

**Regence BlueCross BlueShield of Oregon · Regence BlueShield
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Medication Policy Manual

Policy No: dru042

Topic: OxyContin[®], oxycodone, Controlled-Release

Date of Origin: September 2001

Revised/Effective Date: November 9, 2007

Next Review Date: November 2008

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[®]) 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 the 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 Appendix 2).

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, 4 and 5 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 patient has been evaluated by at least one consulting physician specializing in an area of practice thought to be the source of the chronic non-cancer pain. The attending physician records must contain the written documentation by the consulting physician of corroborating findings, diagnosis and recommendations.

AND

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

Position Summary

- Two studies found that controlled-release oxycodone produced no improvement in quality of life or mood when validated tests were used.^[18, 20] One uncertain study identified a positive effect, but over one-third of patients dropped out because of adverse effects.^[21]

- Controlled-release oxycodone has had an inconsistent effect on the quality of life in patients suffering from chronic pain in clinical studies.
- Controlled-release oxycodone is effective in reducing chronic non-cancer pain but is accompanied by clinically significant adverse effects.
- Controlled-release oxycodone dosed every 12 hours has been shown to be as effective as immediate-release oxycodone dosed every six hours.
- Controlled-release oxycodone is formulated to deliver the opioid analgesic oxycodone over twelve hours, which facilitates convenient dosing, steady blood levels, and consistent pain control.
- The safety and clinical benefit of dosing controlled-release oxycodone more frequently than every 12 hours is currently not known.
- Pharmacokinetic studies sponsored by the manufacturer of controlled-release oxycodone support the feasibility of 12-hour dosing.
- Oxycodone, controlled-release is approved for 12-hour dosing only. The manufacturer does not recommend more frequent dosing.
- The safety and clinical benefit of dosing controlled-release oxycodone more frequently than every 12 hours is currently not known.

Clinical Efficacy

- Four studies directly compared multiple doses of controlled-release oxycodone with controlled-release morphine and found equal effectiveness. These studies did not show consistent differences in side effects. ^[14-17]
- Controlled-release oxycodone has not demonstrated a clinical benefit over immediate-release opioid analgesics or other long-acting narcotics in chronic pain.
- Controlled-release oxycodone has not demonstrated a consistent clinical benefit over immediate-release oxycodone in chronic pain in five clinical studies. ^[9-13]
 - * All studies have proven equal effectiveness.
 - * The majority of studies have found no difference in adverse effects.

Safety

- 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'.
- No study has evaluated the safety and efficacy of total daily doses greater than 120 mg of controlled-release oxycodone in patients with chronic non-cancer pain. ^[21]

Appendix 1: RAND 36-Item Short Form Health Survey (SF-36) 1.0 Questionnaire Items

This tool was developed at RAND Health as part of the Medical Outcomes Study. Reformatted with permission by RegenceRx.

Click [HERE](#) to access SF-36 scoring tool.

Question #	Question	Answer	Score (for MD use)
Example	In general, would you say your health is: Excellent (1) Very good (2) Good (3) Fair (4) Poor (5)	4	25

1	In general, would you say your health is: Excellent (1) Very good (2) Good (3) Fair (4) Poor (5)		
2	Compared to one year ago, how would you rate your health in general now? Much better now than one year ago (1) Somewhat better now than one year ago (2) About the same (3) Somewhat worse now than one year ago (4) Much worse now than one year ago (5)		

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

3	Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports Yes, Limited a Lot (1) Yes, Limited a Little (2) No, Not limited at All (3)		
4	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf Yes, Limited a Lot (1) Yes, Limited a Little (2) No, Not limited at All (3)		
5	Lifting or carrying groceries Yes, Limited a Lot (1) Yes, Limited a Little (2) No, Not limited at All (3)		

Question #	Question	Answer	Score (for MD use)
6	Climbing several flights of stairs Yes, Limited a Lot (1) Yes, Limited a Little (2) No, Not limited at All (3)		
7	Climbing one flight of stairs Yes, Limited a Lot (1) Yes, Limited a Little (2) No, Not limited at All (3)		
8	Bending, kneeling, or stooping Yes, Limited a Lot (1) Yes, Limited a Little (2) No, Not limited at All (3)		
9	Walking more than a mile Yes, Limited a Lot (1) Yes, Limited a Little (2) No, Not limited at All (3)		
10	Walking several blocks Yes, Limited a Lot (1) Yes, Limited a Little (2) No, Not limited at All (3)		
11	Walking one block Yes, Limited a Lot (1) Yes, Limited a Little (2) No, Not limited at All (3)		
12	Bathing or dressing yourself Yes, Limited a Lot (1) Yes, Limited a Little (2) No, Not limited at All (3)		

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?			
13	Cut down the amount of time you spent on work or other activities Yes (1) No (2)		
14	Accomplished less than you would like Yes (1) No (2)		
15	Were limited in the kind of work or other activities Yes (1) No (2)		
16	Had difficulty performing the work or other activities (for example, it took extra effort) Yes (1) No (2)		

Question #	Question	Answer	Score (for MD use)
<p>During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?</p>			
17	<p>Cut down the amount of time you spent on work or other activities Yes (1) No (2)</p>		
18	<p>Accomplished less than you would like Yes (1) No (2)</p>		
19	<p>Didn't do work or other activities as carefully as usual Yes (1) No (2)</p>		
20	<p>During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? Not at all (1) Slightly (2) Moderately (3) Quite a bit (4) Extremely (5)</p>		
21	<p>How much bodily pain have you had during the past 4 weeks? None (1) Very mild (2) Mild (3) Moderate (4) Severe (5) Very severe(6)</p>		
22	<p>During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? Not at all (1) Slightly (2) Moderately (3) Quite a bit (4) Extremely (5)</p>		

Question #	Question	Answer	Score (for MD use)
	These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.		
23	Did you feel full of pep? All of the Time (1) Most of the Time (2) A Good Bit of the Time (3) Some of the Time (4) A Little of the Time (5) None of the Time (6)		
24	Have you been a very nervous person? All of the Time (1) Most of the Time (2) A Good Bit of the Time (3) Some of the Time (4) A Little of the Time (5) None of the Time (6)		
25	Have you felt so down in the dumps that nothing could cheer you up? All of the Time (1) Most of the Time (2) A Good Bit of the Time (3) Some of the Time (4) A Little of the Time (5) None of the Time (6)		
26	Have you felt calm and peaceful? All of the Time (1) Most of the Time (2) A Good Bit of the Time (3) Some of the Time (4) A Little of the Time (5) None of the Time (6)		
27	Did you have a lot of energy? All of the Time (1) Most of the Time (2) A Good Bit of the Time (3) Some of the Time (4) A Little of the Time (5) None of the Time (6)		

Question #	Question	Answer	Score (for MD use)
28	<p>Have you felt downhearted and blue?</p> <p>All of the Time (1) Most of the Time (2) A Good Bit of the Time (3) Some of the Time (4) A Little of the Time (5) None of the Time (6)</p>		
29	<p>Did you feel worn out?</p> <p>All of the Time (1) Most of the Time (2) A Good Bit of the Time (3) Some of the Time (4) A Little of the Time (5) None of the Time (6)</p>		
30	<p>Have you been a happy person?</p> <p>All of the Time (1) Most of the Time (2) A Good Bit of the Time (3) Some of the Time (4) A Little of the Time (5) None of the Time (6)</p>		
31	<p>Did you feel tired?</p> <p>All of the Time (1) Most of the Time (2) A Good Bit of the Time (3) Some of the Time (4) A Little of the Time (5) None of the Time (6)</p>		
32	<p>During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?</p> <p>All of the time (1) Most of the time (2) Some of the time (3) A little of the time (4)</p>		

Question #	Question	Answer	Score (for MD use)
How TRUE or FALSE is each of the following statements for you?			
33	I seem to get sick a little easier than other people. Definitely true (1) Mostly true (2) Don't know (3) Mostly false (4) Definitely false(5)		
34	I am as healthy as anybody I know. Definitely true (1) Mostly true (2) Don't know (3) Mostly false (4) Definitely false(5)		
35	I expect my health to get worse. Definitely true (1) Mostly true (2) Don't know (3) Mostly false (4) Definitely false(5)		
36	My health is excellent. Definitely true (1) Mostly true (2) Don't know (3) Mostly false (4) Definitely false (5)		

Appendix 2: State Guidelines, Administrative Rules, and Statutes Regarding Chronic Opioid Therapy for Non-Malignant Pain.

- FEDERATION OF STATE MEDICAL BOARDS:
http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf
- IDAHO: <http://www.bom.state.id.us/licensees/opioids.html>
- OREGON:
http://www.oregon.gov/BME/topics.shtml#INTRACTABLE_PAIN_AND_PAIN_MANAGEMENT
- UTAH: http://www.dopl.utah.gov/licensing/statutes_and_rules/R156-67.PDF
- WASHINGTON: <http://www.lni.wa.gov/ClaimsIns/Files/OMD/MedTreat/MedTreatGuidelines.pdf>

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

Codes	Number	Description
N/A		