

**Regence BlueCross BlueShield of Oregon • Regence BlueShield  
Regence BlueCross BlueShield of Utah • Regence BlueShield of Idaho  
Independent licensees of the Blue Cross and Blue Shield Association**

**Medication Policy Manual**

**Policy No:** dru042

**Topic:** OxyContin<sup>®</sup>, oxycodone, Controlled-Release  
**Date of Origin:** September 2001

**Revised/Effective Date:** November 14, 2008      **Next Review Date:** November 2009

**IMPORTANT REMINDER**

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

**Description**

Oxycodone, controlled-release (OxyContin<sup>®</sup>) is a potent narcotic pain reliever. It is intended for use in patients with cancer or those suffering from severe, debilitating chronic pain.

## **Policy/Criteria**

- I.** Most contracts do not require prior authorization approval of oxycodone, controlled-release prior to coverage of quantities less than or equal to 160 mg daily.
  
- II.** Oxycodone, controlled-release in quantities exceeding 160 mg daily may be considered medically necessary when either criterion A or B below is met:
  - A.** The member has a diagnosis of cancer, the member is enrolled in a hospice program, or the member meets hospice criteria.

### **OR**

- B.** The member is undergoing treatment of chronic non-cancer pain and all of the following criteria in 1, 2, 3, and 4 are met:
  - 1.** The prescribing physician, prior to the initiation of chronic opioid therapy, performs a formal, consultative evaluation including:
    - a.** Diagnosis.
    - b.** A physical examination with findings that correlate with the diagnosis and severity of symptoms.
    - c.** A complete medical history which includes:
      - i.** Diagnostic studies.
      - ii.** Previous non-opioid medications; dates and duration of treatment and documentation that they have not been adequate to meet goals of pain management.
      - iii.** Previous non-pharmacological therapy that has not been adequate to meet the goals of pain management.

### **AND**

2. A written treatment plan including goals used to determine treatment successes, such as pain relief and improved physical and psychosocial function, is documented prior to the initiation of chronic opioid therapy. Documentation of functional status and levels of pain at baseline and during treatment should be as objective as possible. An example of an objective measure is the RAND 36-Item Short Form Health Survey (SF-36) (see Appendix 1).

**AND**

3. An opioid treatment agreement is signed by the prescribing physician and patient prior to the initiation of chronic opioid therapy. The agreement should include information regarding the risks associated with chronic opioid therapy, conditions under which opioids will be prescribed, the physician's need to document improvement in pain and function and the patient's responsibilities (see Appendices 2-4).

**AND**

4. The prescription, dispensing, or administration of controlled substances are in compliance with applicable federal and state statutes and regulations.

### **III. Administration and Authorization Period**

- A. Regence considers oxycodone, controlled-release to be a self-administered medication.
- B. Authorization shall be reviewed at least every six months to confirm that current medical necessity criteria are met and that the medication is effective for chronic non-cancer pain. Authorization may be renewed if all of the following criteria in 1, 2, 3 and 4 are met:
  1. Member demonstrates measurable progress towards treatment goals after the initiation of chronic opioid therapy. Objective measurements such as the SF-36 are encouraged to document baseline pain and functional status as well as subsequent clinical response.

**AND**

2. Accurate medication records, including date, type, dosage and quantity prescribed, are maintained by the prescribing physician and correspond with medical reasons for continuing or modifying therapy.

**AND**

3. Non-pharmacological therapies are used as indicated in combination with chronic opioid therapy. These therapies may include physical therapy, exercise, or psychological or psychiatric treatment.

**AND**

4. The prescription, dispensing, or administration of controlled substances are in compliance with applicable federal and state statutes and regulations.

## **Position Statement**

### *Summary*

- Controlled-release oxycodone is effective in reducing chronic non-cancer pain but is accompanied by clinically significant adverse effects.
- There is no reliable evidence that one opioid is more effective or safer than another.<sup>[24]</sup>
- Common flaws in clinical trials of pain medications include high drop-out rates (30% or more), subjective and non-validated endpoints, and population studied not representative of patients in clinical practice. These flaws make results unreliable.
- Controlled-release oxycodone has had an inconsistent effect on the quality of life in patients suffering from chronic pain in clinical studies.
- Like other long-acting narcotic analgesics, oxycodone, controlled-release (OxyContin) labeling includes a Black Box Warning to emphasize the potential for accidental overdose, misuse, abuse and diversion.
- Oxycodone, controlled-release is formulated to deliver the opioid analgesic oxycodone over twelve hours, which facilitates convenient dosing, steady blood levels, and consistent pain control.

- Patients may have pain relief, or find that medications are even more effective, when non-medication treatments are used. Some examples include: <sup>[23]</sup>
  - \* Regular exercise: Whenever advised by a physician, exercise can gradually increase general fitness, strength, coordination, range of flexibility and motion, postural and muscle balance. Exercise may include regular walks, swimming, or gentle stretching.
  - \* Healthy sleep habits: Good sleep habits include maintaining a structured sleep schedule (avoid napping, go to sleep at the same time each night, etc.), creating a comfortable sleep environment (reduce noise, lighting, temperature, etc.), and preparing well for sleep (avoid caffeine and large meals close to bedtime, take a warm bath, etc.).
  - \* Relaxation techniques: Some examples include listening to soothing music, meditation, yoga, Tai Chi, deep breathing, visualization, and progressive muscle relaxation.

### *Clinical Efficacy*

- Six studies directly compared multiple doses of controlled-release oxycodone with controlled-release morphine and found equal effectiveness. <sup>[14-17, 26-29]</sup>
- Two studies found that controlled-release oxycodone produced no improvement in quality of life or mood when validated tests were used. <sup>[18, 20]</sup> One unreliable study identified a positive effect, but over one-third of patients dropped out because of adverse effects. <sup>[21]</sup>
- Controlled-release oxycodone has not demonstrated a consistent clinical benefit over immediate-release oxycodone in chronic pain in five clinical studies. <sup>[9-13]</sup>
  - \* All studies have proven equal effectiveness.
  - \* The majority of studies have found no difference in adverse effects.

### *Safety*

- In clinical trials, 1 of 4 (or more) patients dropped out due to adverse effects.
- Constipation is one of most common adverse effects, and does not improve over time.
- Adverse effects resulting from long term use include immunologic effects, hormonal changes, and hyperalgesia.
- Numerous reports of inappropriate use, abuse, and diversion (some which resulted in death)

led the Food and Drug Administration to strengthen the warnings and precautions in the labeling of oxycodone, controlled-release in the form of a Black Box Warning.

- Breaking, chewing or crushing oxycodone CR (OxyContin) tablets eliminates the controlled delivery mechanism. This can result in the rapid release and absorption of a potentially fatal dose of oxycodone. <sup>[2]</sup>

<b>Appendix 1: RAND 36-Item Short Form Health Survey (SF-36)</b>	
-	Click <a href="#">HERE</a> to access SF-36 survey.
-	Click <a href="#">HERE</a> to access SF-36 scoring tool.

<b>Appendix 2: Pain Contract, Treatment Agreements</b>	
<b>Federation of State Medical Boards Model Pain Guidelines:</b>	
"The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including:	
-	urine/serum medication levels screening when requested;
-	number and frequency of all prescription refills; and
-	reasons for which drug therapy may be discontinued (i.e., violation of agreement)."
Sample opioid contracts can be found at: <a href="http://www.ohsu.edu/ahec/pain/form.html">http://www.ohsu.edu/ahec/pain/form.html</a>	

### Appendix 3: Examples of Improved Physical and Psychosocial Functioning

-	Ability to work.
-	Reduced need for healthcare resources.
-	Ability to perform activities of daily living.
-	Quality of life, including the ability to undertake specific activities (patient is able to enjoy hobbies again, etc.).

### Appendix 4: State Guidelines, Administrative Rules, and Statutes Regarding Chronic Opioid Therapy for Non-Malignant Pain

-	FEDERATION OF STATE MEDICAL BOARDS: <a href="http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf">http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf</a>
-	IDAHO: <a href="http://www.bom.state.id.us/licensees/opioids.html">http://www.bom.state.id.us/licensees/opioids.html</a>
-	OREGON: <a href="http://www.oregon.gov/BME/topics.shtml#INTRACTABLE_PAIN_AND_PAIN_MANAGEMENT">http://www.oregon.gov/BME/topics.shtml#INTRACTABLE_PAIN_AND_PAIN_MANAGEMENT</a>
-	UTAH: <a href="http://www.medsch.wisc.edu/painpolicy/domestic/utmbguid2.htm">www.medsch.wisc.edu/painpolicy/domestic/utmbguid2.htm</a>
-	WASHINGTON: <a href="http://www.lni.wa.gov/ClaimsIns/Files/OMD/MedTreat/MedTreatGuidelines.pdf">http://www.lni.wa.gov/ClaimsIns/Files/OMD/MedTreat/MedTreatGuidelines.pdf</a> <a href="http://www.lni.wa.gov/ClaimsIns/Providers/Treatment/Presc/Policy/Opioid/default.asp">http://www.lni.wa.gov/ClaimsIns/Providers/Treatment/Presc/Policy/Opioid/default.asp</a>

### References

1. Anon. Management of cancer pain: adults. *Am J Hosp Pharm* 1994;51:1643-56
2. OxyContin Product Information. Purdue Pharma L.P. Stamford CT. September 2007.
3. World Health Organization. "Cancer pain relief and palliative care: a report of a WHO expert committee." Geneva, Switzerland: World Health Organization 1990
4. Reder RF et al. "Steady-state bioavailability of controlled-release oxycodone in normal subjects." *Clin Ther* 1996;18(1):95-105

5. Kaiko RF. "Pharmacokinetics and pharmacodynamics of controlled-release opioids." *Acta Anaesthesiol Scand* 1997;41:166-174.
6. Benziger et al. "A pharmacokinetic/pharmacodynamic study of controlled-release oxycodone." *J Pain Symptom Manage*. 1997;13(2):75-82.
7. AHRQ Cancer Pain Management of Cancer Pain. Summary, Evidence Report/Technology Assessment: Number 35. AHRQ Publication No. 01-E033, January 2001. Agency for Healthcare Research and Quality, Rockville, MD.  
<http://www.ahrq.gov/clinic/canpainsum.htm>
8. Montauk SL, Martin J. "Treating Chronic Pain." *Amer Fam Physician* 1997;55(4):1151-60.
9. Caldwell JR et al. "Treatment of osteoarthritis pain with controlled release oxycodone or fixed combination oxycodone plus acetaminophen added to nonsteroidal anti-inflammatory drugs: a double blind, randomized, multicenter, placebo controlled trial." *J Rheumatol*. 1999;26(4):862-9.
10. Hale ME et al. "Efficacy and safety of controlled-release versus immediate-release oxycodone: randomized, double-blind evaluation in patients with chronic back pain." *Clin J Pain*. 1999;15(3):179-83.
11. Salzman RT et al. "Can a controlled-release oral dose form of oxycodone be used as readily as an immediate-release form for the purpose of titrating to stable pain control?" *J Pain Symptom Manage*. 1999;18(4):271-9.
12. Parris WC et al. "The use of controlled-release oxycodone for the treatment of chronic cancer pain: a randomized, double-blind study." *J Pain Symptom Manage*. 1998;16(4):205-11.
13. Kaplan R et al. "Comparison of controlled-release and immediate-release oxycodone tablets in patients with cancer pain." *J Clin Oncol*. 1998;16(10):3230-7.
14. Bruera E et al. "Randomized, double-blind, cross-over trial comparing safety and efficacy of oral controlled-release oxycodone with controlled-release morphine in patients with cancer pain." *J Clin Oncol*. 1998;16(10):3222-9.
15. Mucci-LoRussa P et al. "Controlled-release oxycodone compared with controlled-release morphine in the treatment of cancer pain: a randomized, double-blind, parallel-group study." *Eur J Pain*. 1998;2(2):239-249.

16. Heiskanen T, Kalso E. "Controlled-release oxycodone and morphine in cancer related pain." *Pain*. 1997;73(1):37-45.
17. Curtis GB, Johnson GH, Clark P, et al. Relative potency of controlled-release oxycodone and controlled-release morphine in a postoperative pain model. *Eur J Clin Pharmacol* 1999;55:425-9.
18. Watson CPN, Babul N. "Efficacy of oxycodone in neuropathic pain: a randomized trial in postherpetic neuralgia." *Neurology*. 1998;50(6):1837-41.
19. Portenoy RK. "Chronic opioid therapy in nonmalignant pain." *J Pain Symptom Manage*. 1990;5(1 Suppl):S46-62.
20. Roth et al. "Around-the-clock, controlled-release oxycodone therapy for osteoarthritis-related pain: placebo-controlled trial and long-term evaluation." *Arch Intern Med*. 2000;160(6):853-60.
21. Markenson JA, Croft J, Zhang PG, and Richards P. Treatment of persistent pain associated with osteoarthritis with control-release oxycodone tablets in a randomized controlled clinical trial. *Clin J Pain*. 2005; 21 (6): 524-534.
22. Rand Health web site. Available at:  
[http://www.rand.org/health/surveys\\_tools/mos/mos\\_core\\_36item\\_survey.html](http://www.rand.org/health/surveys_tools/mos/mos_core_36item_survey.html). Accessed 8/13/2007.
23. Sanders SH, Harden RN, Vicente PJ. Evidence-based clinical practice guideline for interdisciplinary rehabilitation of chronic non-malignant pain syndrome patients. Chattanooga (TN): Siskin Hospital for Physical Rehabilitation; 2005. 41 p.
24. Chou R. Drug Class Review on Long-Acting Opioid Analgesics. Final Report. 2006 from the OHSU Evidence-based Practice Center. Available at  
[http://www.oregon.gov/OHPPR/HRC/docs/HRC\\_Reports/OPIOID\\_HRC.pdf](http://www.oregon.gov/OHPPR/HRC/docs/HRC_Reports/OPIOID_HRC.pdf) accessed September 31, 2008
25. Matsumoto AK, Babul N, Ahdieh H. Oxymorphone extended-release tablets relieve moderate to severe pain and improve physical function in osteoarthritis: results of a randomized, double-blind, placebo- and active-controlled phase III trial. *Pain Med*. 2005 Sep-Oct;6(5):357-66.

26. Rauck RL, Bookbinder SA, Bunker TR, Alftine CD, Gershon S, de Jong E et al. A randomized, open-label, multicenter trial comparing once-a-day AVINZA (morphine sulfate extended-release capsules) versus twice-a-day OxyContin (oxycodone hydrochloride controlled-release tablets) for the treatment of chronic, moderate to severe low back pain: improved physical functioning in the ACTION trial. *J Opioid Manag.* 2007 Jan-Feb;3(1):35-43.
27. Rauck RL, Bookbinder SA, Bunker TR, Alftine CD, Ghalie R, Negro-Vilar A et al. A randomized, open-label study of once-a-day AVINZA (morphine sulfate extended-release capsules) versus twice-a-day OxyContin (oxycodone hydrochloride controlled-release tablets) for chronic low back pain: the extension phase of the ACTION trial. *J Opioid Manag.* 2006 Nov-Dec;2(6):325-8, 331-3.
28. Rauck RL, Bookbinder SA, Bunker TR, Alftine CD, Ghalie R, Negro-Vilar A et al. The ACTION study: a randomized, open-label, multicenter trial comparing once-a-day extended-release morphine sulfate capsules (AVINZA) to twice-a-day controlled-release oxycodone hydrochloride tablets (OxyContin) for the treatment of chronic, moderate to severe low back pain. *J Opioid Manag.* 2006 May-Jun;2(3):155-66.
29. Nicholson B, Ross E, Sasaki J, Weil A. Randomized trial comparing polymer-coated extended-release morphine sulfate to controlled-release oxycodone HCl in moderate to severe nonmalignant pain. *Curr Med Res Opin.* 2006 Aug;22(8):1503-14.

Cross References
Actiq <sup>®</sup> , fentanyl citrate oral transmucosal dru073
Fentora <sup>®</sup> , fentanyl buccal tablet dru141
Opana <sup>®</sup> ER, oxymorphone, Extended-Release dru142
Opioids for Chronic Non-Cancer Pain dru84

Codes	Number	Description
N/A		