**Long-acting Opioid Analgesics**

**Goals:**
- Restrict use of long-acting opioid analgesics to OHP-funded conditions with documented sustained improvement in pain and function and with routine monitoring for opioid misuse and abuse.
- Restrict use of long-acting opioid analgesics for conditions of the back and/or spine due to evidence of increased risk vs. benefit.
- Promote the safe use of long-acting opioid analgesics by restricting use of high doses that have not demonstrated improved benefit and are associated with greater risk for accidental opioid overdose and death.

**Length of Authorization:**
90 days (except 12 months for end-of-life or cancer-related pain)

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

**Requires a PA:**
- All long-acting opioids and opioid combination products.

**Note:**
- Patients on palliative care with a terminal diagnosis or with cancer-related pain (ICD10 C6900-C799; C800-C802) are exempt from this PA.
- This PA does not apply to pediatric use of codeine products, which is subject to separate clinical PA criteria.

**Table 1. Daily Dose Threshold (90 Morphine Milligram Equivalents per Day) of Opioid Products.**

<table>
<thead>
<tr>
<th>Opioid</th>
<th>90 MME/day</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fentanyl (transdermal</td>
<td>37.5 mcg/hr</td>
<td>Use only in opioid-tolerant patients who have been taking ≥60 MME daily for a ≥1 week. Deaths due to a fatal overdose of fentanyl have occurred when pets, children and adults were accidentally exposed to fentanyl transdermal patch. Strict adherence to the recommended handling and disposal instructions is of the utmost importance to prevent accidental exposure.</td>
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<td></td>
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<tr>
<td>Hydrocodone</td>
<td>90 mg</td>
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<tr>
<td>Hydromorphone</td>
<td>22.5 mg</td>
<td></td>
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<tr>
<td>Morphine</td>
<td>90 mg</td>
<td></td>
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<tr>
<td>Oxycodone</td>
<td>60 mg</td>
<td></td>
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<tr>
<td>Oxymorphone</td>
<td>30 mg</td>
<td></td>
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<tr>
<td>Tapentadol</td>
<td>225 mg</td>
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<tr>
<td>Tramadol</td>
<td>300 mg</td>
<td>300 mg/day is max dose and is not equivalent to 90 MME/day.</td>
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<tr>
<td>Methadone*</td>
<td>20 mg</td>
<td>*DO NOT USE unless very familiar with the complex pharmacokinetic and pharmacodynamics properties of methadone. Methadone exhibits a non-linear relationship due to its long half-life and accumulates with chronic dosing. Methadone also has complex interactions with several other drugs. The dose should not be increased more frequently than once every 7 days. Methadone is associated with an increased incidence of prolonged QTc interval, torsades de pointe and sudden cardiac death.</td>
</tr>
<tr>
<td>Drug Product</td>
<td>Quantity Limit</td>
<td>Drug Product</td>
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<td>-------------------</td>
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<td>-------------------</td>
</tr>
<tr>
<td>AVINZA</td>
<td>1 dose/day</td>
<td>HYSINGLA ER</td>
</tr>
<tr>
<td>BELBUCA</td>
<td>2 doses/day</td>
<td>KADIAN</td>
</tr>
<tr>
<td>BUTTRANS</td>
<td>1 patch/7 days</td>
<td>MORPHABOND</td>
</tr>
<tr>
<td>EMBEDA</td>
<td>2 doses/day</td>
<td>NUCYNTA ER</td>
</tr>
<tr>
<td>EXALGO</td>
<td>1 dose/day</td>
<td>OXANNA ER</td>
</tr>
<tr>
<td>Fentanyl patch</td>
<td>1 dose/72 hr</td>
<td>TROXYCA ER</td>
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</tbody>
</table>

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

**Approval Criteria**

1. **What is the patient’s diagnosis?**
   - Record ICD10 code

2. **Is the diagnosis funded by the OHP?**
   - Yes: Go to #3
   - No: Pass to RPh. Deny; not funded by the OHP.
   - Note: Management of pain associated with back or spine conditions with long-acting opioids is not funded by the OHP*. Other conditions, such as fibromyalgia, TMJ, tension headache and pelvic pain syndrome are also not funded by the OHP.

3. **Is the requested medication a preferred agent?**
   - Yes: Go to #5
   - No: Go to #4

4. **Will the prescriber change to a preferred product?**
   - Yes: Inform prescriber of covered alternatives in class.
   - No: Go to #5
   - Note: Preferred opioids are reviewed and designated as preferred agents by the Oregon Pharmacy & Therapeutics Committee based on published medical evidence for safety and efficacy.

5. **Is the patient being treated for cancer-related pain (ICD10 G89.3) or under palliative care services (ICD10 Z51.5) with a life-threatening illness or severe advanced illness expected to progress toward dying?**
   - Yes: Approve for up to 12 months
   - No: Go to #6

6. **Is the prescriber enrolled in the Oregon Prescription Drug Monitoring Program (www.orpdmp.com) and has the prescriber verified at least once in the past 3 months that the patient has been prescribed opioid analgesics by only a single prescribing practice or prescriber?**
   - Yes: Go to #7
   - No: Pass to RPh. Deny; medical appropriateness

*Note: Management of opioid dependence is funded by the OHP.*
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<tr>
<td><strong>7. Is the prescription for pain associated with migraine or other type of headache?</strong></td>
<td><strong>Yes:</strong> Pass to RPh. Deny; medical appropriateness</td>
<td><strong>No:</strong> Go to #8</td>
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<tr>
<td>Note: there is limited or insufficient evidence for opioid use for many pain conditions, including migraine or other types of headache.</td>
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<td><strong>8. Does the total daily opioid dose exceed 90 MME (see Table 1)?</strong></td>
<td><strong>Yes:</strong> Pass to RPh. Deny; medical appropriateness. Note: Management of opioid dependence is funded by the OHP.</td>
<td><strong>No:</strong> Go to #9</td>
</tr>
<tr>
<td><strong>9. Is the patient concurrently on other short- or long-acting opioids (patients may receive a maximum of one opioid product regardless of formulation)?</strong></td>
<td><strong>Yes:</strong> Pass to RPh. Deny; medical appropriateness. Note: Management of opioid dependence is funded by the OHP.</td>
<td><strong>No:</strong> Go to #10</td>
</tr>
<tr>
<td>Note: There is insufficient evidence for use of concurrent opioid products (e.g., long-acting opioid with short-acting opioid).</td>
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<td><strong>10. Does the prescription exceed quantity limits applied in Table 2 (if applicable)?</strong></td>
<td><strong>Yes:</strong> Pass to RPh. Deny; medical appropriateness</td>
<td><strong>No:</strong> Go to #11</td>
</tr>
<tr>
<td><strong>11. Can the prescriber provide documentation of sustained improvement of at least 30% in pain, function, or quality of life in the past 3 months compared to baseline?</strong></td>
<td><strong>Yes:</strong> Go to #12 Document tool used and score vs. baseline: ________</td>
<td><strong>No:</strong> Pass to RPh. Deny; medical appropriateness. Note: Management of opioid dependence is funded by the OHP.</td>
</tr>
<tr>
<td>Note: Pain control, quality of life, and function can be quickly assessed using the 3-item PEG scale.**</td>
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<td><strong>12. Has the patient had a urinary drug screen (UDS) within the past 1 year to verify absence of illicit drugs and non-prescribed opioids?</strong></td>
<td><strong>Yes:</strong> Approve for up to 90 days.</td>
<td><strong>No:</strong> Pass to RPh. Deny; medical appropriateness. Note: Management of opioid dependence is funded by the OHP.</td>
</tr>
</tbody>
</table>

*See Guideline Note 60 within the Prioritized List of Health Services for conditions of coverage for pain associated with back or spine conditions: [http://www.oregon.gov/OHA/HPA/CSI-HERC/Pages/Prioritized-List.aspx](http://www.oregon.gov/OHA/HPA/CSI-HERC/Pages/Prioritized-List.aspx)*

**The PEG is freely available to the public [http://www.agencymeddirectors.wa.gov/Files/AssessmentTools/1-PEG%203%20item%20pain%20scale.pdf](http://www.agencymeddirectors.wa.gov/Files/AssessmentTools/1-PEG%203%20item%20pain%20scale.pdf).**

*Citation of the original publication: Krebs EE, Lorenz KA, Bair MJ, Damush TA, Wu J, Sutherland JM, Asch SM, Kroenke K. Development and initial validation of the PEG, a 3-item scale assessing pain intensity and interference. *Journal of General Internal Medicine*. 2009 Jun;24:733-738.*
Clinical Notes:
How to Discontinue Opioids.

Selecting the optimal timing and approach to tapering depends on multiple factors. The rate of opioid taper should be based primarily on safety considerations, and special attention is needed for patients on high dose opioids, as too rapid a taper may precipitate withdrawal symptoms or drug-seeking behavior. In addition, behavioral issues or physical withdrawal symptoms can be a major obstacle during an opioid taper. Patients who feel overwhelmed or desperate may try to convince the provider to abandon the taper. Although there are no methods for preventing behavioral issues during taper, strategies implemented at the beginning of chronic opioid therapy such as setting clear expectations and development of an exit strategy are most likely to prevent later behavioral problems if a taper becomes necessary.

1. Consider sequential tapers for patients who are on chronic benzodiazepines and opioids. Coordinate care with other prescribers (e.g. psychiatrist) as necessary. In general, taper off opioids first, then the benzodiazepines.
2. Do not use ultra-rapid detoxification or antagonist-induced withdrawal under heavy sedation or anesthesia (e.g. naxalone or naltrexone with propofol, methohexital, ketamine or midazolam).
3. Establish the rate of taper based on safety considerations:
   a. Immediate discontinuation if there is diversion or non-medical use,
   b. Rapid taper (over a 2 to 3 week period) if the patient has had a severe adverse outcome such as overdose or substance use disorder, or
   c. Slow taper for patients with no acute safety concerns. Start with a taper of ≤10% of the original dose per week and assess the patient’s functional and pain status at each visit.
4. Adjust the rate, intensity, and duration of the taper according to the patient’s response (e.g. emergence of opioid withdrawal symptoms (see Table below)).
5. Watch for signs of unmasked mental health disorders (e.g. depression, PTSD, panic disorder) during taper, especially in patients on prolonged or high dose opioids. Consult with specialists to facilitate a safe and effective taper. Use validated tools to assess conditions.
6. Consider the following factors when making a decision to continue, pause or discontinue the taper plan:
   a. Assess the patient behaviors that may be suggestive of a substance use disorder
   b. Address increased pain with use of non-opioid options.
   c. Evaluate patient for mental health disorders.
   d. If the dose was tapered due to safety risk, once the dose has been lowered to an acceptable level of risk with no addiction behavior(s) present, consider maintaining at the established lower dose if there is a clinically meaningful improvement in function, reduced pain and no serious adverse outcomes.
7. Do not reverse the taper; it must be unidirectional. The rate may be slowed or paused while monitoring for and managing withdrawal symptoms.
8. Increase the taper rate when opioid doses reach a low level (e.g. <15 mg/day MED), since formulations of opioids may not be available to allow smaller decreases.
9. Use non-benzodiazepine adjunctive agents to treat opioid abstinence syndrome (withdrawal) if needed. Unlike benzodiazepine withdrawal, opioid withdrawal symptoms are rarely medically serious, although they may be extremely unpleasant. Symptoms of mild opioid withdrawal may persist for 6 months after opioids have been discontinued (see Table below).
10. Refer to a crisis intervention system if a patient expresses serious suicidal ideation with plan or intent, or transfer to an emergency room where the patient can be closely monitored.
11. Do not start or resume opioids or benzodiazepines once they have been discontinued, as they may trigger drug cravings and a return to use.
12. Consider inpatient withdrawal management if the taper is poorly tolerated.

<table>
<thead>
<tr>
<th>Symptoms and Treatment of Opioid Withdrawal.</th>
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<tbody>
<tr>
<td>Restlessness, sweating or tremors</td>
</tr>
<tr>
<td>Nausea</td>
</tr>
<tr>
<td>Vomiting</td>
</tr>
<tr>
<td>Muscle pain, neuropathic pain or myoclonus</td>
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<tr>
<td>Insomnia</td>
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</tbody>
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P&T Review: 3/17 (MH); 11/16; 05/16
Implementation: Phase implementation initiated 8/21/17
Questions and answers about opioid coverage criteria effective August 21, 2017

Where can I find the new PA criteria for both short- and long-acting opioids?
On or after August 21, 2017, you can find the new PA criteria at www.orpdl.org/drugs under the “Analgesics” category.

Which opioids are restricted to 7 days or less for acute conditions?
Short-acting opioids such as hydrocodone/acetaminophen, oxycodone, and tramadol are restricted to 7 days or less for acute conditions. Long-acting opioids such as fentanyl and extended release morphine sulfate do not have this restriction.

You can find a comprehensive list of preferred and non-preferred short- and long-acting opioids on the Preferred Drug List (PDL) website.


Why are short-acting opioids restricted to 7 days or less for acute conditions?
This decision was based on the 2016 CDC guideline recommendations and will coincide with the Health Evidence Review Commission’s 2014 coverage guidance.

What criteria apply to both short- and long-acting opioids?
Criteria for both short- and long-acting opioids require:

■ A prescription that:
  — Is for a diagnosis which is funded by the OHP
  — Is not for pain associated with migraine or other type of headache, and
  — Does not exceed a total daily opioid dose of 90 morphine milligram equivalents (MME) per day.

■ Documented verification that the patient:
  — Is not high-risk for opioid misuse or abuse,
  — Is not concurrently on other short- or long-acting opioids, and
  — Has sustained improvement of at least 30 percent in pain, function, or quality of life in the past 3 months (compared to baseline).

Do the new criteria apply to cancer-related pain or palliative care services?
No. Besides requiring an OHP-funded diagnosis, the additional new prior authorization criteria requirements do not apply if a patient is:

■ Being treated for cancer-related pain (ICD-10 G89.3), or
■ Under palliative care services (ICD-10 Z51.5) with a life-threatening illness or severe advanced illness expected to progress toward dying.

Providing the ICD-10 diagnosis code on the prescription order and submitting it on the pharmacy claim may expedite the approval process.

Questions?

■ About pharmacy point of sale and prior authorizations for fee-for-service prescriptions: Call the Oregon Pharmacy Call Center at 1-888-202-2126.
■ About physical health prescriptions for patients in a coordinated care organization (CCO): Contact the CCO.