

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

Policy No: dru084

Topic: Opioids for Chronic Non-Cancer Pain

Date of Origin: June 2003

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

Opioids are medications used in the management of moderate to severe pain. Opioids are controlled substances regulated by the Drug Enforcement Administration (DEA). Common opioids include, but are not limited to, codeine, fentanyl, hydrocodone, hydromorphone, levorphanol, methadone, morphine, oxycodone and oxymorphone.

Criteria in drug-specific policies take precedence over the criteria listed in this policy. Therefore, drug-specific policies must be reviewed before applying the criteria listed below.

Policy/Criteria

I. Chronic daily DEA Schedule II opioid therapy may be considered medically necessary when either criterion A or B below is met:

A. The member has a diagnosis of cancer, is enrolled in a hospice program, or 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 that includes:

i. Diagnostic studies.

ii. Previous treatment with non-opioid medications; dates and duration of treatment and documentation confirming treatment has been inadequate to meet the goals of pain management.

iii. Previous non-pharmacological therapy has been inadequate to meet the goals of pain management.

AND

2. A written treatment plan stating 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.

II. Administration and Authorization Period

- A. Regence considers most chronic daily Schedule II opioid oral and topical therapy to be self-administered medications.
- 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, 5, and 6 below are met:
 1. The 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. Opioid therapy in doses exceeding the equivalent of 100-150 mg of morphine daily may be considered medically necessary when 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.

This medication policy has been developed to be consistent with the Federation of State Medical Board's Model Guidelines for the use of Controlled Substances for the Treatment of Chronic Pain^[14]. The Federation of State Medical Boards developed the Model Guidelines in collaboration with the American Society of Law, Medicine and Ethics, the American Pain Society, the American Academy of Pain Medicine, the University of Wisconsin Pain and Policies Studies Group, pharmaceutical companies, and state medical boards. Many states have used the Federation's Model Guidelines in drafting their guidelines and some states have chosen to adopt the Model Guidelines in their entirety.^[14]

Position Summary

- Regence is committed to facilitating the best possible medical care for patients with chronic non-cancer pain. Long-term administration of opioid analgesics may be a necessary component of comprehensive care for some patients with chronic non-cancer pain.
- The use of chronic opioid therapy for patients with chronic non-cancer pain remains controversial, and in some cases can worsen pain syndromes and cause adverse sequelae.^[2, 3, 5, 6, 10, 13]
- The safety and efficacy of chronic administration of opioids for chronic non-cancer pain has yet to be established, despite increasing commercial pressure to routinely use these medications.^[1,10]
- Chronic opioid therapy has not been shown to improve overall patient quality of life in non-cancer pain despite reported improvement in pain.^[12]
- Chronic opioid therapy has not been studied for many causes of chronic non-cancer pain.
- Opioids should be considered when other conservative measures (e.g., NSAIDs, tricyclic antidepressants, antiepileptics and non-pharmacologic therapies) have failed and patient has demonstrated sustained functional improvement with previous opioid trials.^[17]
- Opioids, when administered, must be a component of comprehensive care for chronic pain. Comprehensive care includes non-pharmacologic therapies.^[1, 5, 12]
- The doses needed for the treatment of non-cancer pain are often smaller than those used in cancer-related pain.^[3]
- If treatment goals are not being achieved *despite medication adjustments*, the appropriateness of continued treatment should be re-evaluated. Patient compliance in medication usage and related treatment plan should be examined.^[8, 12, 13]
- Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.^[8]

- Many people with chronic pain require little or no dose escalation in chronic opioid therapy. ^[12]
- Lack of knowledge about pain management by the patient or the patient's physician may result in inadequate pain control. ^[8]
- According to Federal Code, prescriptions for Schedule III or IV controlled substances are only refillable for up to 6 months from the date written.

Efficacy

- Pharmacologic therapy is most effective when it is combined with non-pharmacologic strategies to optimize pain management. All patients with a diminished quality of life as a result of chronic pain are candidates for non-pharmacologic pain management strategies. ^[1, 4, 8]
- Continuation or modification of therapy should depend on progress toward stated treatment objectives such as improvement in patient's pain intensity and improved physical and/or psychosocial function (ability to work, need for health care resources, activities of daily living, and quality of life.) ^[1, 5, 8]
- No long acting opioid analgesic has demonstrated consistently superior efficacy or safety over other opioids in the treatment of chronic non-cancer pain.

Safety

- Inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. ^[8]
- Opioid therapy may be accompanied by troublesome adverse side effects including sedation, nausea, vomiting, pruritus, constipation, physical dependence, and aberrant behavior. ^[2, 3, 4, 10, 11, 12]

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	In general, would you say your health is:		
	Excellent (1)		
	Very good (2)		
	Good (3)	4	25
	Fair (4)		
	Poor (5)		

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)		

Question #	Question	Answer	Score (for MD use)
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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	<p>Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports</p> <p>Yes, Limited a Lot (1)</p> <p>Yes, Limited a Little (2)</p> <p>No, Not limited at All (3)</p>		
4	<p>Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</p> <p>Yes, Limited a Lot (1)</p> <p>Yes, Limited a Little (2)</p> <p>No, Not limited at All (3)</p>		
5	<p>Lifting or carrying groceries</p> <p>Yes, Limited a Lot (1)</p> <p>Yes, Limited a Little (2)</p> <p>No, Not limited at All (3)</p>		
6	<p>Climbing several flights of stairs</p> <p>Yes, Limited a Lot (1)</p> <p>Yes, Limited a Little (2)</p> <p>No, Not limited at All (3)</p>		
7	<p>Climbing one flight of stairs</p> <p>Yes, Limited a Lot (1)</p> <p>Yes, Limited a Little (2)</p> <p>No, Not limited at All (3)</p>		

Question #	Question	Answer	Score (for MD use)
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)		

Question #	Question	Answer	Score (for MD use)
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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)		

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	Cut down the amount of time you spent on work or other activities Yes (1) No (2)		
18	Accomplished less than you would like Yes (1) No (2)		

Question #	Question	Answer	Score (for MD use)
19	<p>Didn't do work or other activities as carefully as usual</p> <p>Yes (1)</p> <p>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?</p> <p>Not at all (1)</p> <p>Slightly (2)</p> <p>Moderately (3)</p> <p>Quite a bit (4)</p> <p>Extremely (5)</p>		
21	<p>How much bodily pain have you had during the past 4 weeks?</p> <p>None (1)</p> <p>Very mild (2)</p> <p>Mild (3)</p> <p>Moderate (4)</p> <p>Severe (5)</p> <p>Very severe(6)</p>		

Question #	Question	Answer	Score (for MD use)
22	<p>During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?</p> <p>Not at all (1)</p> <p>Slightly (2)</p> <p>Moderately (3)</p> <p>Quite a bit (4)</p> <p>Extremely (5)</p>		

	<p>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.</p>		
23	<p>Did you feel full of pep?</p> <p>All of the Time (1)</p> <p>Most of the Time (2)</p> <p>A Good Bit of the Time (3)</p> <p>Some of the Time (4)</p> <p>A Little of the Time (5)</p> <p>None of the Time (6)</p>		

Question #	Question	Answer	Score (for MD use)
24	<p>Have you been a very nervous person?</p> <p>All of the Time (1)</p> <p>Most of the Time (2)</p> <p>A Good Bit of the Time (3)</p> <p>Some of the Time (4)</p> <p>A Little of the Time (5)</p> <p>None of the Time (6)</p>		
25	<p>Have you felt so down in the dumps that nothing could cheer you up?</p> <p>All of the Time (1)</p> <p>Most of the Time (2)</p> <p>A Good Bit of the Time (3)</p> <p>Some of the Time (4)</p> <p>A Little of the Time (5)</p> <p>None of the Time (6)</p>		
26	<p>Have you felt calm and peaceful?</p> <p>All of the Time (1)</p> <p>Most of the Time (2)</p> <p>A Good Bit of the Time (3)</p> <p>Some of the Time (4)</p> <p>A Little of the Time (5)</p> <p>None of the Time (6)</p>		

Question #	Question	Answer	Score (for MD use)
27	<p>Did you have a lot of energy?</p> <p>All of the Time (1)</p> <p>Most of the Time (2)</p> <p>A Good Bit of the Time (3)</p> <p>Some of the Time (4)</p> <p>A Little of the Time (5)</p> <p>None of the Time (6)</p>		
28	<p>Have you felt downhearted and blue?</p> <p>All of the Time (1)</p> <p>Most of the Time (2)</p> <p>A Good Bit of the Time (3)</p> <p>Some of the Time (4)</p> <p>A Little of the Time (5)</p> <p>None of the Time (6)</p>		
29	<p>Did you feel worn out?</p> <p>All of the Time (1)</p> <p>Most of the Time (2)</p> <p>A Good Bit of the Time (3)</p> <p>Some of the Time (4)</p> <p>A Little of the Time (5)</p> <p>None of the Time (6)</p>		

Question #	Question	Answer	Score (for MD use)
30	<p>Have you been a happy person?</p> <p>All of the Time (1)</p> <p>Most of the Time (2)</p> <p>A Good Bit of the Time (3)</p> <p>Some of the Time (4)</p> <p>A Little of the Time (5)</p> <p>None of the Time (6)</p>		
31	<p>Did you feel tired?</p> <p>All of the Time (1)</p> <p>Most of the Time (2)</p> <p>A Good Bit of the Time (3)</p> <p>Some of the Time (4)</p> <p>A Little of the Time (5)</p> <p>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)</p> <p>Most of the time (2)</p> <p>Some of the time (3)</p> <p>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	<p>I seem to get sick a little easier than other people.</p> <p>Definitely true (1)</p> <p>Mostly true (2)</p> <p>Don't know (3)</p> <p>Mostly false (4)</p> <p>Definitely false(5)</p>		
34	<p>I am as healthy as anybody I know.</p> <p>Definitely true (1)</p> <p>Mostly true (2)</p> <p>Don't know (3)</p> <p>Mostly false (4)</p> <p>Definitely false(5)</p>		
35	<p>I expect my health to get worse.</p> <p>Definitely true (1)</p> <p>Mostly true (2)</p> <p>Don't know (3)</p> <p>Mostly false (4)</p> <p>Definitely false(5)</p>		

Question #	Question	Answer	Score (for MD use)
36	My health is excellent.		
	Definitely true (1)		
	Mostly true (2)		
	Don't know (3)		
	Mostly false (4)		
	Definitely false (5)		

Appendix 2: Pain contracts, treatment agreements

Federation of State Medical Boards Model Pain Guidelines:

"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)."

Appendix 3: Example of improved physical and psychosocial function

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

- Federal Code: http://www.access.gpo.gov/nara/cfr/waisidx_99/21cfr1306_99.html
- Idaho: <http://www.bom.state.id.us/licensees/opioids.html>
- Oregon: http://www.oregon.gov/BME/topics.shtml#INTRACTABLE_PAIN_AND_PAIN_MANAGEMENT
- Utah: www.medsch.wisc.edu/painpolicy/domestic/utmbguid2.htm
- Washington: <http://www.lni.wa.gov/ClaimsIns/Providers/Treatment/Presc/Policy/Opioid/default.asp>

Appendix 5: Oral morphine equivalents, chronic dosing: ^[15]

Opioid	Equianalgesic Dose
morphine	100 to 150 mg per 24 hours
fentanyl	25 to 50 mcg per hour
hydrocodone	100 to 150 mg per 24 hours
hydromorphone	25 to 37.5 mg per 24 hours
levorphanol	3 to 5 mg per 24 hours
meperidine	1000 to 1500 mg per 24 hours
methadone	7.5 to 20 mg per 24 hours
oxycodone	60 to 100 mg per 24 hours
codeine	660 to 1000 mg per 24 hours

References

1. Anon. "Clinical practice guidelines for chronic non-malignant pain syndrome patients II: and evidence-based approach." *Journal of Back and Musculoskeletal Rehabilitation* 1999;13:47-58.
2. Anon. "Practice guidelines for chronic pain management." *Anesthesiology* 1997;86:995-1004.
3. Anon. "The management of chronic pain in older persons." *Geriatrics* 1998;53:S8-S24.
4. Anon. "The management of persistent pain in older adults. AGS panel on persistent pain in older adults." *Journal of the American Geriatrics Society* 2002;50:S205-224.
5. Ashburn MA, Staats PA. "Management of chronic pain." *The Lancet* 1999;353:1865-1869.
6. Idaho Board of Medicine. Prescribing Opioids for Chronic Pain. 2000
www.bom.state.id.us/licensees/opioids.html.
7. Mior S. "Exercise in the treatment of chronic pain." *The Clinical Journal of Pain* 2001;17:S77-S85.
8. "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain." May 1998 Federation of State Medical Boards of the United States, Inc.
http://www.fsmb.org/Policy%20Documents%20and%20White%20Papers/model_pain_guidelines.htm.
9. Moulin DE. "Systemic drug treatment for chronic musculoskeletal pain." *The Clinical Journal of Pain* 2001;17:S86-S93.
10. Reid MC et al. "Use of opioid medications for chronic noncancer pain syndromes in primary care." *Journal of General Internal Medicine* 2002;17:173-179.
11. Rischitelli DG, Karbowicz SH. "Safety and efficacy of controlled-release oxycodone: a systematic literature review." *Pharmacotherapy*. 2002;22:898-904.
12. Savage SR. "Opioid use in the management of chronic pain." *Medical Clinics of North America* 1999;83:761-786.
13. State of Washington Department of Labor and Industries. "Guidelines for outpatient prescription of oral opioids for injured workers with chronic, noncancer pain." Olympia WA. PB 00-04.
<http://www.lni.wa.gov/ClaimsIns/Files/OMD/MedTreat/MedTreatGuidelines.pdf>
14. "Position of the Federation of State Medical Boards in support of adoption of pain management guidelines." Federation of State Medical Boards of the United States. 2000.
<http://www.medsch.wisc.edu/painpolicy/domestic/FSMBwp.htm>.
15. Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain, 4th Edition,

Skokie, IL: The American Pain Society, 1999.

16. Rand Health web site. Available at:
http://www.rand.org/health/surveys_tools/mos/mos_core_36item_survey.html. Accessed 8/13/2007.
17. Interagency guideline on opioid dosing for chronic non-cancer pain: an educational pilot to improve care and safety with opioid treatment. Washington State Agency Medical Director's Group. 2007. Available at:
<http://www.lni.wa.gov/news/files/AMDGOpioidGuidelinesDraft.pdf>.

Cross References
- Actiq [®] , fentanyl citrate oral transmucosal lozenges dru073
- Fentora [®] , fentanyl buccal tablet dru141
- OxyContin [®] , oxycodone controlled-release dru042
- Opana [®] ER, oxymorphone, Extended-Release dru142

Codes	Number	Description
N/A		