

## Criteria for Nonformulary Use Oxymorphone Oral Tablets

VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel

*These criteria were based on the best clinical evidence currently available. The recommendations in this document are dynamic, and will be revised as new clinical information becomes available. This guidance is intended to assist practitioners in providing consistent, high-quality, cost-effective drug therapy. These criteria are not intended to interfere with clinical judgment; the clinician must ultimately decide the course of therapy based on individual patient situations.*

Criteria for Use	Yes	No									
<b>Patient must meet all of the following criteria to use oxymorphone oral tablets.</b>											
Patient has moderate to severe pain	<input type="checkbox"/>	<input type="checkbox"/>									
Patient is able to take oral solid medications (intact tablets)	<input type="checkbox"/>	<input type="checkbox"/>									
Patient has had documented intolerable adverse effects to ALL of the opioids listed below (according to oxymorphone formulation), and the adverse effects persisted despite aggressive measures to alleviate them and prevented upward titration of dosage to achieve a satisfactory level of analgesia.	<input type="checkbox"/>	<input type="checkbox"/>									
<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; border-bottom: 1px solid black;">Oxymorphone formulation</th> <th style="text-align: left; border-bottom: 1px solid black;">Prior opioid trials required</th> <th style="border-bottom: 1px solid black;"></th> </tr> </thead> <tbody> <tr> <td style="border-right: 1px solid black; vertical-align: top;">                     Immediate-release tablet                 </td> <td style="border-right: 1px solid black; vertical-align: top;">                     Hydrocodone / Acetaminophen Morphine Oxycodone Hydromorphone                 </td> <td style="vertical-align: top;">                     * Methadone should ideally be initiated by or in consultation with a practitioner who has knowledge in titration of this agent. In situations where there is no practitioner or consultant with experience in using methadone for chronic pain, another long-duration opioid may be used until such consultation can be obtained. Also refer to <b>Methadone Dosing Recommendations for Treatment of Chronic Pain</b> available at <a href="http://www.pbm.va.gov">http://www.pbm.va.gov</a>.                 </td> </tr> <tr> <td style="border-right: 1px solid black; vertical-align: top;">                     Extended-release tablet                 </td> <td style="border-right: 1px solid black; vertical-align: top;">                     Morphine Methadone (see exception*) Oxycodone Fentanyl transdermal Levorphanol (nonformulary)                 </td> <td style="vertical-align: top;"></td> </tr> </tbody> </table>	Oxymorphone formulation	Prior opioid trials required		Immediate-release tablet	Hydrocodone / Acetaminophen Morphine Oxycodone Hydromorphone	* Methadone should ideally be initiated by or in consultation with a practitioner who has knowledge in titration of this agent. In situations where there is no practitioner or consultant with experience in using methadone for chronic pain, another long-duration opioid may be used until such consultation can be obtained. Also refer to <b>Methadone Dosing Recommendations for Treatment of Chronic Pain</b> available at <a href="http://www.pbm.va.gov">http://www.pbm.va.gov</a> .	Extended-release tablet	Morphine Methadone (see exception*) Oxycodone Fentanyl transdermal Levorphanol (nonformulary)			
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Patient is under the care of a pain management specialist.	<input type="checkbox"/>	<input type="checkbox"/>									
<p><i>It is recommended that providers ask patients to review and sign an Opioid Agreement. Providers should also advise patients to take oxymorphone tablets consistently on an empty stomach, avoid alcohol consumption during therapy with oxymorphone tablets, and inform their provider if they are unable to adhere to these precautions.</i></p>											

Exclusions	Yes	No
<b>Patient should not receive oxymorphone if any of the following criteria are met.</b>		
Applicable to both immediate- and extended-release tablets		
Patient has mild pain	<input type="checkbox"/>	<input type="checkbox"/>
Patient has decreased consciousness or gastrointestinal obstruction	<input type="checkbox"/>	<input type="checkbox"/>
Patient has a documented or suspected contraindication (e.g., drug hypersensitivity) to the use of oxymorphone or morphine analogs, or contraindication to other opioids (e.g., significant respiratory depression (without resuscitative equipment or careful medical monitoring), acute or severe bronchial asthma or hypercarbia, or known or suspected paralytic ileus).	<input type="checkbox"/>	<input type="checkbox"/>
Patient has moderate or severe hepatic impairment	<input type="checkbox"/>	<input type="checkbox"/>

*continued*

Exclusions (continued)	Yes	No
Applicable to immediate-release tablets only		
Initial dose is more than 20 mg in patients considered to be opioid naïve. <i>Single doses of 30 mg did not provide additional benefit over 20 mg and were associated with a higher incidence of naloxone use postoperatively.</i>	<input type="checkbox"/>	<input type="checkbox"/>
Applicable to extended-release tablets only:		
Patient requires tablets to be broken, chewed, crushed, or dissolved before administration	<input type="checkbox"/>	<input type="checkbox"/>
Patient is not expected to have pain for an extended period of time (e.g., more than several days)	<input type="checkbox"/>	<input type="checkbox"/>
Patient is not previously taking the drug and requires rapid onset of analgesia for pain in the immediate post-operative period (first 12 to 24 h after surgery) or does not have moderate to severe postoperative pain that is expected to persist for an extended period of time	<input type="checkbox"/>	<input type="checkbox"/>
Patient only requires rapid onset of analgesia, such as in the treatment of acute pain, incident pain (episodic increases in chronic pain intensity that may or may not be related to movement or activity), or breakthrough pain (chronic pain that is inadequately treated);	<input type="checkbox"/>	<input type="checkbox"/>
Patient only requires an as-needed (p.r.n.) analgesic	<input type="checkbox"/>	<input type="checkbox"/>
Co-ingestion of alcohol, including alcohol contained in nonprescription or prescription medications <i>Alcohol may increase oxymorphone plasma levels and the risk of potentially fatal toxicity.</i>	<input type="checkbox"/>	<input type="checkbox"/>