

**Regence BlueCross BlueShield of Oregon · Regence BlueShield
Regence BlueCross BlueShield of Utah · Regence BlueShield of Idaho
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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 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

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 Appendices 2 and 4).

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 therapies 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, and 4 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. 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

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 chronic 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]
- There is no reliable evidence that one opioid is more effective or safer than another. [19]
- 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.
- 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-medication therapies. Some examples of non-medication treatments are: [1, 5, 12, 18]
 - * 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.

- 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]

- 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.

Appendix 1: RAND 36-Item Short Form Health Survey (SF-36)	
-	Click HERE to access SF-36 survey.
-	Click HERE to access SF-36 scoring tool.

Appendix 2: Pain Contract, 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)."
Sample opioid contracts can be found at: http://www.ohsu.edu/ahec/pain/form.html	

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: 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: www.medsch.wisc.edu/painpolicy/domestic/utmbguid2.htm
-	Washington: http://www.lni.wa.gov/ClaimsIns/Providers/Treatment/Presc/Policy/Opioid/default.asp http://www.lni.wa.gov/ClaimsIns/Files/OMD/MedTreat/MedTreatGuidelines.pdf

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

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Cross References
Actiq [®] , fentanyl citrate oral transmucosal dru073
Fentora [®] , fentanyl buccal tablet dru141
Opana [®] ER, oxymorphone, Extended-Release dru142
Opana [®] ER, oxymorphone, Extended-Release dru142

Codes	Number	Description
N/A		