

## Medical Policy



### Title: Oxycodone Extended Release (ER)

#### For information concerning Prior Authorization Prescription Drugs:

[http://www.bcbsks.com/CustomerService/PrescriptionDrugs/prior\\_authorization.htm](http://www.bcbsks.com/CustomerService/PrescriptionDrugs/prior_authorization.htm)

#### Prior Authorization Form:

[http://www.bcbsks.com/CustomerService/Forms/pdf/OxyContin\\_PriorAuth.pdf](http://www.bcbsks.com/CustomerService/Forms/pdf/OxyContin_PriorAuth.pdf)

#### Link to Drug List (Formulary):

[http://www.bcbsks.com/CustomerService/PrescriptionDrugs/drug\\_list.htm](http://www.bcbsks.com/CustomerService/PrescriptionDrugs/drug_list.htm)

#### Professional

Original Effective Date: December 2004

Revision Date(s): December 1, 2011;  
July 1, 2012; June 10, 2013

Current Effective Date: June 10, 2013

#### Institutional

Original Effective Date: January 3, 2012

Revision Date(s): July 1, 2012;  
June 10, 2013

Current Effective Date: June 10, 2013

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The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

**DESCRIPTION**

The intent of the quantity limit for oxycodone extended-release (ER) is to allow for quantities that permit dose choices that individualize the treatment plan for chronic pain to the needs of the patient. Requests for larger quantities will be reviewed if the prescriber provides evidence that the requested dose is appropriate for the patient.

**FDA Approved Indications and Dosage**

Drug	Indication	Dosage
<b>Oxycodone extended release tablets (Oxycontin):</b> 10mg, 15mg, 20mg, 30mg, 40mg, 60mg, 80mg	Management of moderate-to-severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time ( not to be used as a prn analgesic)	<u>Opiate-naive patients</u> <ul style="list-style-type: none"> <li>Initially 10 mg every 12 hours. Dosage adjustments may be carried out every 1-2 days based upon the total amount of oxycodone/day required (controlled-release dose + breakthrough doses). It is most appropriate to increase the dose rather than the dosing frequency.</li> </ul> <u>Opioid-tolerant patients*</u> <ul style="list-style-type: none"> <li>Determine total daily dose of the other opiate agonist and convert to an equivalent total daily dose of oral oxycodone. There is no maximum dose of oxycodone; however, careful titration of oxycodone is required until tolerance develops to some of the side effects (i.e., drowsiness and respiratory depression). Individualize dosage carefully.</li> </ul>

\*60 mg and 80 mg for use in opioid-tolerant patients only; prn = as needed

**POLICY****Prior Authorization Criteria for Approval**

Quantities above the program set limit for **oxycodone ER** will be approved when ONE of the following is met:

1. The oxycodone ER is being prescribed for treatment of cancer-related pain  
**OR**
2. The oxycodone ER is being used more often than every 12 hours AND ALL of the following:
  - a. The patient has tried restricting dosing to every 12 hours  
**AND**
  - b. ONE of the following:
    - i. The prescriber has considered administration of immediate-release forms of medication between the controlled-release doses  
**OR**

- ii. The physician considers a dosing interval of less than 12 hours the most beneficial option for controlling pain in this patient
- AND**
- c. The prescriber has submitted documentation in support of use more often than every 12 hours for the intended diagnosis
- OR**
- 3. The oxycodone ER is not being used more often than every 12 hours AND BOTH of the following:
    - a. The quantity (dose) requested cannot be achieved using a lesser quantity of a higher strength

**AND**

    - b. The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis

**Length of Approval:** 1 month for dose titration requests  
12 months for all other requests

#### Quantity Limit Target Drugs – Recommended Limits

Brand (generic)	Quantity Per Day Limit
10 mg tablet	2 tablets
15 mg tablet	2 tablets
20 mg tablet	2 tablets
30 mg tablet	2 tablets
40 mg tablet	2 tablets
60 mg tablet	2 tablets
80 mg tablet	4 tablets

#### **RATIONALE**

Opioid analgesics, including oxycodone ER, are widely accepted for the treatment of severe acute pain and chronic pain related to active cancer or at the end of life.<sup>2,3</sup> Use of opioids to treat chronic noncancer pain remains controversial although guidelines conclude that chronic opioid therapy can be an effective therapy if patients are carefully selected and monitored and benefits are balanced with risks.<sup>2,3</sup>

#### **Safety**

Pharmacological effects of opioid agonists include anxiolysis, euphoria, feelings of relaxation, respiratory depression, constipation, miosis, and cough suppression, as well as analgesia. With pure opioid agonist analgesics, there is no defined maximum dose; the ceiling to analgesic effectiveness is imposed only by side effects, the more serious of which may include somnolence and respiratory depression.<sup>1</sup> The oxycodone product labeling contains a boxed warning detailing abuse potential of Schedule II controlled substances as well as adverse effects.<sup>1</sup>

An education program has been developed (and mandated by the FDA) to provide healthcare professionals with important safety information about oxycodone products. The Healthcare Provider training program consists of three steps:

- First, read the Dear Healthcare Professional Letter which describes the goals of the oxycodone Risk Evaluation Mitigation Strategy (REMS) and is designed to convey and reinforce risks associated with oxycodone.
- Second, read the Healthcare Provider Training Guide specifically designed to concisely describe the potential risks of abuse, misuse, overdose, and addiction from exposure to oxycodone.
- Third, complete the Education Confirmation Form to acknowledge and verify your understanding of the safe use of oxycodone.<sup>5</sup>

Oxycodone ER tablets are designed to provide controlled delivery of oxycodone over 12 hours for the management of moderate to severe pain that requires a continuous around-the-clock analgesic for an extended period of time.<sup>1</sup> For the patients who experience breakthrough pain and require dosage adjustments or rescue medication, product labeling recommends an increase in the every 12-hour dose rather than the dosing frequency. There is no clinical information on dosing intervals shorter than every 12 hours.<sup>1</sup>

The National Comprehensive Cancer Network Guideline v2. 2012: Adult Cancer Pain states that adding a long acting opioid formulation is recommended to provide background analgesia for control of chronic persistent pain controlled on stable doses of short acting opioids.<sup>4</sup>

## **REVISIONS**

12-01-2011	Policy added to the bcbsks.com web site.
07-01-2012	Added FDA Approved Indications and Dosage chart
	In Policy section: <ul style="list-style-type: none"> <li>▪ Removed from 2 c and 3 b the following wording: "which has been reviewed and approved by the Clinical Review pharmacist" as this is the process for all components of the medical policy criteria and not unique to 2 c and 3 b</li> <li>▪ Revised Length of Approval from: "Indefinite" to "Length of Approval: 1 month for dose titration requests Indefinite for all other requests"</li> </ul>
	Rational section added
	References updated
06-10-2013	Revised title from "Oxycodone Extended Release (ER) Quantity Limit Criteria" to "Oxycodone Extended Release (ER)"
	In Policy section: <ul style="list-style-type: none"> <li>▪ Revised the Length of Approval from "Indefinite for all other requests" to "12 months for all other requests"</li> <li>▪ Revised the Quantity Limit Target Drugs chart to remove the GPI column.</li> </ul>
	Rationale section updated
	References updated

**REFERENCES**

1. Oxycontin Prescribing Information. Purdue Pharma, L.P, Stamford, CT. November 2010.
2. Chou R, Fanciullo GJ, Fine PG, et al. Opioid Treatment Guidelines. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *The Journal of Pain* 2009;10(2):113-130.
3. Trescot AM, Hansen H, Benyamin R, et al. Opioids in the management of chronic non-cancer pain: An update of American Society of the Interventional Pain Physicians' (ASIPP) Guidelines. *Pain Physician* 2008;11:S5-S62.
4. National Comprehensive Cancer Network Guideline: Adult cancer pain. V2.2012 Available at: [www.NCCN.org](http://www.NCCN.org) . Accessed 2012.
5. Oxycontin Risk Evaluation Mitigation Strategy Website. Available at: <http://www.oxycontinrems.com/hcp.aspx> . Accessed October 5, 2011.