Division of
Medical Assistance Programs
*Pharmaceutical Services*

# Oregon Medicaid

## Fee-For-Service

# Prior Authorization Approval Criteria

**March 17, 2014**

# Division of Medical Assistance Programs
# Oregon Medicaid Fee-For-Service
# Prior Authorization Approval Criteria
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# Division of Medical Assistance Programs
# Pharmaceutical Services Program

# Prior Authorization Approval Criteria Booklet
# Quick Instructions:

**Harcopy Users:** The Table of Contents was created for hardcopy users and is not linked for online users.

**Online Users:**

- See the “bookmarks” on the left identifying each item on the TOC.
- Click on the “Bookmark” tab to open or close this list.
- Click on the bookmark to view the first page of that item.
- To view pages between bookmarks, use the page changer at the bottom of this document or the scroll bar on the right.

**Plus or Minus Signs:**

- Click on a plus sign to view more items related to that bookmark.
- Click on the minus sign to close that section.

# Oregon Medicaid Fee-For-Service
# Prior Authorization Approval Criteria

## Updated Information

## Effective: March 17, 2014

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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:**

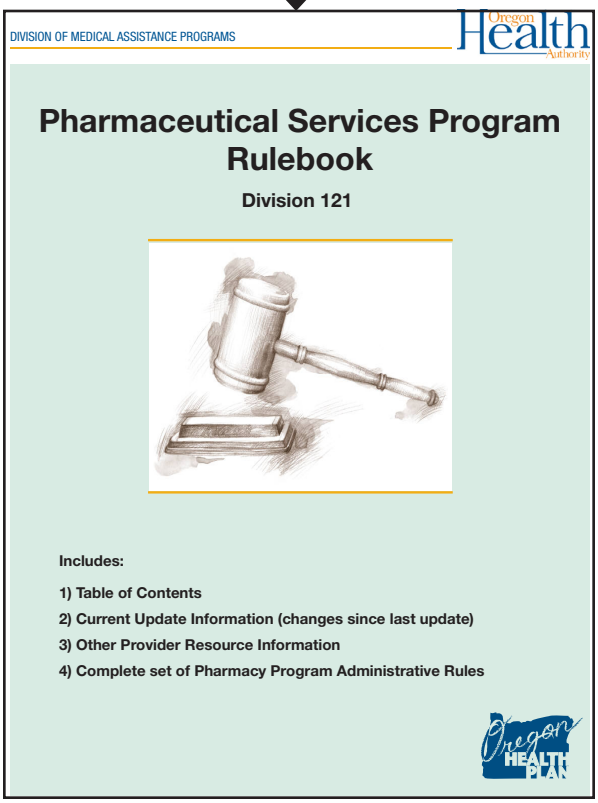
- Removed Finolimod (Gilenya®) page, included in Oral MS Drugs
- Oral Direct Factor Xa Inhibitors (Rivaroxaban and Apixaban)
- Oral Direct Thrombin Inhibitors (Dabigatran)

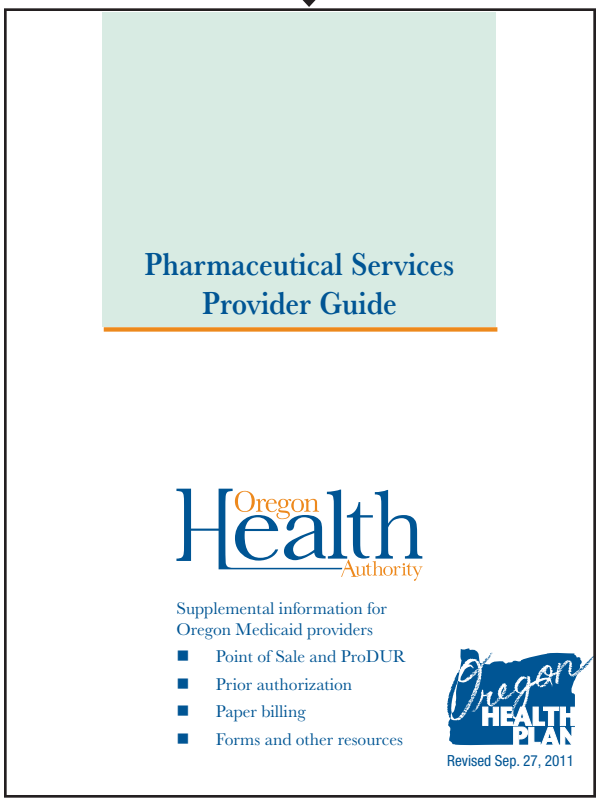
For questions, contact the DMAP Pharmacy Policy at:
dmap.rxquestions@state.or.us

**DMAP provides the information and instructions contained in this booklet to be used in conjunction with current:**

Official program policies found in the Pharmaceutical Services **Rulebook**

Billing information found in the Pharmaceutical Services **Supplemental Information**




Find both documents here:
http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/main.html

# General Prior Authorization Information

The following pages include information about prior authorization taken from the DMAP Pharmaceutical Services Supplemental Information document found at:

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

# Prior Authorization

## Overview

For drugs that require prior authorization (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 the Oregon Health Plan (OHP) and consistent with the Prioritized List of Health Services and its corresponding treatment guidelines (see OAR 410-141-0480 and 410-141-0520).

For information regarding drugs requiring prior authorization, please refer to Oregon Medicaid PA Criteria at www.dhs.state.or.us/policy/healthplan/guides/pharmacy/clinical.html#pa.

## 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 prior authorization (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 prior authorization (PA)

For clients enrolled in an OHP managed care plan, contact the plan for their PA procedures.

For OHP fee-for-service ("open card") clients, and 7/11 carve-out prescriptions for managed care clients, 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. See the Forms section of this manual for forms prescribers should use when submitting PA requests to the Call Center.

## 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

See Forms section for sample forms and instructions.

## 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 the General Rules at www.dhs.state.or.us/policy/healthplan/guides/genrules/main.html

# Forms

All DMAP forms are available electronically on the Web at:
https://aix-xweb1p.state.or.us/es_xweb/FORMS/

## DMAP 3978 - Pharmacy Prior Authorization Request

Prescribers should submit their PA requests for fee-for-service prescriptions and oral nutritional supplements with required documentation to:

**Oregon Pharmacy Call Center**
888-202-2126
Fax: 888-346-0178

This form is also available on the DHS Web site at http://dhsforms.hr.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.<br>➢ FQHC/RHC and AI/AN providers - Also enter the pharmacy or clinic NPI for your facility. |
| Section II | Type of PA Request: Mark “Pharmacy.”<br>➢ 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 (ICD-9-CM); |
| Section V: | Drug name, strength, size and quantity of medication.<br>➢ Participating pharmacy: Include the dispensing pharmacy’s name and phone number (if available). |
| Section VI: | Date of PA Request<br>Begin and End Dates of Service |
| Section VII: | Complete for EPIV and oral nutritional supplements only. |
| Section VIII: | Complete for oral nutritional supplements only. |

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Print Clear Form

**For Internal Use Only:** *PA Number*

DHS Oregon Department of Human Services

# 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 ___ / ___ / _____

## 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 | | | | | 0.00 | 0.00 | 0.00 |
| 2 | | | | | 0.00 | 0.00 | 0.00 |
| 3 | | | | | 0.00 | 0.00 | 0.00 |
| 4 | | | | | 0.00 | 0.00 | 0.00 |
| 5 | | | | | 0.00 | 0.00 | 0.00 |
| | | | Total Units | 0 | | | $0.00 |

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

| *Question* | *Yes* | *No* |
|---|---|---|
| Is the patient fed via G-tube? | ☐ | ☐ |
| Is the patient currently on oral nutritional supplements?<br>- If Yes, date product started: _____<br>- 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:<br>- Long-term care facility?<br>- Chronic home care facility?<br>- If Yes, list name of residence: _____ | <br>☐<br>☐ | <br>☐<br>☐ |
| Does the patient have:<br>- Increased metabolic need from severe trauma (*e.g.*, severe burn, major bone fracture)?<br>- Malabsorption difficulties (*e.g.*, Crohn's Disease, cystic fibrosis, bowel resection/removal, Short Gut Syndrome, gastric bypass, renal dialysis, dysphagia, achalasia)?<br>- A diagnosis that requires additional calories and/or protein intake (*e.g.*, cancer, AIDS, pulmonary insufficiency, MS, ALS, Parkinson's, cerebral palsy, Alzheimer's)? | <br>☐<br>☐<br>☐ | <br>☐<br>☐<br>☐ |

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:** _____

## Specific Drug Prior Authorization and Contact Information

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 Drug Use Review (DUR) / Pharmacy and Therapeutic Committee (P&T) and is subject to the DMAP administrative rule writing process. (See the Web page at http://pharmacy.oregonstate.edu/drug_policy/index.php?nav=dur_board )

For general questions about prior authorization policy, contact:

**Roger A. Citron, RPh**

OSU College of Pharmacy
Drug Use Research & Management at
DHS Division of Medical Assistance Programs
500 Summer Street NE, E-35
Salem, OR 97301-1079
citron@ohsu.edu
roger.a.citron@state.or.us
Telephone voice mail: 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?<br>Message:<br>• Preferred products do not require PA.<br>• 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?<br>• Contraindications include:<br>• Renal disease or renal dysfunction<br>• Known hypersensitivity to metformin and/or sulfonylureas<br>• Acute or chronic metabolic acidosis<br>• 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?<br>Message:<br>• Preferred products do not require PA.<br>• 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<br>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?<br>Message:<br>• Preferred products do not require PA for <4 days/week.<br>• 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?<br><br>Generic Name / Brand Name<br>Metoclopramide / Reglan<br>Prochlorperazine / Compazine<br>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<br><br>All other indications need to be evaluated as to whether they are above the line or below the line.<br><br>• Above: Deny, (Medical Appropriateness)<br>• 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?<br>Message:<br>• Preferred products do not require PA.<br>• 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?<br>• 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<br>• Does the client have a diagnosis of HIV/AIDS? OR<br>• 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<br>• Does client have sickle cell anemia?</td><td>Yes: Record ICD-9 code. Approve as follows: (Immunocompromised client)<br>ORAL<br>• Toenails = 12 weeks. Max 1 course per year.<br>• Fingernails = 6 weeks. Max 1 course every 6 months.<br>ORAL & TOPICAL<br>• All other diagnosis = course of treatment only with PRN renewals.<br>• 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.<br><br>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)<br>ORAL<br>• Toenails = 12 weeks. Max 1 course per year.<br>• Fingernails = 6 weeks. Max 1 course every 6 months.<br>ORAL & TOPICAL<br>• All other diagnosis = course of treatment only with PRN renewals.<br>• 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).
        - Deny Non-fungal diagnosis (Medical Appropriateness)
        - Deny Fungal ICD-9 codes that do not appear on the OHP list pending a more specific diagnosis code (Not Covered by the OHP).
        - Forward any fungal ICD-9 codes not found in the Tables 1, 2, or 3 to the Lead Pharmacist. These codes will be forwarded to DMAP to be added to the Tables for future requests.

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*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?<br>Message:<br>• Preferred products do not require a PA.<br>• 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?<br><br>*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?<br>• Acute or chronic inflammation of the orbit (376.0 – 376.12)<br>• Chronic Sinusitis (473.xx)<br>• Acute Sinusitis (461.xx)<br>• Sleep apnea (327.20,327.21,327.23327.29,780.51, 780.53, 780.57)<br>• 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?<br><br>• Above: Deny, yesterday's date (Medical Appropriateness)<br><br>• 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.**

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*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<br>12.5 mg tab<br>(blister pack 6, 12) | 4 | 12/45d |
| Eletriptan | Relpax | 20-40 mg. Rpt in 2 hr | 80 mg | 20 mg tab<br>40 mg tab<br>(blister pack 6, 12) | 3 | 12/60d |
| Frovatriptan | Frova | 2.5-5 mg Rpt in 4 hr | 7.5 mg | 2.5 mg tab<br>(blister pack 9) | 4 | 9/30d |
| Naratriptan | Amerge | 1-2.5 mg Rpt in 4hr | 5 mg | 1 mg tab<br>2.5 mg tab (blister pack 9) | 4 | 9/30d |
| Rizatriptan | Maxalt<br>Maxalt MLT | 5-10 mg Rpt in 2hr | 30 mg | 5 mg tab<br>10 mg tab (blister pack 6, 12) | 4 | 12/30d |

| | | | | | | |
|---|---|---|---|---|---|---|
| Sumatriptan | Imitrex & generics | 25-100 mg po rpt In 2 hr<br><br>5-10 mg NS Rpt in 2 hr<br><br>3-6 mg SQ Rpt in 2hr | 200 mg<br><br>40 mg<br><br>12 mg | 25 mg tab, 50mg tab, 100 mg tab (blister pack 9)<br><br>5 mg, 10 mg NS (box of 6)<br><br>6 mg SQ (box 2 syr), kit (2 syr per kit), 6mg/0.5ml vials | 4<br><br>4<br><br>4 | 9/30d<br><br>6/30d<br><br>6/30d<br>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<br>Zomig ZMT<br><br>Zomig NS | 1.25-5 mg Rpt in 2hr<br><br>5mg NS Rpt in 2hr | 10 mg<br><br>10mg | 2.5 mg tab (blister pack, 6)<br><br>5 mg tab (blister pack, 3)<br><br>5mg NS (box of 6) | 3<br><br>4 | 6/30d<br><br>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?<br><br>Message:<br>• Preferred products do not require PA within recommended dose limits.<br>• 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)<br><br>• 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).<br>• One life-time 90-day taper may be approved at pharmacist discretion.<br>• Document. | No: Trouble-shoot claim payment (days supply?);<br>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<br>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?<br>Message:<br>• Preferred products do not require PA.<br>• 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?<br><br>Message:<br>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.<br><br>Current recommended treatment duration:<br>• 5 days for the following: Relenza, Tamiflu,<br>• 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.)<br><br>• High-risk persons during 2 weeks after vaccination before adequate immunity develops<br><br>• Patients >1 years of age at high risk for complications for whom the vaccine is contraindicated, unavailable or expected to have low effectiveness<br><br>• Residents in institutions such as nursing homes or long-term care facilities that are experiencing an influenza outbreak<br><br>• Persons at high-risk of complications of influenza, such as transplant and immunocompromised patients<br><br>• 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<br><br>• Persons within a household with suspected or confirmed influenza cases if any family member is at high risk of complications<br><br>• 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.<br><br>Current recommended duration of prophylaxis;<br><br>Relenza: 10 days for prophylaxis in a household setting, up to 28 days in a community outbreak setting.<br><br>Tamiflu: at least 10 days following close contact with an infected individual; up to 6 weeks in a community outbreak setting.<br><br>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.


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| | |
|---|---|
| *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?<br><br>Message:<br>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.<br><br>• Current (not history of) diagnosis of cancer AND is currently undergoing Chemotherapy or Radiation? Document therapy and length of treatment<br>• 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:<br><br>(If drug not in list below, Pass to RPh for evaluation)<br><br>Immunosuppressive drugs include, but are not limited to:<br><br>**Generic Names** / **Brand Names**<br>Azathioprine / Imuran<br>Basiliximab / Simulect<br>Cyclosporine / Sandimmune,<br>Cyclosporine / Neoral<br>Sirolimus / Rapamune<br>Tacrolimus / Prograf<br>Methotrexate / Rheumatrex<br>Hydroxychloroquine / Plaquenil<br>Etanercept / Enbrel<br>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?<br><br>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.<br><br>• If not immuno-compromised deny (Not Covered by the OHP).<br><br>• If immuno-compromised approve for 1 year. |

| Approval Criteria | | |
|---|---|---|
| 7. RPH only<br><br>All other indications need to be evaluated as to whether they are above the line or below the line diagnosis.<br><br>• 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)<br><br>• If below, Deny, (Not Covered by the OHP).<br><br>• Deny Non-viral diagnoses (Medical Appropriateness).<br><br>• 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?<br><br>Message:<br>• Preferred products do not require PA.<br>• 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?<br><br>Message:<br>• Preferred products do not require a PA.<br>• 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:<br><br>**Above the line** covered diagnoses related to prostate may be approved for 1 year<br><br>**Below the line** diagnoses (e.g. Hair growth, erectile dysfunction) should be denied (Not Covered by the OHP).<br><br>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.<br><br>• 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.<br><br>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<br>All other indications need to be evaluated as to whether they are above the line or below the line diagnosis.<br>• 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.<br>• 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?<br><br>Message:<br>• Preferred products do not require a PA.<br>• 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?<br><br>Examples include:<br>• Postmenopausal women with osteoporosis<br>• Men with primary or hypogonadal osteoporosis<br>• 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<br>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?<br>• 304.00 Opioid type dependence unspecified use<br>• 304.01 Opioid type dependence continuous use<br>• 304.70 Opioid type dependence continuous use<br>• 304.70 Combinations of opioid type drug with other drug dependence unspecified use<br>• 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)?<br>OR<br>Prescriber provides copy of SAMSHA certification request pending with "Immediate Need" checked? (once MD meets criteria SAMHSA may take 45 days to process.)<br><br>*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.<br>**Go to 6.** | **No:** Go to #5. |
| 5. Does MD qualify for waiver from separate registration?<br>a) Must have a valid DEA license AND<br>b) Board certified in addiction medicine<br>OR<br>c) Employed by an opioid treatment program<br>OR<br>d) Federally employed physicians (e.g. IHS or VA) | **Yes:** Go to #6 | **No: PASS TO RPH,** Deny for medical appropriateness.<br><br>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)?<br><br>Examples of long-acting opioids include:<br>methadone (e.g. Dolophine, Methadose)<br>Levodromoran<br>Long-acting morphine (e.g. MS Contin, Oramorph SR, Kadian, Avinza)<br>Long-acting oxycodone (e.g. OxyContin)<br>Fentanyl patches (e.g. Duragesic)<br>Opana XR | **Yes: PASS TO RPH.** Deny for medical appropriateness.<br><br>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.<br><br>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?<br><br>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.<br><br>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.<br>**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.

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*DUR / P&T Action:* *5/31/12 (MH)*
*Revision(s):*
*Initiated:* *8/20/12*

# Central Nervous System (CNS) Sedatives – Benzodiazepine 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:**

- Non-preferred drugs

**Covered Alternatives:**

- Preferred alternatives listed at www.orpdl.org
- Zolpidem (NDC's priced as generic), trazodone, mirtazapine, diphenhydramine or tricyclic antidepressants may be alternatives for some clients.

| | TC | HSN | Generic | Brand |
|---|---|---|---|---|
| **Requires PA:** Quantity **Exceeding** Limit of 15 doses / 30 days | 47 | 001592 | Temazepam | Restoril |
| | 47 | 001593 | Flurazepam HCL | Dalmane |
| | 47 | 001594 | Triazolam | Halcion |
| | 47 | 001595 | Quazepam | Doral |
| | 47 | 006036 | Estazolam | Prosom |

| 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. |

| Approval Criteria | | |
|---|---|---|
| 3. Is client on CPAP? | Yes: Approve for up to 1 year. The use of CPAP essentially negates the sedative contraindication and they are often prescribed to help clients cope with the mask. | No: Pass to RPH, Deny, (Medical appropriateness). Due to the depressant effects of sedative/ hypnotics, sedative/hypnotics are contraindicated for this diagnosis and are not approvable. |
| 4. Is the client being treated for co-morbid depression, 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 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?<br><br>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:* *5/18/06, 2/23/06, 11/10/05, 9/15/05, 2/24/04, 2/5/02, 9/7/01*
*Revision(s):* *1/1/07, 7/1/06, 11/15/05*
*Initiated:* *11/15/02*

# 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

| TC | HSN | Generic | Brand |
|---|---|---|---|
| 47 | 007842 | ** | Ambien, Ambien CR, Ambien PAK |
| 47 | 020347 | Zaleplon | Sonata |
| 47 | 026791 | Eszopiclone | Lunesta |
| 47 | 033126 | Ramelteon | Rozerem |

**Covered Alternatives:**

Preferred alternatives listed at www.orpdl.org

| | |
|---|---|
| • Zolpidem (NDC's priced as generic)<br>• Trazodone<br>• Mirtazapine<br>• Diphenhydramine<br>• 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. |

| Approval Criteria | | |
|---|---|---|
| 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:<br>• Co-morbid depression,<br>• Anxiety,<br>• Bipolar disorder or<br>• Panic<br><br>(i.e. Is there an existing claim history of:<br>• Antidepressants,<br>• Lithium,<br>• Antipsychotics, or<br>• 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?<br><br>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?<br><br>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-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:**

- Non-preferred drugs
- 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.

| TC | HSN | Generic | Brand |
|---|---|---|---|
| 47 | 001592 | Temazepam | Restoril |
| 47 | 001593 | Flurazepam HCL | Dalmane |
| 47 | 001594 | Triazolam | Halcion |
| 47 | 001595 | Quazepam | Doral |
| 47 | 006036 | Estazolam | Prosom |
| 47 | 007842 | Zolpidem | Ambien, Ambien CR, Ambien PAK |
| 47 | 020347 | Zaleplon | Sonata |
| | 026791 | Eszopiclone | Lunesta |
| | 033126 | Ramelteon | Rozerem |

**Covered Alternatives:**

Preferred alternatives listed at www.orpdl.org

| | |
|---|---|
| Trazodone<br>Mirtazapine<br>Diphenhydramine<br>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. |

| Approval Criteria | | |
|---|---|---|
| 2. Is this a switch in sedative therapy due to intolerance, allergy or ineffectiveness? | Yes: Document reason for switch and approve duplication for 30 days. | No: Pass to RPH; Deny, (Medical appropriateness). There is no evidence to support the use of two different sedatives concurrently. Continuous use of a single sedative is approvable for covered diagnoses. (See benzo quantity limit sedative and non-benzo PA) |

*P&T / DUR Action:* *5/18/06*
*Revision(s):*
*Initiated:* *1/1/07*

# 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?<br>Message:<br>• Preferred products do not require PA for FDAapproved doses.<br>• 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:*

# Combination Short Acting Bronchodilator Inhalers

**Goal(s):**

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

**Initiative:**

Short Acting Bronchodilator Step Therapy

**Length of Authorization:**

1 year

**Requires PA:**

Non-preferred combination short acting bronchodilators

**Covered Alternatives:**

Preferred alternatives listed at www.orpdl.org

**Step Therapy Required prior to coverage.**

| Approval Criteria | | |
|---|---|---|
| 1. What diagnosis is being treated? | Record ICD9 code. | |
| 2. Does the patient have COPD (ICD-9 496)? | **Yes:** Go to #3 | **No:** Pass to RPh; Deny (Medical Appropriateness). |
| 3. Will the prescriber change to a preferred product? | **Yes**: Inform provider of covered alternatives in class | **NO:** Go to #4 |
| 4. Has patient failed an inhaled Short acting beta agonist (albuterol) OR<br><br>An inhaled short acting anticholinergic agent (ipratropium)? | **Yes:** Approve for one year | **No:** Pass to RPh, Deny (Medical appropriateness) |

*P&T / DUR Action:* *1/31/2013 (MH)*
*Revision(s):* *7/1/2013*
*Initiated:* *9/1/2013*

# 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).<br><br>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*

# 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<br>• 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*

# 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 #**Error! Reference source not found.** | 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 #**Error! Reference source not found.** |
| 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%<br>AND<br>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%<br>AND<br>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%<br>AND<br>Is the transferrin saturation >20% and/or ferritin >100ng/ml<br>AND<br>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


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*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<br>OAR 410-121-0147 Exclusions and Limitations<br>(DMAP Pharmaceutical Services Program) |
|---|
| 1) The following items are not covered for payment by the Division of Medical Assistance Programs (DMAP) Pharmaceutical Services Program:<br>(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;<br>(b) Home pregnancy kits;<br>(c) Fluoride for individuals over 18 years of age;<br>(d) Expired drug products;<br>(e) Drug products from non-rebatable manufacturers, with the exception of selected oral nutritionals, vitamins, and vaccines;<br>(f) Active Pharmaceutical Ingredients (APIs) and Excipients as described by Centers for Medicare and Medicaid (CMS);<br>(g) Drug products that are not assigned a National Drug Code (NDC) number;<br>(h) Drug products that are not approved by the Food and Drug Administration (FDA);<br>(i) Drug products dispensed for Citizen/Alien-Waived Emergency Medical client benefit type;<br>(j) Drug Efficacy Study Implementation (DESI) drugs (see OAR 410-121-0420);<br>(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.<br><br>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)<br><br>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 =<br>018751<br>002111<br>002112<br>002070<br>002113<br>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;<br>Except HSN=<br>002466<br>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;<br>Except HSN = 002577<br>002576<br>002574<br>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 +<br>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 +<br>ROA=TOPICAL | Erythromycin Topical | Acne Not Covered on OHP List |
| HSN=025510 | Rosac | Acne Not Covered on OHP List |
| TC = 93;<br>Except HSN =<br>002363 (dextranomer)<br>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:<br><br>"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:<br>• Morphine greater than 60 mg per day? OR<br>• Transdermal fentanyl 50 mcg per hour? OR<br>• Equianalgesic dose of another opioid for at least one week? | **Yes:** Go to #5. | **No:** Pass to RPH; Deny, (Medical Appropriateness), *with message:*<br><br>*"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:*<br><br>*"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:*<br><br>*"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?<br><br>Message:<br>• 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) - 16 years and up
- telbivudine (Tyzeka) - safety and effectiveness not approved in pediatrics

| 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? | 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):* *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 6-10 weeks (depending on regimen)
- Continuation of therapy up to 48 weeks of total therapy

**Requires PA:**

- Telaprevir
- Boceprevir

| Approval Criteria | | |
|---|---|---|
| 1. Is the request for treatment of Chronic Hepatitis C?<br>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?<br>Record Genotype: | **Yes:** Go to #3. | **No:** Pass to RPH; Deny for medical appropriateness. |
| 3. 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-alpha and ribavirin? | **Yes:** Go to #4. | **No:** Pass to RPH; Deny for medical appropriateness. |
| 4. 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 #5. |
| 5. Does the patient have a Child-Pugh score <7 (compensated liver disease)? | **Yes:** Go to #6. | **No:** Pass to RPH; Deny for medical appropriateness. |
| 6. 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 #7. | **No:** Pass to RPH; Deny for medical appropriateness. |
| 7. If the patient has been treated with peginterferon and ribavirin before, do they have documented compliance/adherence to their previous treatment? | **Yes:** Go to #8. | **No:** Pass to RPH; Deny for medical appropriateness. |

| Approval Criteria | | |
|---|---|---|
| 8. Does the patient have a biopsy to indicate moderate to severe fibrosis (stage 2 or greater) OR radiologic, laboratory, or clinical evidence of cirrhosis? OR has extrahepatic manifestations (vasculitis, glomerulonephritis, cryoglobulins)? | **Yes:** Go to #9. | **No:** Pass to RPH; Deny for medical appropriateness. |
| 9. Does the patient have an HIV coinfection? | **Yes:** Go to #10. | **No:** Go to #11. |
| 10. Is the patient under the supervision of an HIV specialist? | **Yes:** Go to #11. | **No:** Pass to RPH; Deny for medical appropriateness. |
| 11. Has the patient previously been treated with boceprevir or telaprevir? | **Yes:** Pass to RPH; Deny for medical appropriateness. | **No:** Go to #12. |
| 12. Is the request for telaprevir 750mg (two tabs) TID 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 #13 (If dose is different pass to RPH for appropriateness). |
| 13. 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:** Pass to RPH; Deny for medical appropriateness. |

| Continuation of Therapy - Telaprevir | | |
|---|---|---|
| 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:<br><br>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<br>(Medical Appropriateness)<br><br>Patients with inadequate viral response are unlikely to achieve SVR, and may develop treatment-emergent resistance substitutions.<br><br>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:<br><br>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<br>(Medical Appropriateness)<br><br>Patients with inadequate viral response are unlikely to achieve SVR, and may develop treatment-emergent resistance substitutions.<br><br>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:<br><br>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<br>(Medical Appropriateness) |

| Continuation of Therapy - Telaprevir | | |
|---|---|---|
| 4. Is the patient treatment-naïve with documented cirrhosis that has undetectable HCV-RNA at weeks 4 and 12? | Yes: Approve as follows:<br><br>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<br>(Medical Appropriateness)<br><br>Patients with inadequate viral response are unlikely to achieve SVR, and may develop treatment-emergent resistance substitutions.<br><br>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<br>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)<br>Week 24: Detectable Discontinue peginterferon and ribavirin.<br>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:<br><br>Approve additional 14 weeks of boceprevir for total treatment duration of 28 weeks (4 week lead-in, 24 weeks triple therapy) | No: DENY<br>(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:<br><br>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<br>(Medical Appropriateness) |

| Continuation of Treatment - Boceprevir | | |
|---|---|---|
| 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:<br><br>Approve additional 22 weeks of boceprevir for total treatment duration of 36 weeks (4 week lead-in, 32 weeks triple therapy) | No: DENY<br>(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:<br><br>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<br>(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:<br><br>Continue triple therapy with boceprevir for a total treatment duration of 48 weeks (4 week lead-in, 44 weeks triple therapy). | No: DENY<br>(Medical Appropriateness) |
| *TREATMENT FUTILITY RULES<br>If the patient has HCV-RNA results greater than or equal to 100 IU/mL at TW12, then discontinue three-medicine regimen.<br>If the patient has confirmed, detectable HCV-RNA at TW24, then discontinue three-medicine regimen. | | |

*P&T / DUR Action:* *9/26/13 (MH), 1/26/12(KS)*
*Revision(s):* *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?<br>• Turner's Syndrome (758.6)<br>• Noonan Syndrome (759.89)<br>• Pre-transplant chronic renal insufficiency (CRI) (593.9)<br>• Prader - Willi Syndrome(PWS) (759.81)<br>• Neonatal Hypoglycemia associated with Growth Hormone Deficiency (775.6)<br>• X-linked Hypophosphotemia<br>• Pituitary Dwarfism (253.3)<br>• 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?<br>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?<br><br>Message:<br>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<br>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?<br>• central precocious puberty (CPP) aka precocious sexual development & puberty NOC ICD-9 259.1;<br>• endometriosis ICD-9 617.0-617.9;<br>• prostate cancer ICD-9 185, 189, 198;<br>• uterine fibroids 218.9<br><br>• Note that CPP is often associated with hydrocephalus, cranial irradiation, Silver-Russell syndrome, hypothalamic tumor, or hamartoma.<br>• All above diagnosis & conditions are rare in children and adolescents. | Yes: Approve through:<br><br>• Age 12 for female<br>• Age 13 for male | No: Pass to RPH; Go to #4. |
| 4. RPH only<br><br>All other indications need to be evaluated as to whether they are above the line or below the line.<br><br>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.<br><br>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?<br><br>• Ovarian failure (256.31, 256.39)<br>• Testicular Hypofunction (257.2)<br>• Hypopituitarism and related disorders (253.2, 253.4, 253.7, 253.8)<br>• AIDS-related cachexia (253.2) | Yes: Go to #3. | No: Pass to RPH<br>RPH go to #4. |
| 3. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>• 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.<br><br>Approve for 6 months. | No: Approve for 6 months. |

| Approval Criteria | | |
|---|---|---|
| 4. RPH only<br><br>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?<br><br>Contraindications include:<br>• Renal disease or renal dysfunction<br>• Known hypersensitivity to therapies<br>• Acute or chronic metabolic acidosis<br>• Patients at increased risk of lactic acidosis (CHF, advanced age, impaired hepatic function)<br>• 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 insulin mimetics.

**Length of Authorization:**

Up to 12 months

**Requires PA:**

- Non-preferred drugs

**Covered Alternatives:**

Preferred alternatives listed at www.orpdl.org

| Approval Criteria | | |
|---|---|---|
| 1. Does the patient have a diagnosis of Type 2 diabetes? | **Yes:** Go to #2. | **No:** Pass to RPH; Deny for medical appropriateness. |
| 2. Will the prescriber consider a change to a preferred product?<br><br>Message:<br>Preferred products do not require PA.<br>Preferred products are evidence-based reviewed for comparative effectiveness & safety by the Health Resources Commission (HRC).<br><br>Reports available at:<br>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?<br><br>Contraindications to metformin:<br>• Renal disease or renal dysfunction<br>• Known hypersensitivity<br>• Acute or chronic metabolic acidosis<br>• Increased risk of lactic acidosis (CHF, advanced age, impaired hepatic function)<br>Contraindications to sulfonylureas:<br>• Known hypersensitivity<br>• Increased risk of hypoglycemia | **Yes:** Go to #4. | **No:** Pass to RPH; Deny for medical appropriateness.<br><br>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.<br><br>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.

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*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?<br>• 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:<br>• Does the patient have physical dexterity problems/vision impairment<br>• Comprehension related issues<br>• Dosing errors with use of vials<br>• The patient is on a low dose of insulin (≤40 units/day)<br>• 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?<br><br>Message:<br>Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Health Resource Commission (HRC).<br><br>• Yes: Inform provider of covered alternatives in class. www.oregon.gov/DHS/healthplan/tools_prov/dl.shtml.<br><br>For insulin pens approve for 1 year (other preferred products covered without a PA)<br><br>• No: Approve for 1 year |
| 6. RPh only<br><br>• Requests for insulin pens and cartridges on a client-specific basis.<br>• Refer to the PDL for the preferred pens.<br>AND/OR<br>• 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 mutation in the CFTR gene?<br>• If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the G551D 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 of the following medications below:<br>- Dornase alfa (Pulmozyme®) AND<br>- Hypertonic saline (Hyper-Sal®) AND<br>- 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. |
| 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.

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*P&T / DUR Action:* *6/28/12 (KS), 4/26/12 (MH/KS)*
*Revision(s):*
*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:<br>• failed an inhaled corticosteroid or other controller medication OR<br>• Had ≥2 exacerbations requiring oral systemic corticosteroids in the past year, OR<br>• Is there documentation of step 3 asthma or higher OR<br>• Is there a hospital admission or ER visit related to asthma or reactive airway disease within last 60 days? | **Yes:** Document the following:<br>Date of trial, drug, reason(s) for failure or contraindications OR chart notes of asthma severity in the PA record<br><br>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?:<br>• Cancer (140-239)<br>• Diabetes (250)<br>• 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?<br><br>**A** Dietary modification—increased dietary fiber (25 g/day)<br>**B** Fiber supplementation/bulk laxatives (Psyllium, Metamucil,Perdiem, Fibercon, etc)<br>**C** Saline laxatives (milk of magnesia, magnesium citrate, Fleet phospho-soda, etc)<br>**D** Stimulant laxative (senna, bisacodyl, cascara sagrada, etc)<br>**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<br>All other indications need to be evaluated to see if they are above or below the line.<br><br>• 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.<br><br>• 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?<br>• Acute or chronic inflammation of the orbit (376.0 – 376.12)<br>• Chronic Sinusitis (473.xx)<br>• Acute Sinusitis (461.xx)<br>• Sleep apnea (327.20,327.21,327.23-327.29,780.51, 780.53, 780.57)<br>• Wegener's Granulomatosis (ICD-446.4) | Yes: Go to #5. | No: Pass to RPH; Deny,<br>(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)<br><br>Use clinical judgment to approve for 1 month starting today to allow time for appeal.<br><br>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."<br><br>(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:<br>• low dose needed due to debilitation from a medical condition or age;<br>• unable to tolerate higher doses;<br>• stable on current dose; or<br>• impaired drug clearance? | Yes: Approve for up to 1 year. | No: Deny, (Medically Appropriate).<br>• Provide tapering schedule if needed. See below.<br>• 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).

# Lyrica® (Pregabalin)

**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?<br>• Diabetic neuropathy (ICD9: 250.6 & subsets) – Document diabetic therapy (supporting meds)<br>• Post-herpetic neuralgia (ICD9: 053 & subsets)<br>• 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?<br>• TCAs<br>• Carbamazepine<br><br>Document drugs tried or contraindications. | Yes: Approve for 90 days with subsequent approvals dependent on documented* positive response for lifetime (12-31-2036)<br>*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?<br>• SSRIs<br>• TCAs<br>• Benzodiazepines<br>• Buspirone<br><br>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*

# Marinol® (Dronabinol)

**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:**

- Marinol® (dronabinol)

**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.<br>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?<br>Generic Name / Brand Name<br>Metoclopramide / Reglan®<br>Prochlorperazine / Compazine®<br>Promethazine / Phenergan®<br><br>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<br>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*

# 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)<br><br>Recommend UDS. |
| 3. Has patient been continuously on opioids other than codeine over the past 90 days? | Yes: Go to #4<br><br>Document previous opioid therapy. | No: Pass to RPH; Deny (Medical Appropriateness)<br><br>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?<br><br>Dose Calculator at: | | Yes: Pass to RPH; Deny (Medical Appropriateness)<br><br>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<br><br>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.<br><br>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.<br><br>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.

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*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*

# 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.<br><br>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.<br><br>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)<br><br>**OR**<br><br>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.<br><br>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;<br><br>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.<br><br>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?<br>(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?<br>• Acute or chronic inflammation of the orbit (376.0 – 376.12)<br>• Chronic Sinusitis (473.xx)<br>• Acute Sinusitis (461.xx)<br>• Sleep apnea (327.20,327.21,327.23-327.29,780.51, 780.53, 780.57)<br>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.<br><br>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.

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*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).<br><br>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?<br>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:<br>• 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**<br>• 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?<br>Document:<br>• Residence<br>• Current weight<br>• Normal weight | Yes: Go to #9. | No: Request more documentation OR Pass to RPH; Deny, (Medical Appropriateness) |
| 9. Does the client have:<br>• An increased metabolic need resulting from severe trauma (e.g. Severe burn, major bone fracture, etc.)? OR<br>• Malabsorption difficulties (e.g. Crohns Disease, Cystic Fibrosis, bowel resection/ removal, Short Gut Syndrome, gastric bypass, renal dialysis, dysphagia, achalasia, etc)? OR<br>• 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?<br><br>• Yes: Approve for 1 month and reply:<br>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.<br><br>Go to: http://www.dhs.state.or.us/policy/healthplan/guides/homeiv/main.html<br><br>• 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.<br><br>For complete information of how to file a claim, go to:<br>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).<br><br>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:<br>• An increased metabolic need resulting from severe trauma (e.g. Severe burn, major bone fracture, etc.)? OR<br>• Malabsorption difficulties (e.g. Crohns Disease, Cystic Fibrosis, bowel resection/ removal, Short Gut Syndrome, gastric bypass, renal dialysis, dysphagia, achalasia, etc)? . OR<br>• 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:<br>• 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<br>• 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?<br><br>• Yes: Approve for 1 month and reply:<br>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.<br><br>Please visit: http://www.dhs.state.or.us/policy/healthplan/guides/homeiv/main.html<br><br>• 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.<br><br>For complete information of how to file a claim, go to:<br>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***

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

# 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<br>Sustained-release: 15mg q 12 hours | Adjust dose for renal impairment. |
| **Oxycodone** | 80mg per 24 hours | Immediate-release: 5mg q 4–6 hours<br>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:<br>a. Reflex loss<br>b. Dermatomal muscle weakness<br>c. Dermatomal sensory loss<br>d. EMG or NCV evidence of nerve root impingement<br>e. Cauda equina syndrome<br>f. Neurogenic bowel or bladder<br><br>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?<br>• Family history of "long QTc syndrome", syncope, sudden death<br>• Potassium depletion primary or secondary to drug use ( i.e. diuretics)<br>• Concurrent use of C34 inhibitors or QTc prolonging drugs (see table below)<br>• 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)<br>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:<br>a. Oncology pain (ICD-9 338.3)<br>b. Terminal diagnosis (<6 months)<br>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)<br><br>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)<br><br>In general, the total dose of opioid should not exceed 120mg MED Risks substantially increase at doses at or above 100mg MED.<br><br>Alternatives:<br>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)<br><br>Recommend Urine Drug Screen |
| 13. Is the patient seeing a single prescribing practice & pharmacy for pain treatment (short and long acting opioids)? | **Yes**: Go To #14 | **No:** <u>Approve 30-90 days;</u><br><br>Refer to Rx Lock-In program for evaluation.<br><br>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.**<br><br>**Quantity Limits Apply, e.g.:**<br>Avinza: 1 dose / day<br>Butrans: 1 patch / week<br>Embeda: 2 doses / day<br>Exalgo: 1 dose / day<br>Fentanyl: 1 patch / 72 hours<br>Kadian: 2 doses / day<br>Opana XR: 2 doses / day<br>Oxycodone ER: 2 doses / day | **No:** Approve 30-90 days to allow for potential tapering of dose.<br><br>Refer to Rx Lock-In program for evaluation.<br><br>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?<br><br>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**<br>(Medical Appropriateness)<br><br>**May approve for taper only.**<br><br>Refer to Rx Lock-In program for evaluation.<br><br>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:<br>• unstable INR<br>• allergy<br>• contraindications to therapy<br>• drug-drug interactions<br>• 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:<br>• unstable INR<br>• allergy<br>• contraindications to therapy<br>• drug-drug interactions<br>• 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:<br>• unstable INR<br>• warfarin allergy<br>• contraindications to warfarin therapy<br>• drug-drug interactions<br>• intolerable side effects | **Yes:** Go to #4. | **No:** Deny.<br><br>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:<br>• unstable INR<br>• allergy<br>• contraindications to warfarin therapy<br>• drug-drug interactions<br>• 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?<br>• 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*

# 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?<br><br>Message:<br>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.<br><br>• If above the line and clinic provides supporting literature: Approve for length of treatment.<br><br>• 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?<br>Message:<br>- 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?<br>Document appropriate ICD9 code:<br>(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?<br><br>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?<br>• severe or uncontrolled psychiatric disorder<br>• decompensated cirrhosis or hepatic<br>• encephalopathy<br>• hemoglobinopathy<br>• untreated hyperthyroidism<br>• severe renal impairment or transplant<br>• autoimmune disease<br>• pregnancy<br>• 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.<br>Note: For ribavirin approve the generic only. | No: Deny; Pass to RPH (Medical Appropriateness) |
| 11. Is the request for Pegasys and the treatment of confirmed, compensated Chronic Hepatitis B? | Yes: Go to #11 | No: Deny; Pass to RPH (Medical Appropriateness) |
| 12. Is the patient currently on LAMIVUDINE (EPIVIR HBV), ADEFOVIR (HEPSERA), ENTECAVIR (BARACLUDE), TELBIVUDINE (TYZEKA) and the request is for combination Pegasys-oral agent therapy? | Yes: Deny; Pass to RPH (Medical Appropriateness) | No: Go to #12 |
| 13. Has the member received previous treatment with pegylated interferon? | Yes: Deny; Pass to RPH (Medical Appropriateness) Recommend: LAMIVUDINE (EPIVIR HBV) ADEFOVIR (HEPSERA) | No: Approve Pegasys #4 x 1ml vials or #4 x 0.5 ml syringes per month for 12 months (maximum per lifetime). |

<table>
<tr><th colspan="3">Continuation of Therapy- HCV</th></tr>
<tr>
<td>1. Does the client have undetectable HCV RNA or at least a 2-log reduction (+/- one standard deviation) in HCV RNA measured at 12 weeks?</td>
<td>Yes: Approve as follows:<br><br>Approval for beyond quantity and duration limits requires approval from the medical director.
<table>
<tr><th>Geno-type</th><th>Approve for:</th><th>Apply</th></tr>
<tr><td>1 or 4</td><td>An additional 36 weeks or for up to a total of 48 weeks of therapy (whichever is the lesser of the two).</td><td>Ribavirin quantity limit of 200 mg tablets QS# 180 / 25 days (for max daily dose =1200 mg).</td></tr>
<tr><td>2 or 3</td><td>An additional 12 weeks or for up to a total of 24 weeks of therapy (whichever is the lesser of the two).</td><td>Ribavirin quantity limit of 200 mg tab QS# 120 / 25 days (for max daily dose = 800 mg).</td></tr>
<tr><td>For all genotypes and HIV co-infection</td><td>An additional 36 weeks or for up to a total of 48 weeks of therapy (whichever is the lesser of the two)</td><td>Ribavirin quantity limit of 200 mg tablets QS# 180 / 25 days (for max daily dose = 1200 mg).</td></tr>
</table>
</td>
<td>No: DENY (Medical Appropriateness)<br><br>Treatment with pegylated interferon-ribarvirin does not meet medical necessity criteria because there is poor chance of achieving an SVR.</td>
</tr>
</table>

**<u>Clinical Notes:</u>**

- 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

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*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.<br><br>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.<br><br>• If above the line and clinic provides supporting literature: Approve for length of treatment.<br><br>• 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?<br><br>(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:<br>• Greater than 75 years old<br>• Less than 60 kg<br>• 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:<br>• clopidogrel allergy<br>• contraindications to clopidogrel therapy (document)<br>• drug-drug interactions (document)<br>• intolerable side effects | Yes: Go to #8 | No: Pass to RPh. Deny<br><br>Recommend clopidogrel trial |

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

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

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

| | | | | |
|---|---|---|---|---|
| | | | tetracycline | each given four times a day<br>**add an H2 receptor antagonist |
| Oral | 017026 | Prevpac | lansoprazole, amoxicillin, clarithromycin | lansoprazole 30 mg<br>+ amoxicillin 1 gm<br>+ clarithromycin 500 mg,<br>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,<br>3 capsules given four times a day<br>**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<br>• Zollinger-Ellison (251.5)?<br>• Barrett's esophagus (530.85)?<br>• Multiple Endocrine Adenoma (237.4)?<br>• Malignant Mastoma (202.6)?<br>• 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:<br>• 65 years<br>• requires > 3 months of NSAIDs, aspirin or steroids<br>• on anticoagulation (warfarin, enoxaparin, etc.)<br>• 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.<br><br>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.<br><br>May approve BID dosing for pediatrics <12 years old | No: Go to #11. |
| 11. Is diagnosis:<br>• Ulcer of esophagus (530.2x)<br>• Stricture & stenosis of esophagus (530.3)<br>• 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.<br>• Diagnoses below the line and where PPI is appropriate should be denied as not covered.<br>• 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:<br>• 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.<br>• 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)*

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*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**—<br>• Patients with pulmonary hypertension but without resulting limitation of physical activity.<br>• Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or syncope. |
| **Class II**—<br>• Patients with pulmonary hypertension resulting in slight limitation of physical activity.<br>• They are comfortable at rest.<br>• Ordinary physical activity causes undue dyspnea or fatigue, chest pain, or syncope. |
| **Class III**—<br>• Patients with pulmonary hypertension resulting in marked limitation of physical activity.<br>• They are comfortable at rest.<br>• Less than ordinary activity causes undue dyspnea or fatigue, chest pain, or syncope. |
| **Class IV**—<br>• Patients with pulmonary hypertension with inability to carry out any physical activity without symptoms.<br>• These patients manifest signs of right heart failure.<br>• Dyspnea and/or fatigue may even be present at rest.<br>• 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:<br><br>• 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**<br>• The following collagen diseases: systemic lupus erythematosus, systemic deramtomyositis (ICD-9 710.0, 710.3, 710.4)?, **OR**<br>• Dermatologic diseases such as erythema multiforme, Stevens-Johnson syndrome (ICD-9 695.1, 695.13, 695.14)?, **OR**<br>• Ophthalmic diseases such as keratitis, iritis, uveitis, optic neuritis, or chorioretinitis (ICD-9 970, 364.0-364.3, 377.3, 363.2)?, **OR**<br>• 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?<br>• Medication lost<br>• Medication dose contaminated<br>• Increase in dose or decrease in dose<br>• Medication stolen<br>• Admission to a long term care facility<br>• Any other reasonable explanation? | Yes: Approve for date of service only<br>(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.<br>(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<br><br>AND<br><br>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)?<br>**AND**<br>2. Is the patient remaining compliant with the Phe-restricted diet? | **Yes:** Approve for 12 months | **No:** Deny for lack of treatment response. |

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

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

In addition to the recommended Phe concentrations, often, a 30% or more reduction in blood Phe is considered a clinically significant change from baseline and should occur after the initial trial.[2] If not, the patient is a nonresponder and will not benefit from Kuvan therapy.

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

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

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*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

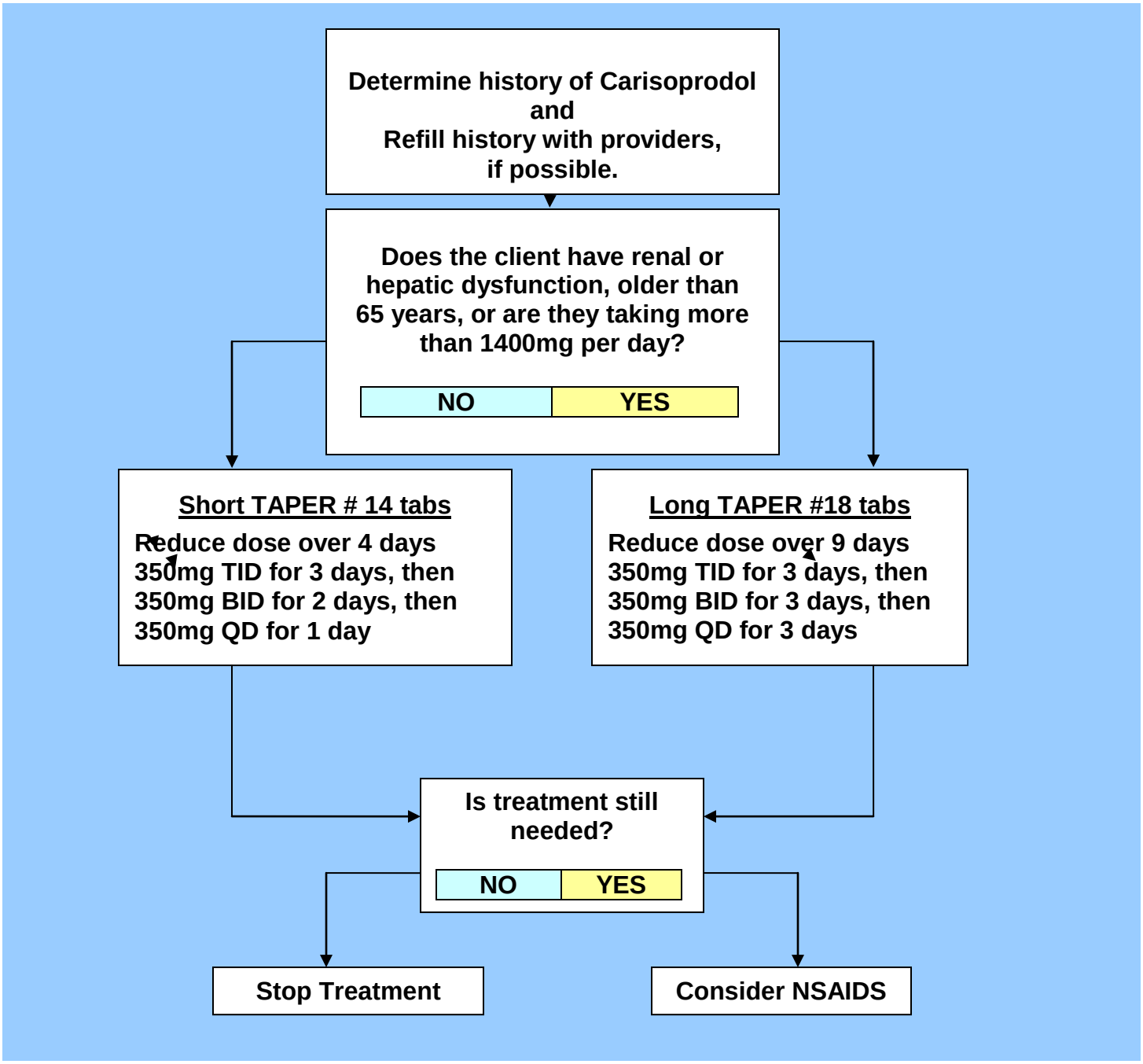
**Covered Alternatives:**

- 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?<br><br>Message:<br>• Preferred products do not require PA<br>• 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?<br><br>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:<br><br>• Carisoprodol cannot be approved for long term usage.<br>• Patients are limited to 56 tablets in a 90 day period.<br>• 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.<br>• The amount and length of taper depends upon the patient's condition. Does the patient meet one or more of the following?:<br>o >65 years old<br>o Renal Failure<br>o Hepatic failure<br><br>Take > 1400mg per day (>3.5 tablets) | Yes: Document reason and approve long taper:<br><br>• Authorize 18 tablets<br>• Reduce dose over 9 days<br>• 350mg TID X 3 days, then<br>• 350mg BID X 3 days, then<br>• 350mg QD x 3 days then evaluate | No: Approve short taper:<br><br>• Authorize 10 tablets<br>• Reduce dose over 4 days<br>• 350 mg tid x 1 day, then<br>• 350 mg bid x 2 days, then<br>• 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?<br><br>Message:<br>• Preferred products do not require a PA for initial treatment.<br>• 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?<br><br>Contraindications include:<br>• Renal disease or renal dysfunction<br>• Known hypersensitivity to therapies<br>• Acute or chronic metabolic acidosis<br>• Patients at increased risk of lactic acidosis (CHF, advanced age, impaired hepatic function)<br>• 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.*

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

# Synagis® (Palivizumab)

**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)?<br><br>* 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)<br><br>**Region** / **Counties**<br>**NW Oregon- SW Washington**: Benton, Clackamas, Clatsop, Columbia, Lane, Lincoln, Linn, Marion, Multnomah, Polk, Tillamook, Washington, Yamhill<br>**Central Oregon**: Crook, Deschutes, Grant, Harney, Jefferson, Wheeler<br>**Columbia Gorge – NE Oregon**: Baker,, Gilliam, Hood River, Morrow, Sherman, Umatilla, Union, Wasco, Wallowa<br>**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**<br>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:<br>a. bronchodilators<br>b. chronic corticosteroid therapy<br>c. home oxygen therapy<br>d. diuretics | Yes: Go to #12 | No: Go to #6 |
| 6. **GROUP B**<br>Does the patient have hemodynamically significant congenital heart disease (CHD) ICD9 746xx or 747xx and at least one of the following:<br>a. Receiving treatment for congestive heart failure or<br>b. Have moderate to severe pulmonary hypertension or<br>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**<br>Is the gestational age ≤ 28 weeks? | Yes: Go to #12 | No: Go to #9 |
| 9. **GROUP D**<br>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**<br>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**<br>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:<br>a. Daycare attendance<br>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.<br><br>**May approve for the following on a case by case basis:**<br>**a. > 5 doses or additional doses after March 31st.**<br>**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<br><br>Weight:_____<br>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 5$^{th}$ dose will be well above the protective concentration therefore five doses will provide more than 20 weeks of protection.

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*DUR/P&T Action:* *5/17/11 (DO/KK), 5/24/12 (KS)*
*Revision(s):* *3/30/12 (KS)*
*Initiated:* *8/20/12*

# 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)?<br><br>* 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?<br>**OR**<br>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?<br>**OR**<br>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?<br>• ICD-9 296 and subsets<br>• 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:<br>• Lithium<br>• Valproate and derivatives<br>• Lamotrigine<br>• Carbamazepine<br>• Atypical antipsychotic<br><br>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.<br><br>All other indications need to be evaluated for appropriateness:<br><br>• Neuropathic pain<br>• Post-Traumatic Stress Disorder (PTSD)<br>• Substance abuse | Use is off-label: Deny, (Medical Appropriateness) Other treatments should be tried as appropriate.<br><br>Below the line diagnoses: Deny, (Not covered by the OHP)<br><br>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.<br><br>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*