



**Medication Policy Manual**

**Policy No:** dru042

**Topic:** OxyContin<sup>®</sup>, oxycodone, Controlled-Release

**Date of Origin:** September 2001

**Revised/Effective Date:** December 10, 2009

**Next Review Date:** November 2010

**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 current 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.
        - iv. 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 2-4).

**AND**

4. The prescription, dispensing, or administration of controlled substances is 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 prescription, dispensing, or administration of controlled substances are in compliance with applicable federal and state statutes and regulations.  
**AND**
  5. The prescriber has performed a random urinalysis drug toxicology screening within the past 12 months. A quantitative urinalysis is preferred.

### 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 CR (OxyContin) labeling includes a Black Box Warning to emphasize the potential for accidental overdose, misuse, abuse and diversion.
- 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.
- 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, going 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.

### *Urinalysis*

- Random urinalysis testing can provide useful clinical information to prescribers of chronic high-dose opioids for non cancer pain. Random urinalysis testing is recognized as a useful tool in the monitoring of these patients by The Washington State Agency Medical Directors' Group <sup>[14]</sup>, and American Society of the Interventional Pain Physicians' (ASIPP). <sup>[15]</sup>
  - In clinical practice, urine drug tests are used to identify the use of undisclosed substances, to uncover diversion, and to evaluate compliance with prescribed controlled substances therapies. <sup>[15]</sup>
  - There are basically two types of urine drug tests, first is a screening test that determines the presence of a specific chemical in the urine (qualitative). The second is a confirmatory test (quantitative).
- Both qualitative and quantitative urinalysis testing are covered by Regence without prior authorization.

#### *Qualitative Urinalysis*

- Screening tests are usually done by immunoassay (EMIT, ELISA, and RIA are the most common).
- The most common urine screens are the 5-Panel Drug Tests, like the Substance Abuse and Mental Health Services Administration (SAMHSA) “SAMHSA-5”, or National Institute on Drug Abuse (NIDA) “NIDA 5” that screens for 5 categories of drugs:
  - \* Marijuana (THC)
  - \* Cocaine
  - \* Amphetamines/Methamphetamines
  - \* Opiates (including codeine, morphine, hydrocodone (e.g., Vicodin<sup>®</sup>), hydromorphone (e.g., Dilaudid<sup>®</sup>), oxycodone (e.g., OxyContin<sup>®</sup>, Percocet<sup>®</sup>) and oxymorphone (e.g., Opana<sup>®</sup>)
  - \* Phencyclidine (PCP)

#### *Quantitative Urinalysis*

- The confirmation test in most laboratories is performed using mass spectrometry, which is extremely precise but also more expensive than immunoassay. Findings are also confirmed by gas chromatography - mass spectrometry (GC-MS) methodology.
- Because opioids are transformed into other metabolites it is important to understand which opioids metabolize into other active metabolites. (see Table I for some examples)
- Interpretation of the test results may require specialized consultation because the specific metabolic products identified in the urine may differ from the prescribed medication. (Such as oxymorphone which is a metabolite of oxycodone).

**Table I: Opioids and potential metabolites present in the urine**

<b>Prescribed medication</b>	<b>Metabolites expected presence in the urine*</b>
codeine	morphine
morphine	morphine-6-glucuronide
heroin	morphine, 6-monoacetylmorphine (6-MAM)
oxycodone	noroxycodone, oxymorphone
hydrocodone	hydromorphone and norhydrocodone
*metabolites may be affected by dose, time of administration and variation in individual patients' metabolism.	

*Safety*

- In clinical trials, 1 of 4 (or more) patients drop 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>

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

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

1	<b>In general, would you say your health is:</b> Excellent (1) Very good (2) Good (3) Fair (4) Poor (5)		
2	<b>Compared to one year ago, how would you rate your health in general now?</b> 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	<b>Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports</b> Yes, Limited a Lot (1) Yes, Limited a Little (2) No, Not limited at All (3)		
4	<b>Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</b> Yes, Limited a Lot (1) Yes, Limited a Little (2) No, Not limited at All (3)		
5	<b>Lifting or carrying groceries</b> Yes, Limited a Lot (1) Yes, Limited a Little (2) No, Not limited at All (3)		

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

<b>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?</b>			
13	<b>Cut down the amount of time you spent on work or other activities</b> Yes (1) No (2)		
14	<b>Accomplished less than you would like</b> Yes (1) No (2)		
15	<b>Were limited in the kind of work or other activities</b> Yes (1) No (2)		

Question #	Question	Answer	Score (for MD use)
16	<b>Had difficulty performing the work or other activities (for example, it took extra effort)</b> Yes (1) No (2)		

**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)?**

17	<b>Cut down the amount of time you spent on work or other activities</b> Yes (1) No (2)		
18	<b>Accomplished less than you would like</b> Yes (1) No (2)		
19	<b>Didn't do work or other activities as carefully as usual</b> Yes (1) No (2)		
20	<b>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?</b> Not at all (1) Slightly (2) Moderately (3) Quite a bit (4) Extremely (5)		
21	<b>How much bodily pain have you had during the past 4 weeks?</b> None (1) Very mild (2) Mild (3) Moderate (4) Severe (5) Very severe(6)		
22	<b>During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?</b> Not at all (1) Slightly (2) Moderately (3) Quite a bit (4) Extremely (5)		

Question #	Question	Answer	Score (for MD use)
	<b>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.</b>		
23	<b>Did you feel full of pep?</b> 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	<b>Have you been a very nervous person?</b> 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	<b>Have you felt so down in the dumps that nothing could cheer you up?</b> 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	<b>Have you felt calm and peaceful?</b> 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	<b>Did you have a lot of energy?</b> 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)		
28	<b>Have you felt downhearted and blue?</b> All of the Time (1) Most of the Time (2)		

Question #	Question	Answer	Score (for MD use)
	A Good Bit of the Time (3) Some of the Time (4) A Little of the Time (5) None of the Time (6)		
29	<b>Did you feel worn out?</b> 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)		
30	<b>Have you been a happy person?</b> 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)		
31	<b>Did you feel tired?</b> 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)		
32	<b>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.)?</b> All of the time (1) Most of the time (2) Some of the time (3) A little of the time (4)		

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

<b>Appendix 2: Pain contracts, treatment agreements</b>
<p><b>Federation of State Medical Boards Model Pain Guidelines:</b></p> <p>"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:</p> <ul style="list-style-type: none"> <li>- urine/serum medication levels screening when requested;</li> <li>- number and frequency of all prescription refills; and</li> <li>- reasons for which drug therapy may be discontinued (i.e., violation of agreement)."</li> </ul> <p>Samples of opioid contract can be found at: <a href="http://www.ohsu.edu/ahec/pain/form.html">http://www.ohsu.edu/ahec/pain/form.html</a></p>

**Appendix 3: Examples of improved physical and psychosocial functioning**

- Ability to work.
- Need for health care 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:  
[http://www.fsmb.org/pdf/2004\\_grpol\\_Controlled\\_Substances.pdf](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](http://www.oregon.gov/BME/topics.shtml#INTRACTABLE_PAIN_AND_PAIN_MANAGEMENT)
- UTAH: [www.medsch.wisc.edu/painpolicy/domestic/utmbguid2.htm](http://www.medsch.wisc.edu/painpolicy/domestic/utmbguid2.htm)
- WASHINGTON: <http://www.lni.wa.gov/ClaimsIns/Files/OMD/MedTreat/MedTreatGuidelines.pdf>  
<http://www.lni.wa.gov/ClaimsIns/Providers/Treatment/Presc/Policy/Opioid/default.asp>

**Cross References**

Actiq<sup>®</sup>, fentanyl citrate oral transmucosal Fentora<sup>®</sup>, fentanyl buccal tablet Onsolis dru073

Embeda, morphine/naltrexone dru192

Opana<sup>®</sup> ER, oxymorphone, Extended-Release dru142

Opioids for Chronic Non-Cancer Pain dru84

Codes	Number	Description
N/A		

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<b>Cross References</b>		
Actiq <sup>®</sup> , fentanyl citrate oral transmucosal Fentora <sup>®</sup> , fentanyl buccal tablet Onsolis dru073		
Embeda, morphine/naltrexone dru192		
Opana <sup>®</sup> ER, oxymorphone, Extended-Release dru142		
Opioids for Chronic Non-Cancer Pain dru84		

<b>Codes</b>	<b>Number</b>	<b>Description</b>
N/A		