the patient have a diagnosis of nonvalvular atrial fibrillation?	**Yes:** Go to #2.	**No:** Go to #6.
2. Will the prescriber consider a change to a preferred warfarin product?	**Yes:** Additional information can be found at: http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/clinical.html	**No:** Go to #3.
3. Is the patient unable to take warfarin therapy due to one of the following: • unstable INR • warfarin allergy • contraindications to warfarin therapy • drug-drug interactions • intolerable side effects	**Yes:** Go to #4.	**No:** Deny. Recommend warfarin trial.
4. Does the patient have normal renal function (CrCl >30 mL/min) and is prescribed dabigatran 150mg twice daily or reduced renal function (CrCl 15-30 mL/min) and is prescribed dabigatran 75mg twice daily?	**Yes:** Go to #5.	**No:** Deny (Medical Appropriateness)
5. Does the patient have a mechanical prosthetic heart valve?	**Yes:** Deny (Contraindicated)	**No:** Approve for up to 1 year.
6. Does the patient have a diagnosis requiring acute or chronic DVT or PE treatment?	**Yes:** Go to #7.	**No:** Deny (Medical Appropriateness)

Approval Criteria		
7. Will the prescriber consider a change to warfarin or the preferred LMWH?	**Yes:** Additional information can be found at: http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/clinical.html	**No:** Go to #8.
8. Is the patient unable to tolerate warfarin or the preferred LMWH due to one of the following: • unstable INR • allergy • contraindications to warfarin therapy • drug-drug interactions • intolerable side effects	**Yes:** Approve for up to 1 year.	**No:** Deny. Recommend trial of warfarin or preferred LMWH.

P&T / DUR Action: *3/28/13 (KS), 1/26/12(KS)*
Revision(s):
Initiated: *4/9/12 (KS)*

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*

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. Is the request for immunoprophylaxis between the months of November and March?	Yes: Go to #4	No: Go to #3
3. 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%, with a minimum number of 10 tests per region (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 #4	No: Pass to RPH: DENY (Medical Appropriateness). Prophylaxis is indicated only during high viral activity.
4. Is the current age of the patient < 24 months at start of RSV season?	Yes: Go to #5	No: Pass to RPH: DENY (Medical Appropriateness). Synagis not recommended for patients ≥24 months old.

Approval Criteria		
5. **GROUP A** Does the patient have the CLD (chronic lung disease) ICD9 7485x or 7486x and in the past 6 months has required medical treatment with at least one of the following: a. bronchodilators b. chronic corticosteroid therapy c. home oxygen therapy d. diuretics	Yes: Go to #12	No: Go to #6
6. **GROUP B** Does the patient have hemodynamically significant congenital heart disease (CHD) ICD9 746xx or 747xx and at least one of the following: a. Receiving treatment for congestive heart failure or b. Have moderate to severe pulmonary hypertension or c. Cyanotic heart disease	Yes: Go to #12	No: Go to #7
7. Will the patient be < 12 months at start of RSV season?	Yes: Go to #8	No: Pass to RPH: DENY (Medical Appropriateness) .
8. **GROUP C** Is the gestational age ≤ 28 weeks?	Yes: Go to #12	No: Go to #9
9. **GROUP D** Infants with congenital abnormalities of the airway or neuromuscular disease compromising handling of secretions?	Yes: Go to #12	No: Go to #10
10. **GROUP E** Will the patient be < 6 months at the start of the RSV season and the gestational age ≤ 29-31 weeks and 6 days?	Yes: Go to #12	No: Go to #11
11. **GROUP F** Will the patient be < 90 days at the start of the RSV season AND have a gestational age of ≤ 32-34 weeks and 6 days AND have at least one of the following risk factors: a. Daycare attendance b. Siblings less than 5 years of age	Yes: Go to #12	No: Pass to RPH: DENY (Medical Appropriateness) .

Approval Criteria		
12. Is the request for more than 5 doses within the same RSV season or for dosing <28 days apart?	Yes: Pass to RPH: DENY (Medical Appropriateness) . Prophylaxis is indicated for 5 months maximum and doses should be administered ≥28 days apart. **May approve for the following on a case by case basis:** **a. > 5 doses or additional doses after March 31st.** **b. Prophylaxis for a second/ subsequent RSV season.**	No: Go to #13
13. Has the patient had a weight taken within the last 30 days?	Yes: Document weight and date and go to #14 Weight:_____ Date:_____	No: Pass to RPH: obtain recent weight so accurate dose can be calculated.

14. 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 (#3) 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	GROUP A-D (Child is <24 or <12 mo. old at start of season)	GROUP E (Child is <6 mo. old at start of season)	GROUP F (Child is <3 mo. old at start of season)
November 1 – March 31 of previous RSV season	5	Zero doses; infant will be older than 6 months at start of RSV season	Zero doses; infant will be older than 90 days at start of RSV season
April	5	Zero doses; infant will be older than 6 months at start of RSV season	
May	5	5	
June	5	5	
July	5	5	
August	5	5	1*
September	5	5	2*
October	5	5	3*
November	5	5	3*
December	4	4	3*
January	3	3	3*
February	2	2	2*
March	1	1	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	GROUP A-D (Child is <24 or <12 mo. old at start of season)	GROUP E (Child is <6 mo. old at start of season)	GROUP F (Child is <3 mo. old at start of season)
November 1 – March 31 of previous RSV season	5	Zero doses; infant will be older than 6 months at start of RSV season	Zero doses; infant will be older than 90 days at start of RSV season
April	5	5	
May	5	5	
June	5	5	
July	5	5	1*
August	5	5	2*
September	5	5	3*
October	5	5	3*
November	5	5	3*
December	4	4	3*
January	3	3	3*
February	2	2	2*
March	1	1	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: *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 for an above-the-line condition.

Initiative:

- PDL: Preferred Drug List

Length of Authorization:

Up to 12 months

Requires PA:

- Non-preferred drugs

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

Note:

A complete list of PDL classes is available 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 #4.
3. Will the prescriber consider a change to a preferred product? Message: Preferred products do not require a PA. Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Health Resource Commission (HRC).	Yes: Inform provider of covered alternatives in class.	No: Approve for 1 year or length of prescription, whichever is less.
4. 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/DO), 9/24/09(DO), 5/21/09*
Revision(s): *1/1/11, 9/16/10 (KS/DO)*
Initiated:

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*

Platelet Inhibitors

Goal(s):

- Approve platelet inhibitors for covered 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

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?	Yes: Inform provider of covered alternatives in class.	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 diagnosis being treated ACS? (ICD9 =410xx or 411.0 or 411.1 or 411.81 or 411.89)?	Yes: Go to #6	No: Deny (Medical Appropriateness)
6. Is the request for prasugrel AND one of the following: • Greater than 75 years old • Less than 60 kg • s/p stroke or TIA	Yes: Pass to RPh. Deny for appropriateness	No: Go to #7
7. Is the patient unable to take clopidogrel due to one of the following: • clopidogrel allergy • contraindications to clopidogrel therapy (document) • drug-drug interactions (document) • intolerable side effects	Yes: Go to #8	No: Pass to RPh. Deny Recommend clopidogrel trial

Approval Criteria		
8. Is request for ticagrelor AND is the patient unable to take prasugrel due to one of the following: • prasugrel allergy • contraindications to prasugrel therapy (document) • drug-drug interactions (document) • intolerable side effects	Yes: Pass to RPh, Deny. Recommend prasugrel trial.	No: Approve for 1 year

P&T / DUR Action: *11/17/11(KS)*
Revision(s):
Initiated: *4/9/12 (KS)*

Pregabalin (Lyrica®)

Goal(s):

- Cover pregabalin only for above-the-line diagnoses that are supported by the medical literature (e.g. Epilepsy, diabetic neuropathy, post-herpetic neuralgia).
- Pregabalin has not demonstrated superiority to other first-line treatments for neuropathic pain and its use should be reserved for treatment failure.

Length of Authorization:

90 days to lifetime (criteria specific)

Requires PA:

- Non-preferred drugs
- Pregabalin (Lyrica®)

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org
- Anxiety: SSRIs, TCAs, Benzodiazepines, Buspirone
- Neuropathic pain: TCAs, Tramadol, Carbamazepine, Gabapentin capsules

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Does client 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 client have rheumatism, unspecified or fibrositis, fibromyalgia/ myalgia or myositis or below the line neuralgia/neuritis? (729.0, 729.1 or 729.2)	Yes: Pass to RPH; Go to #7.	No: Go to #4.
4. Does client have diagnosis of one the following? • Diabetic neuropathy (ICD9: 250.6 & subsets) – Document diabetic therapy (supporting meds) • Post-herpetic neuralgia (ICD9: 053 & subsets) • Trigeminal and other above the line neuralgias (ICD9 350, 352)	Yes: Go to #5.	No: Go to #6.

Approval Criteria		
5. Has the client tried or are they contraindicated to gabapentin capsules AND one of the following? • TCAs • Carbamazepine Document drugs tried or contraindications.	Yes: Approve for 90 days with subsequent approvals dependent on documented* positive response for lifetime (12-31-2036) *Documented response means that follow-up and response is noted in client's chart per clinic staff	No: Pass to RPH; Deny, (Medical Appropriateness) and recommend trial of covered alternative.
6. Does the client have an anxiety disorder (ICD9 300xx)	Yes: Go to #7.	No: Go to #8.
7. Has the client tried or are they contraindicated to at least two of the following drug classes? • SSRIs • TCAs • Benzodiazepines • Buspirone Document drugs tried.	Yes: Approve for 90 days with subsequent approvals dependent on documented* positive response for lifetime (12-31-2036) approval.	No: Pass to RPH; Deny, (Medical Appropriateness) and recommend trial of covered alternative.

Approval Criteria

8. Pass to RPH
   - For Bipolar affective disorder: there is no data to support its use for this indication, (Deny Medical Appropriateness) recommend other alternatives (lithium, valproate, carbamazepine, lamotrigine)

   - For Migraine prophylaxis: there is no data to support its use for this indication, (Deny Medical Appropriateness) recommend other alternatives (beta-blockers, calcium channel blockers, valproate, gabapentin, TCAs) Refer to American Academy of Neurology Guideline http://www.neurology.org/cgi/reprint/55/6/754.pdf

   - If clinically warranted, may DENY yesterdays date (Medical Appropriateness) and use clinical judgement 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."

   All other indications need to be evaluated to see if diagnosis is above or below the line:

   - Above the line neuropathies found in table 1 (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)

   **** Also, see footnote.**

   - Below the line neuropathies such as those found in table 2 (list is not all inclusive) that are related to above the line diagnoses found in table 3 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).

   **** Also, see footnote.**

   Below the line diagnoses should be: **Denied, (Not covered by the OHP).**

   **** Forward any neuropathy/neuralgia ICD-9 codes not found in the Table 1 to the Lead Pharmacist. These codes will be forwarded to DMAP for consideration.**

Table 1 – Examples of other above the line neuropathies

ICD-9	Description
337.0	Idiopathic Peripheral autonomic neuropathy
354.2	Ulner nerve lesion
356 – 356.9	Hereditary and idiopathic peripheral autonomic neuropathy
357.89, 357.9	Inflamatory Polyneuropathy
723.4	Brachial neuritis or radiculitis
724.4	Thoracic or Lumbosacral neuritis or radiculitis unspecified

Table 2 – Examples of below the line diagnosis that can be approved ONLY if it's due to a condition that is found in Table 3

ICD-9	Description
337.2	Reflex sympathetic dystrophy
337.3	Autonomic Dysreflection
724.3	Sciatia –Neuralgia or neuritis of sciatic nerve
729.1	Myalgia Myositis
729.2	Neuralgia/Neuritis and Radiculitis Unspecified

Table 3 – Above the line condition that can be the basis of below the line neuropathy found in Table 2

ICD-9	Above the line Condition
336.9	Unspecified disease of spinal cord
340	Multiple sclerosis
344.0	Quadraplegia
344.1	Paraplegia
754.2	Scoleosis
737.3	Kyphoscolosis
907.0	Late effects of injuries to nervous system

P&T / DUR Action: *9/20/2007, 11/29/2007*
Revision(s): *1/1/11*
Initiated: *4/1/08*

Proton Pump Inhibitors (PPI)

Goal(s):

- Promote PDL options.
- Restrict chronic use (greater than eight weeks) to patients who failed H2-antagonist, preferred PPIs or who have severe disease, e.g. Barrett's, or Zollinger Ellison syndrome.
- Restrict BID use to patients with severe disease, H.pylori or pediatric patients.

Notes:

- This is a "global" PA.
- If an active PA for a PPI already exists, then any PPI will pay.
- A new PA is required if the dosing schedule changes, e.g., an active PA for once daily dosing restricts the PPI to once a day.
- BID dosing requires a new PA, however, the strength of the dose could be increased without an additional PA, e.g., a change from 20 mg daily could be increased to 40 mg ONCE a day without an additional PA.

Length of Authorization:

2 weeks to lifetime (criteria specific)

Requires PA:

- Non-preferred drugs

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org
- Individual components for treatment of H.Pylori that are preferred products

Route	HICL	Brand	Generic	Formulations
Oral	021607	Nexium	Esomeprazole	Capsules, delayed-release: 20, 40mg Suspension, delayed-release pkts: 10, 20, 40mg
Oral	008993	Prevacid	Lansoprazole	Capsules, delayed-release: 15, 30 mg Enteric coated granules for oral suspension, delayed release: 15, 30mg Solu Tab: 15, 30 mg orally disintegrating tablet
Oral	025742	Prevacid NapraPAC	Lansoprazole + Naproxen	Delayed release capsules + naproxen tablets kit - 15 – 375, 15 -500
Oral	004673	Zegerid	Omeprazole	Packet for solution: 20, 40mg Capsules: 20, 40mg
Oral	036085	Dexilant	Dexlansoprazole	Capsules, delayed-release: 30, 60mg
Oral	011590 022008	Protonix	Pantoprazole	Tablets, delayed-release: 20 mg, 40 mg Suspension, delayed-release: 40mg
Oral	011590	Pantoprazole	Pantoprazole	Tablets, delayed-release: 20 mg, 40 mg
Oral	011796	Helidac	bismuth subsalicylate, metronidazole,	metronidazole 250 mg + tetracycline 500 mg + bismuth subsalicylate 525 mg,

			tetracycline	each given four times a day **add an H2 receptor antagonist
Oral	017026	Prevpac	lansoprazole, amoxicillin, clarithromycin	lansoprazole 30 mg + amoxicillin 1 gm + clarithromycin 500 mg, each given twice a day
Oral	020019	Pylera	bismuth subcitrate potassium, metronidazole, tetracycline	bismuth subcitrate potassium 140 mg + metronidazole 125 mg + tetracycline HCl 125 mg, 3 capsules given four times a day **add omeprazole 20 mg twice a day

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?	Yes: Inform provider of covered alternatives in class.	No: Go to #4.
4. Is diagnosis • Zollinger-Ellison (251.5)? • Barrett's esophagus (530.85)? • Multiple Endocrine Adenoma (237.4)? • Malignant Mastoma (202.6)? • MEN Type I (258.01)?	Yes: Approve for a life-time; BID dosing OK.	No: Go to #5.
5. Is the diagnosis dyspepsia (536.8)?	Yes: Pass to RPH; Deny, (OHP coverage) - Diagnosis is below the line; preferred agents are available without PA.	No: Go to #6.
6. Has patient tried and failed a preferred PPI QD for 8 week trial (2 weeks for H. Pylori)?	Yes: Go to #7.	No: Go to #12.
7. Is diagnosis H.Pylori?	Yes: Approve for 2 weeks – BID dosing OK or approve 1 pack if Helidac, Prevpac, or Pylera	No: Go to #8.

Approval Criteria		
8. Is diagnosis active GI bleed? (531.0-531.2, 532.0-532.2, 533.0-533.2, 534.0-534.2)	Yes: Approve for 8 weeks – BID dosing OK	No: Go to #9.
9. Is diagnosis Gastric or Duodenal Ulcer (531.3-531.9, 531.3-532.9, 533.3-533.9, 534.3-534.9) and/or does patient have 2 or more of the following risk factors: • 65 years • requires > 3 months of NSAIDs, aspirin or steroids • on anticoagulation (warfarin, enoxaparin, etc.) • History of GI Bleed or Ulcer?	Yes: Approve QD for 1 year, if previously failed an 8 week QD trial at highest dose approve BID for 1 year. May approve BID dosing for pediatrics <12 years old	No: Go to #10.
10. Is the diagnosis symptomatic GERD (530.81, 530.10 – 530.19)	Yes: Approve QD for 1 year, if previously failed an 8 week QD trial at highest dose approve BID for 1 year. May approve BID dosing for pediatrics <12 years old	No: Go to #11.
11. Is diagnosis: • Ulcer of esophagus (530.2x) • Stricture & stenosis of esophagus (530.3) • Perforation of esophagus (530.4)	Yes: Approve up to BID for 1 year.	No: Go to #13.
12. Is the request for tube administration?	Yes: Approve QD dosing for 1 year. May approve BID dosing for pediatrics <12 years old.	No: Pass to RPH. Deny (Cost-effectiveness). Recommend omeprazole 20 mg QD or BID.

Approval Criteria	
13. All other diagnoses will need to be evaluated by a pharmacist for appropriateness and OHP line coverage.	• Diagnoses above the line and where PPI is appropriate can be covered. • Diagnoses below the line and where PPI is appropriate should be denied as not covered. • Diagnoses above the line but where PPIs are not appropriate should be denied and not medically appropriate.

Clinical Notes:

FDA safety alerts:

Medication	FDA Alert
Clostridium difficile-associated diarrhea[10]	PPIs may be associated with an increased risk of *Clostridium difficile*–associated diarrhea (CDAD). A diagnosis of CDAD should be considered for patients taking PPIs who develop diarrhea that does not improve.
Low magnesium level associated with long-term PPI use[11]	Prescription PPIs may cause low serum magnesium levels (hypomagnesemia) if taken for prolonged periods of time (in most cases, longer than one year). In approximately one-quarter of the cases reviewed, magnesium supplementation alone did not improve low serum magnesium levels and the PPI had to be discontinued.
Avoid concomitant use of Plavix® and omeprazole[12]	FDA issued a reminder that it **continues to warn against the concomitant use of Plavix (clopidogrel) and omeprazole** because the co-administration can result in significant reductions in clopidogrel's active metabolite levels and antiplatelet activity. This information was added to the drug label of Plavix in November 2009, and has been the source of continued discussion in the medical literature. Patients at risk of heart attacks or strokes, who are given Plavix to prevent blood clots, will not get the full anti-clotting effect if they also take omeprazole. Omeprazole is found in prescription products (Prilosec, Zegerid, and generic products) and over-the-counter products (Prilosec OTC, Zegerid OTC, and generic products).FDA wishes to emphasize additional facts that may be a source of confusion among healthcare professionals: • With regard to the proton pump inhibitor (PPI) drug class, this recommendation **applies only to omeprazole** and not to all PPIs. Not all PPIs have the same inhibitory effect on the enzyme (CYP 2C19) that is crucial for conversion of Plavix into its active form. • Pantoprazole (Protonix) may be an alternative PPI for consideration. It is a weak inhibitor of CYP2C19 and has less effect on the pharmacological activity of Plavix than omeprazole.

P&T / DUR Action:	*1/13/13 (MH), 2/23/12 (TW), 9/16/10 (DO), 3/18/10 (KK), 12/03/09 (DO/KK), 5/21/09; 5/7/02; 2/5/02; 9/7/01, 9/11/98*
Revision(s)	*5/1/13, 5/14/12, 1/1/11, 4/23/10 (DO), 1/1/10; 9/1/06, 7/1/06, 10/14/04, 3/1/04*
Initiated:	

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*

Pulmonary Arterial Hypertension (PAH)

Goal(s):

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

Length of Authorization:

Up to 12 months

Requires PA:

- Non-preferred drugs

Covered Alternatives:

Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. What 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. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH)?	Yes: Go to #4.	No: Pass to RPH. RPH go to #7.
4. Will the prescriber consider a change to a preferred product?	Yes: Inform provider of covered alternatives in class.	No: Go to #5.
5. Does the patient have a World Health Organization (WHO) Functional Class (FC) of II-IV?	Yes: Go to #6.	No: Pass to RPH; Deny (Medical Appropriateness)
6. Is the drug being prescribed by a pulmonologist or a cardiologist?	Yes: Approve for 12 months.	No: Pass to RPH; Deny, (Medical Appropriateness)
7. RPh Only: Is the diagnosis above the line and has the clinic provided supporting literature for use?	Yes: Approve for length of treatment.	No: Deny (not covered by the OHP)

WHO Functional Classification of Pulmonary Hypertension*

Class I— • Patients with pulmonary hypertension but without resulting limitation of physical activity. • Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or syncope.
Class II— • Patients with pulmonary hypertension resulting in slight limitation of physical activity. • They are comfortable at rest. • Ordinary physical activity causes undue dyspnea or fatigue, chest pain, or syncope.
Class III— • Patients with pulmonary hypertension resulting in marked limitation of physical activity. • They are comfortable at rest. • Less than ordinary activity causes undue dyspnea or fatigue, chest pain, or syncope.
Class IV— • Patients with pulmonary hypertension with inability to carry out any physical activity without symptoms. • These patients manifest signs of right heart failure. • Dyspnea and/or fatigue may even be present at rest. • Discomfort is increased by any physical activity.

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

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*

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

<u>References:</u>

1) National Institutes of Health Consensus Development Conference Statement: Phenylketonuria: Screening and Management, October 16-18, 2000. *Pediatrics* 2001;108;972.
2) Blau N., Belanger-Quintana A., Demirkol M. Optimizing the use of sapropterin (BH_4) in the management of phenylketonuria. *Molecular Genetics and Metabolism* 2009;96:158-163.

P&T Action: *11/21/13 (MH), 9/26/2013 (MH); 7/25/2013(BL/MH)*
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 drugs

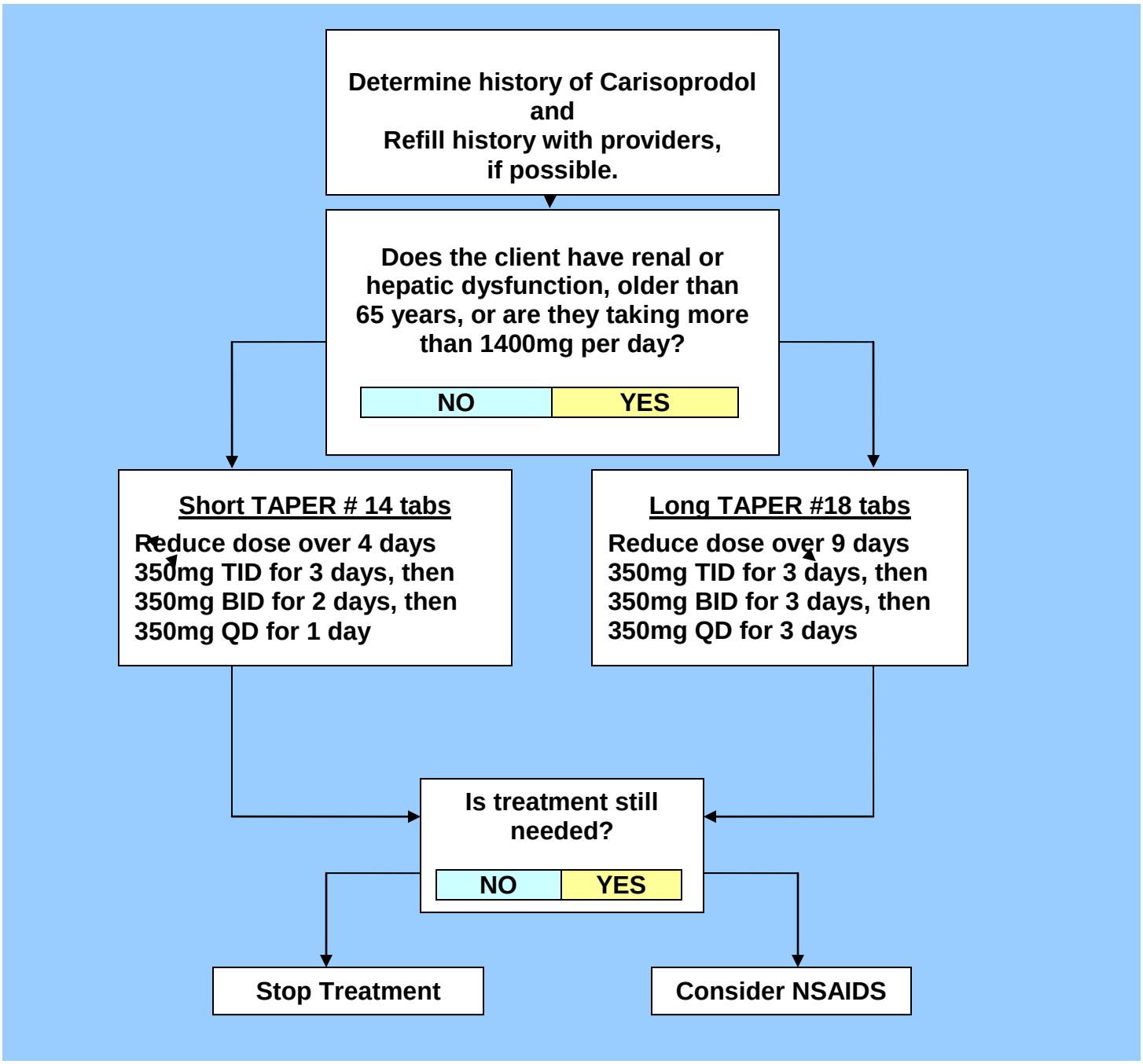
Covered Alternatives:

- 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: *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): *1/1/14, 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/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. Has the patient tried and failed other third-line treatments for diabetes?	**Yes:** Approve for up to 12 months.	**No:** Recommend 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 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: *9/26/13 (KS)*
Revision(s):
Initiated: *1/1/14 (KS)*

Sofosbuvir (Sovaldi®)

Goal(s):

- Approve cost effective treatments of chronic hepatitis C which are supported by the medical literature and where there is medical evidence of effectiveness and safety.

Length of Authorization:

- Initial trial of 12 weeks
- Continuation of therapy up to 24-48 weeks of total therapy based on therapy regimen, genotype, and patient population.

Requires PA:

- Sofosbuvir

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Is the request for treatment of Chronic Hepatitis C?	**Yes:** Go to #3	**No:** Pass to RPh; Deny for appropriateness.
3. 2. Is the request for continuation of therapy?	**Yes:** Go to "Continuation of Therapy"	**No:** Go to #4.
4. Is the medication being prescribed by or in consultation with a specialist in the field of gastroenterology, infectious disease, or hepatitis C?	**Yes:** Go to #5.	**No:** Pass to RPh; Deny for appropriateness.
5. If the patient has been treated with peginterferon and ribavirin before, do they have documented noncompliance to their previous treatment?	**Yes:** Pass to RPh; Deny for medical appropriateness.	**No:** Go to #6.

Approval Criteria		
6. Does the patient have a biopsy or other non-invasive technology (Fibroscan), including serum tests (Fibrosure, Fibrotest) to indicate severe fibrosis (stage 3 or greater) OR radiologic, laboratory, or clinical evidence of cirrhosis? OR has extrahepatic manifestations (vasculitis, glomerulonephritis, cryoglobulins). Note: Occasional patients with HCV and hepatocellular carcinoma who do not have advanced fibrosis (Stage 3-4) should be included for treatment. Discuss with physician to confirm these particular cases.	**Yes:** Go to #7.	**No:** Pass to RPh; Deny for appropriateness.
7. Does the patient have a HIV coinfection?	**Yes:** Go to #8.	**No:** Go to #9.
8. Is the patient under the supervision of an HIV specialist?	**Yes:** Go to #9.	**No:** Pass to RPh; Deny for medical appropriateness.
9. If applicable, has the patient been abstinent from IV drug use or alcohol abuse for ≥ 6 months?	**Yes:** Go to #10.	**No:** Pass to RPh; Deny for appropriateness.
10. Does the patient have significant renal impairment (CrCl < 30 ml/min) or end stage renal disease (ESRD)?	**Yes:** Pass to RPh; Deny for appropriateness.	**No:** Go to #11.
11. What Hepatitis C genotype is the patient? Record Genotype:	Record Genotype and go to #12.	
12. Does the patient have genotype 1 or 4 chronic hepatitis C?	**Yes:** Go to #13.	**No:** Go to #16.
13. Is the medication being used as triple therapy with both ribavirin and peginterferon alfa?	**Yes:** Approve for 12 weeks total therapy.	**No:** Go to #14.
14. Is the medication being used with ribavirin or simeprevir?	**Yes:** Go to #15.	**No:** Pass to RPh; Deny for appropriateness.

Approval Criteria		
15. Is the patient interferon ineligible defined by having one of the following conditions: • Previous adverse reaction or hypersensitivity to interferon • Decompensated liver disease • Severe or uncontrolled psychiatric disorder in consult with a psychiatrist • Autoimmune hepatitis or other autoimmune disorders • Unstable cardiac disease Note: Patient's or prescribers not wanting to go through treatment with interferon does not meet the criteria for being "interferon ineligible".	**Yes:** Approve initial trial of 12 weeks for total therapy of 12 weeks for sofosbuvir + simeprevir combination **OR** a total of 24 weeks for sofosbuvir + ribavirin therapy.	**No:** Pass to RPh; Deny for appropriateness.
16. Does the patient have genotype 2 chronic hepatitis C?	**Yes:** Go to #17.	**No:** Go to #18.
17. Is the medication being used with ribavirin?	**Yes:** Approve for 12 weeks total therapy.	**No:** Pass to RPh; Deny for appropriateness.
18. Does the patient have genotype 3 chronic hepatitis C?	**Yes:** Go to #19.	**No:** Pass to RPh; Deny for appropriateness.
19. Is the medication being used with both ribavirin and peginterferon alfa?	**Yes:** Approve for 12 weeks total therapy.	**No:** Go to #20.
20. Is the medication being used with only ribavirin and the patient is interferon ineligible as defined by the conditions listed above in #15?	**Yes:** Approve for 12 weeks initial fill for a total 24 weeks of therapy.	**No:** Pass to RPh; Deny for appropriateness.

Continuation of Therapy- Sofosbuvir		
Has the patient been adherent to and tolerated initial therapy?	**Yes:** Approve for additional 12 weeks in genotype 3 patients and genotype 1 patients who are interferon ineligible (refer to dosage and administration table below).	**No:** Deny for medical appropriateness.

P&T / DUR Action: 1/30/14 (MH0
Revision(s): 3/27/14 (MH)
Initiated:

Targeted Immune Modulators (TIMS)

Goal(s):

- Cover TIMs 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

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
Certolizumab	Cimzia	RA, Crohn's disease
Etanercept	Enbrel	RA, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, plaque psoriasis
Golimumab	Simponi	RA, psoriatic arthritis, ankylosing spondylitis
Infliximab*	Remicade	RA, Crohn's disease, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, plaque psoriasis
Natalizumab*	Tysabri	Crohn's disease
Rituximab*	Rituxan	RA
Tocilizumab*	Actemra	RA, juvenile idiopathic arthritis
Ustekinumab	Stelara	Plaque psoriasis

Abbreviations: RA: rheumatoid arthritis

* Must be billed via HCPC 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 (medical appropriateness)
3. Will the provider change to a preferred product?	Yes: Inform provider of covered alternatives in class.	No: Go to #4.

Approval Criteria		
4. Is the diagnosis 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: Refer to anti-psoriatic PA criteria.	No: Go to #5.
5. 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 #6.
6. 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 #7.	No: Go to #8.
7. 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: Approve treatment for up to 1 year.	No: Pass to RPH; Deny (medical appropriateness).
8. Is the diagnosis Crohn's disease (ICD-9 555) and the product requested FDA approved for Crohn's (see table above)?	Yes: Go to #9.	No: Pass to RPH; Deny (medical appropriateness).
9. Has the patient had a trial and inadequate response to conventional therapy including immunosuppressive therapy (mercaptopurine, azathioprine) and/or corticosteroid treatments? **OR** Has intolerance or contraindications to conventional therapy?	Yes: Approve treatment for up to 1 year.	No: Pass to RPH; Deny (medical appropriateness)

P&T Action: *8/30/12 (MH)*
Revision(s):
Initiated: *2/21/13*

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*

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:

- Clients >18 years old

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Does client 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 client 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 client 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 client 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 client 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: *2/23/12, 9/20/2007, 11/29/2007*
Revision(s): *5/14/12, 1/24/12*
Initiated: *1/1/11*