

5.70.64

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Analgesics and Anesthetics	Original Policy Date:	October 20, 2017
Subject:	Opioid Powders	Page:	1 of 9

Last Review Date: March 12, 2021

Opioid Powders

Description

Buprenorphine Powder, Butorphanol Powder, Codeine Powder, Hydrocodone Powder, Hydromorphone Powder, Levorphanol Powder, Meperidine Powder, Methadone Powder, Morphine Powder, Oxycodone Powder, Oxymorphone Powder

Background

Pharmacy compounding is an ancient practice in which pharmacists combine, mix or alter ingredients to create unique medications that meet specific needs of individual patients. Some examples of the need for compounding products would be: the dosage formulation must be changed to allow a person with dysphagia (trouble swallowing) to have a liquid formulation of a commercially available tablet only product, or to obtain the exact strength needed of the active ingredient, to avoid ingredients that a particular patient has an allergy to, or simply to add flavoring to medication to make it more palatable.

Buprenorphine, butorphanol, codeine, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, oxycodone, and oxymorphone powders are opioid drugs that are used for pain control. The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death (1-15).

Regulatory Status

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FDA-approved indications:

1. Buprenorphine, butorphanol, codeine, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, oxycodone, and oxymorphone powders are opioid agonists indicated for the relief of moderate to severe acute and chronic pain where an opioid is appropriate (1-11).
2. Buprenorphine and methadone are indicated for detoxification or maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

Buprenorphine, butorphanol, codeine, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, oxycodone, and oxymorphone powders have boxed warnings for the following (1-11):

- Respiratory depression is the chief hazard of opioid agonists, which if not immediately recognized and treated, may lead to respiratory arrest and death. Risk is increased in patients receiving concurrent CNS depressants (including alcohol), patients with chronic obstructive pulmonary disease, orthostatic hypotension, increased intracranial pressure, biliary tract diseases, and seizure disorders. To reduce the risk of respiratory depression, proper dosing, titration, and monitoring are essential.
- All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use.
- Accidental ingestion of extended-release opioids, especially in children, can result in fatal opioid overdose.
- Prolonged use of opioid agonists during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening.
- Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

Other boxed warnings include the following:

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- Concomitant use with CYP 3A4 inhibitors (or discontinuation of CYP 3A4 inducers) can result in a fatal overdose of hydrocodone and oxycodone (9, 11).

The Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain recommends that when opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day. The extended-release opioid drug initial quantity limits are set to encompass the usual/starting dosage and frequency range recommendations in labeling without exceeding 90 MME per day (12-13).

CDC guidelines find that concurrent use of benzodiazepines and opioids might put patients at greater risk for potentially fatal overdose. Three studies of fatal overdose deaths found evidence of concurrent benzodiazepine use in 31%–61% of decedents (12-13). The FDA also states that benzodiazepines “are also commonly abused and misused, often together with opioid pain relievers and other medicines” (17).

The CDC Guideline for Prescribing Opioids for Chronic Pain states that when starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting opioids. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids (12-13).

The American Pain Society Opioid Treatment Guidelines state that a reasonable definition for high dose opioid therapy is >200 mg daily of oral morphine (or equivalent). The Institute for Clinical Systems Improvement Chronic Pain Guideline states that among patients receiving opioids for non-malignant pain, the daily dose is strongly associated with opioid-related mortality. An average dose of 200 mg or more morphine (or equivalent) was associated with a nearly nine-fold increase in the risk of overdose relative to low doses (<20 mg of morphine or equivalent) (12 -15).

The FDA has determined that a REMS is necessary for all opioid analgesics intended for outpatient use to ensure that the benefits of these drugs continue to outweigh the risks. The Opioid Analgesic REMS is a strategy to reduce the risk of abuse, misuse, addiction, overdose, and deaths due to prescription opioid analgesics (16).

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Related policies

Abstral, Actiq, Butrans, Duragesic, Extended Release Opioid Drugs, Fentanyl Powder, Fentora, Immediate Release Opioid Drugs, IR Opioid Combo Drugs, Methadone, Opioid Injectables, Suboxone Drug Class, Subsys

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Buprenorphine, butorphanol, codeine, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, oxycodone, and oxymorphone powders may be considered **medically necessary** for patients 18 years and older for moderate to severe acute or chronic pain or opioid dependence (buprenorphine and methadone only) and if the conditions indicated below are met.

Buprenorphine, butorphanol, codeine, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, oxycodone, and oxymorphone powders may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Prior authorization is not required if prescribed by an oncologist and/or the member has paid pharmacy claims for an oncology medication(s) in the past 6 months

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Moderate to severe pain

AND ALL of the following:

- a. **NO** dual therapy with other short acting opioid analgesic(s)
- b. Alternative treatment options have been ineffective, not tolerated or inadequate for controlling the pain

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- i. These include: non-opioid analgesics and immediate release analgesics
 - c. Prescriber agrees to assess the benefits of pain control (i.e. care plan, signs of abuse, severity of pain) after 3 months of therapy
 - d. Prescriber agrees to assess patient for signs and symptoms of serotonin syndrome
 - e. Prescriber agrees to participate in the Opioid Analgesic REMS program and to monitor for abuse, misuse, addiction, and overdose and discontinue if necessary
(<https://opioidanalgesicrems.com>)
 - f. **NO** dual therapy with opioid addiction treatment or methadone
 - g. **NO** dual therapy with an anti-anxiety benzodiazepine(s)
 - i. Alprazolam (Xanax)
 - ii. Clonazepam (Klonopin)
 - iii. Diazepam (Valium)
 - iv. Lorazepam (Ativan)
 - v. Oxazepam (Serax)
 - vi. Chlordiazepoxide (Librium)
 - vii. Clorazepate dipotassium (Tranxene)
 - h. **NO** cumulative morphine milligram equivalent (MME) over 300 MME
2. Opioid dependence (**buprenorphine and methadone only**)

AND ALL of the following:

- a. Prescribed by a physician qualified by HHS (Health and Human Services) and registered with SAMHSA (Substance Abuse and Mental Health Services Administration)
- b. Patient will **NOT** be receiving other opioids
 - i. Patients currently on opioid therapy must be tapered off within 30 days
- c. Patient will receive counseling and psychosocial support
- d. Patient will be monitored during therapy for signs and symptoms of abuse / misuse as well as compliance and the potential diversion to others
- e. Patient is **NOT** taking **exclusively** for pain control

AND ALL of the following for **BOTH** indications:

- 1. The requested dosage form is oral use only

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2. The requested dose/ strength does **NOT** exceed 90 MME for the requested ingredient (See MME Appendix)
3. The requested dose is **NOT** commercially available

Prior – Approval *Renewal* Requirements

Same as above

[Policy Guidelines](#)

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Duration 12 months

[Rationale](#)

Summary

Buprenorphine, butorphanol, codeine, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, oxycodone, and oxymorphone powders are opioid agonists indicated for the relief of moderate to severe acute and chronic pain where an opioid is appropriate.

Buprenorphine and methadone is also indicated for detoxification or maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services. Opioid powders should only be prescribed by healthcare professionals, who are knowledgeable in the use of Schedule II opioids for pain or addiction therapy (1-11).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of buprenorphine, butorphanol, codeine, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, oxycodone, and oxymorphone powders while maintaining optimal therapeutic outcomes.

References

1. Buprenorphine HCL sublingual tablet [package insert], Columbus, OH, West-Ward Pharmaceuticals Corp.; November 2019.

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3. Codeine sulfate [package insert]. Eatontown, NJ. West-Ward Pharmaceuticals Corp.; August 2017.
4. Dilaudid [package insert]. Stamford, CT: Purdue Pharma L.P.; February 2017.
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16. Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS). Drug Safety and Availability: U.S. Food & Drug Administration. September 19, 2018.
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Policy History

Date	Action
October 2017	Addition to PA
December 2017	Annual review
March 2017	Annual review
October 2018	Addition of Opioid Analgesic REMS requirement
November 2018	Annual review and reference update. Addition of Opioid Analgesic REMS link per SME
March 2019	Annual review
December 2019	Annual review. Addition of requirement of no cumulative MME over 300

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March 2020	Annual editorial review and reference update. Updated Opioid Analgesic REMS link
March 2021	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.

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MME Appendix

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

Morphine milligram equivalent (MME) doses for commonly prescribed opioids

Opioid	Conversion Factor
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
1–20 mg/day	4
21–40 mg/day	8
41–60 mg/day	10
≥61–80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3
Tapentadol [†]	0.4

Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day

Source: Adapted from Von Korff M, Saunders K, Ray GT, et al. Clin J Pain 2008;24:521–7 and Washington State Interagency Guideline on Prescribing Opioids for Pain (<http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf>).