

Opioid Analgesics

Goals:

- Restrict use of opioid analgesics to OHP-funded conditions with documented sustained improvement in pain and function and with routine monitoring for opioid misuse and abuse.
- Promote the safe use of 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.
- Limit the use of non-preferred opioid analgesic products.

Length of Authorization:

3 to 12 months (criteria-specific)

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Requires a PA:

- All non-preferred opioids and opioid combination products.
- Any opioid listed in Table 1 or opioid combination product that contains an opioid listed in Table 1 that exceeds 90 morphine milligram equivalents (MME) per day.
- Any opioid product listed in Table 2 that exceeds quantity limits.

Note:

- Preferred opioid products that do not exceed 90 MME per day are exempt from this PA.
- 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 MME/day) of Opioid Products.

Opioid	Dose Threshold (90 MME/day)	Recommended starting dose for opioid-naïve patients	Considerations
<p>Note: Any opioid exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing an opioid and monitor all patients regularly for the development of these behaviors or conditions.</p>			
Codeine	600 mg/24 hours	30 mg q 4-6 hours	Codeine is a prodrug of morphine. Metabolism and conversion to morphine is subject so multiple polymorphisms in different populations. Subsequently, persons may be hypersensitive to the analgesic and respiratory effects of codeine or may be resistant to the effects of codeine. Dosing limits based on combinations (e.g., acetaminophen) may further limit the maximum daily dose.
Fentanyl (transdermal patch)	37.5 mcg/hour (q 72 hr)	12.5 mcg/hour q 72 hours	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.

Opioid	Dose Threshold (90 MME/day)	Recommended starting dose for opioid-naïve patients	Considerations
Hydrocodone	90 mg/24 hours	IR: 5-10 mg q 4-6 hours	Dosing limits based on combinations (e.g., acetaminophen) may further limit the maximum daily dose.
		ER: 10 mg q 12 hours	Use the ER formulation with extreme caution due to potentially fatal interaction with alcohol or medications containing alcohol. Accidental consumption of even 1 dose of the ER formulation, especially by children, can result in a fatal overdose.
Hydromorphone	22.5 mg/24 hours	IR: 2 mg q 4–6 hours	Hydromorphone is a potent opioid. Accidental ingestion of even one dose of hydromorphone ER, especially by children, can result in a fatal overdose of hydromorphone.
		ER 8 mg q 24 hours	
Methadone	20 mg/24 hours	2.5-5 mg BID or TID	Methadone is a very effective and inexpensive opioid but should be reserved to prescribers very familiar with the complex pharmacokinetic and pharmacodynamics variability of this drug. 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.
Morphine	90 mg/24 hours	IR 10 mg q 4 hours	Co-ingestion of alcohol with morphine ER may result in increased plasma levels and a potentially fatal overdose of morphine. Accidental ingestion of even one dose of morphine, especially by children, can result in a fatal overdose of morphine.
		ER 15 mg q 12 hours	

Oxycodone	60 mg/24 hours	IR: 5 mg q 4-6 hours	<p>Accidental ingestion of even one dose of oxycodone ER, especially by children, can result in a fatal overdose of oxycodone. The concomitant use of oxycodone ER with all cytochrome P450 (CYP-450) 3A4 inhibitors may result in an increase in oxycodone plasma concentrations, which could increase or prolong adverse drug effects and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used CYP3A4 inducer may result in an increase in oxycodone plasma concentration. Monitor patients receiving oxycodone ER and any CYP3A4 inhibitor or inducer.</p> <p>Avoid concurrent use of any products containing acetaminophen (maximum combined APAP dose = 4000 mg/day for <10 days or 2500 mg/day for ≥10 days)</p>
		ER: 10 mg q12 hours	
Oxymorphone	30 mg/24 hours	IR: 5–10 mg q 4-6 hours	<p>Accidental ingestion of even 1 dose of oxymorphone ER, especially by children, can result in a fatal overdose of oxymorphone.</p> <p>Instruct patients not to consume alcoholic beverages or use prescription or nonprescription products that contain alcohol while taking oxymorphone ER. Co-ingestion of alcohol with oxymorphone ER may result in increased plasma levels and a potentially fatal overdose of oxymorphone.</p>
		ER: 10 mg q 12 hours	
Tapentadol	225 mg/24 hours	IR: 50 mg q 4-6 hours	<p>Accidental ingestion of even one dose of tapentadol ER, especially by children, can result in a fatal overdose of tapentadol.</p> <p>Instruct patients not to consume alcoholic beverages or use prescription or nonprescription products that contain alcohol while taking tapentadol ER. Co-ingestion of alcohol with tapentadol ER may result in increased plasma tapentadol levels and a potentially fatal overdose of tapentadol.</p> <p>Tramadol also possesses SSRI-like properties and interacts with multiple drugs. Use with caution with other drugs that may increase risk of serotonin syndrome or decrease seizure threshold.</p>
		ER: 50 mg q 12 hours	
Tramadol	400 mg/24 hours (IR)	IR: 50 mg q 4-6 hours	<p>The threshold is based on maximum daily dosing for the IR and ER formulations. The threshold is not equivalent to 90 MME per day.</p> <p>Tramadol also possesses SSRI-like properties and interacts with multiple drugs. Use with caution with other drugs that may increase risk of serotonin syndrome or decrease seizure threshold.</p>
	300 mg/24 hours (ER)	ER: 100 mg per 24 hours	

Abbreviations: ER = extended-release or sustained-release formulation(s); IR = immediate-release formulation(s); MME = morphine milligram equivalent.

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

Drug Product	Quantity Limit	Drug Product	Quantity Limit	Drug Product	Quantity Limit
AVINZA	1 dose/day	HYSINGLA ER	2 doses/day	XTAMPZA ER	2 doses/day
BELBUCA	1 dose/day	KADIAN	2 doses/day	ZOHYDRO ER	2 doses/day
BUTRANS	1 patch/7 days	MORPHABOND	2 doses/day		
EMBEDA	2 doses/day	NUCYNTA ER	2 doses/day		
EXALGO	1 dose/day	OPANA ER	2 doses/day		
Fentanyl patch	1 dose/72 hrs	OXYCONTIN	2 doses/day		
		XARTEMIS XR	4 doses/day		

Approval Criteria

1. What is the patient's diagnosis?	Record ICD10	
2. Is the request for renewal of current therapy?	Yes: Go to Renewal Criteria	No: Go to #3
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? <u>Note:</u> Preferred opioids are reviewed and designated as preferred agents by the Oregon Pharmacy & Therapeutics Committee based on published medical evidence for safety and efficacy. Both oral and transdermal options are available.	Yes: Inform prescriber of covered alternatives in class.	No: Go to #5
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 diagnosis funded by the OHP?	Yes: Go to #7	No: Pass to RPh. Go to #15
7. Is the opioid prescription for pain associated with a back or spine condition or for migraine headache?	Yes: Pass to RPh. Go to #15	No: Go to #8
8. Will the prescriber change to a preferred product, not to exceed 90 MME per day and not to exceed quantity limits in Table 2? <u>Note:</u> Preferred products that do not exceed 90 MME per day and do not exceed quantity limits in Table 2 do not require prior authorization.	Yes: Inform prescriber of covered alternatives in class.	No: Go to #9
9. Does the total daily opioid dose exceed 90 MME?	Yes: Pass to RPh. Go to #15	No: Go to #10
10. Is the patient concurrently on other short- or long-acting opioids (patients are permitted to be on only one opioid product total at a time)?	Yes: Pass to RPh. Go to #15	No: Go to #11
11. Does the prescription exceed quantity limits applied in Table 2 (if applicable)?	Yes: Pass to RPh. Go to #15	No: Go to #12

<p>12. Can the prescriber provide documentation of sustained improvement of both pain and function in the past 3 months compared to baseline (e.g., validated tools to assess function include: Oswestry, Neck Disability Index, SF-MPQ, and MSPQ)?</p>	<p>Yes: Go to #13</p>	<p>No: Pass to RPh. Go to #15</p>
<p>13. Is the prescriber enrolled in the Oregon Prescription Drug Monitoring Program (PDMP) and has the prescriber verified at least once in the past 3 months that the patient has been prescribed analgesics by only a single prescribing practice or prescriber and has received those analgesics by only a single pharmacy?</p>	<p>Yes: Go to #14</p>	<p>No: Pass to RPh. Go to #15</p>
<p>14. Has the patient had a urinary drug screen (UDS) within the past 1 year to verify absence of illicit drugs and non-prescribed opioids?</p>	<p>Yes: Approve for up to 3 months. Subsequent approvals will require:</p> <ul style="list-style-type: none"> • Verification of patient's opioid claims history in the Oregon PDMP at least every 3 months • Documentation of sustained improvement in both baseline pain and function at least every 3 months • Documented UDS at least every 12 months 	<p>No: Pass to RPh. Go to #15</p>
<p>15. Is the request to initiate new opioid therapy or to increase the total daily MME dose?</p>	<p>Yes: Pass to RPh. Deny; medical appropriateness.</p>	<p>No: Pass to RPh. Approve for 3 months.</p> <p><u>Note:</u> Documentation of progress towards meeting all criteria in this PA will be required for approval of subsequent claims. All future opioid claims are subject to Renewal Criteria 3 months from this index claim.</p>

Renewal Criteria

<p>1. Has the patient had a urinary drug screen (UDS) within the past 1 year to verify absence of illicit drugs and non-prescribed opioids?</p>	<p>Yes: Go to #2</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>2. Is the prescriber enrolled in the Oregon Prescription Drug Monitoring Program (PDMP) and has the prescriber verified at least once in the past 3 months that the patient has been prescribed analgesics by only a single prescribing practice or prescriber and has received those analgesics by only a single pharmacy?</p>	<p>Yes: Go to #3</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>3. Can the prescriber provide documentation of sustained improvement of both pain and function in the past 3 months compared to baseline (e.g., validated tools to assess function include: Oswestry, Neck Disability Index, SF-MPQ, and MSPQ)?</p>	<p>Yes: Go to #4</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>4. Does the prescription exceed quantity limits applied in Table 2 (if applicable)?</p>	<p>Yes: Approve for up to 3 months if there is documentation of an individualized taper plan with progress to meet the quantity limits applied in Table 2.</p>	<p>No: Go to #5 if not applicable. Without documentation, pass to RPh. Deny; medical appropriateness.</p>
<p>5. Is the patient concurrently on other short- or long-acting opioids (patients are permitted to be on only one opioid product total at a time)?</p>	<p>Yes: Approve for up to 3 months if there is documentation of an individualized taper plan with progress to be managed on one short- or long-acting opioid only.</p>	<p>No: Go to #6 if not applicable. Without documentation, pass to RPh. Deny; medical appropriateness.</p>
<p>6. Does the total daily opioid dose exceed 90 MME?</p>	<p>Yes: Approve for up to 3 months if there is documentation of an individualized taper plan with progress toward meeting ≤ 90 MME per day.</p>	<p>No: Go to #7 if not applicable. Without documentation, pass to RPh. Deny; medical appropriateness.</p>

Renewal Criteria

7. Is the diagnosis funded by the OHP?

Yes: Approve for up to 3 months. Subsequent approvals will require:

- Verification of patient's opioid claims history in the Oregon PDMP at least every 3 months
- Documentation of sustained improvement in both baseline pain and function at least every 3 months
- Documented UDS at least every 12 months

No: Approve for up to 3 months if there is documentation of an individualized taper plan with progress toward tapering off opioid.

Without documentation, pass to RPh. Deny; medical appropriateness.

P&T Review: 05/16 (AG)

Implementation: TBD