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5.70.064

Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	October 20, 2017
Subject:	Buprenorphine and Methadone Powders	**Page:**	1 of 8

Last Review Date: December 8, 2023

Buprenorphine and Methadone Powders

Description

Buprenorphine Powder, Methadone Powder

Background
Buprenorphine and methadone powders are opioid drugs that are used for pain control and opioid dependence. 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. These powders are included 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 (1-8).

Maximum daily limit of any combination of opioid medications with a PA is 200 MME/day.
Regulatory Status
FDA-approved indications: (1-2)

1. Buprenorphine and methadone powders are opioid agonists indicated for the relief of moderate to severe acute and chronic pain where an opioid is appropriate.

2. Buprenorphine and methadone powders 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 and methadone powders have boxed warnings for the following (1-2):

- 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.

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 (3-4).

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 (3-4). The FDA also states that benzodiazepines “are also commonly abused and misused, often together with opioid pain relievers and other medicines” (8).

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 (3-4).

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) (3-8).

The FDA has determined that a Risk Evaluation and Mitigation Strategy (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. Prescribers should counsel patients and caregivers about the use of naloxone for opioid overdose and consider prescribing naloxone if clinically indicated (7).

Related policies

Abstral, Actiq, Fentanyl Powder, Fentora, Methadone, Opioid Drugs, 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 and methadone powders may be considered **medically necessary** if the conditions indicated below are met.

Buprenorphine and methadone powders may be considered **investigational** 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 (i.e., 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 evaluate patient's response to therapy before changing dose or adding additional opioid medications
   e. Prescriber agrees to assess patient for signs and symptoms of serotonin syndrome
   f. 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*)
   g. **NO** dual therapy with opioid addiction treatment or methadone
   h. **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)

i. **NO** cumulative morphine milligram equivalent (MME) over 200 MME/day
(e.g., https://www.mdcalc.com/morphine-milligram-equivalents-mme-calculator, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf, https://www.cdc.gov/opioids/providers/prescribing/app.html)

2. Opioid dependence

AND ALL of the following:
a. Patient will **NOT** be receiving other opioids
i. Patients currently on opioid therapy must be tapered off within 30 days
b. Patient will receive counseling and psychosocial support
c. Patient will be monitored during therapy for signs and symptoms of abuse/misuse as well as compliance and the potential diversion to others
d. Patient is **NOT** taking **exclusively** for pain control
e. **NO** morphine milligram equivalent (MME) over 200 MME/day
(e.g., https://www.mdcalc.com/morphine-milligram-equivalents-mme-calculator, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf, https://www.cdc.gov/opioids/providers/prescribing/app.html)

AND ALL of the following for **BOTH** indications:
1. The requested dosage form is oral use only
2. The requested dose is **NOT** commercially available
3. The requested dose/ strength does **NOT** exceed 90 MME for the requested ingredient *(e.g., https://www.mdcalc.com/morphine-milligram-equivalents-mme-calculator, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf, https://www.cdc.gov/opioids/providers/prescribing/app.html)*

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

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

None

Prior - Approval Limits

Quantity

- **Maximum daily limit of any combination of opioid medications with a PA is 200 MME/day.**

Duration 6 months

Prior – Approval *Renewal* Limits

Quantity

- **Maximum daily limit of any combination of opioid medications with a PA is 200 MME/day.**

Duration 12 months

Rationale

Summary
Buprenorphine and methadone powders are opioid agonists indicated for the relief of moderate to severe acute and chronic pain where an opioid is appropriate. Buprenorphine and methadone powders are also indicated for detoxification or maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services. These powders should only be prescribed by healthcare professionals who are knowledgeable in the use of Schedule II opioids for pain or addiction therapy (1-8).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of buprenorphine and methadone powders while maintaining optimal therapeutic outcomes.

References

1. Buprenorphine HCL sublingual tablet [package insert], Columbus, OH, West-Ward Pharmaceuticals Corp.; November 2019.
2. Dolophine Tablets [package insert]. Eatontown, NJ. West-Ward Pharmaceuticals Corp.; October 2019.
3. Dowell D, Haegerich T, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain. CDC Guidelines 2016.

4. FDA Safety Release. FDA Drug Safety Communication: FDA warns about several safety issues with opioid pain medicines; requires label changes. March 22, 2016.
5. Chou R, Fanciullo G, Fine P, et al. Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain the Journal of Pain 2009;10:113-130.
6. Hooten W, Timming R, Belgrade M, et al. Institute for Clinical Systems Improvement. Assessment and Manage-ment of Chronic Pain. Updated November 2013.
7. Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS). Drug Safety and Availability: U.S. Food & Drug Administration. September 19, 2018.
8. FDA News Release. FDA Drug Safety Communication: FDA requiring labeling changes for benzodiazepines. September 23, 2020.

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
March 2020	Annual editorial review and reference update. Updated Opioid Analgesic REMS link
March 2021	Annual review
December 2021	Annual review. Per FEP, decreased the requirement that cumulative MME cannot exceed 200 MME/day from 300 MME/day. Added requirement “Prescriber agrees to evaluate patient’s response to therapy before changing dose or adding additional opioid medications.”
February 2022	Updated Pre-PA allowance with oncology step edit statement. Per FEP: added “Prescribers should counsel patients and caregivers about the use of naloxone for opioid overdose” under regulatory status, and added MME calculating links
March 2022	Annual review
September 2023	Annual review. Per SME, addition to regulatory status that prescriber should consider prescribing naloxone if clinically indicated. Changed policy number to 5.70.064

November 2023	Removed all powders from policy to add to 5.70.061 Opioid Drugs except for buprenorphine and methadone powders. Also removed SAMHSA requirement. Renamed policy Buprenorphine and Methadone Powders
December 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.