Opioid Step Policy

Background
Opioids are Schedule II-V controlled substances used in the treatment of chronic and acute pain. Opioids have a high potential for abuse. This should be considered when prescribing or dispensing them in a situation where misuse, abuse, or diversion are a concern. The prescriber should ensure that before prescribing opioids, the patient is assessed for a history of substance abuse. Patients taking opioids chronically are at risk of suicide and should be screened for depression and suicidal ideation.

Suboxone, Zubsolv, Bunavail, Probuphine and buprenorphine sublingual tablets are Schedule III narcotics with a single indication, the maintenance treatment of opioid dependence. Buprenorphine is a partial pain receptor agonist at mu-opioid receptors unlike typical opioids of dependence, which are full agonists. Naloxone is an opioid receptor antagonist. Treatment using buprenorphine with or without naloxone should occur only under the care of a physician who meets qualifying requirements per Health and Human Services (HHS). The use of buprenorphine with or without naloxone should also be part of a comprehensive plan which includes counseling and psychosocial support. They should not be used for analgesia or in opioid naïve patients (1).

Methadone hydrochloride is a long-acting opioid agonist at mu-opioid receptors that is used to manage pain that requires long-term, daily opioid treatment when other pain treatments do not
manage pain sufficiently or are not tolerated. It is also used for detoxification and maintenance treatment of opioid addiction, such as heroin or other morphine-like drugs, as part of a comprehensive plan that includes appropriate medical and social services (2).

Opioids and opioid dependence therapy medications should not be taken together because of the following: (1-7)

- 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/or seizure disorders. Proper dosing, titration and monitoring are essential to reduce the risk of respiratory depression.

- 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 with appropriate medical use.

- Prolonged use of opioid agonists during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening.

- Patients should not consume alcohol or any products containing alcohol.

**Regulatory Status**

FDA-approved indication:

1. Extended release opioids are indicated for the management of pain severe enough to require daily, around-the-clock, long term opioid treatment and for which alternative treatment options are inadequate (3).

2. Immediate-release opioids are indicated for the management of moderate to severe pain where the use of an opioid analgesic is appropriate (4).

3. Opioid Dependence medications are indicated for maintenance treatment of opioid dependence. Prescription use of these products are limited under the Drug Addiction Treatment Act (1-2).

Opioids have the potential for misuse, abuse, and diversion. Patient use should be monitored as part of a counseling and psychosocial support during treatment and precautions taken against potential abuse. As with other opioids, physical dependence, respiratory depression, and overdose may also occur; hence monitoring and frequent patient evaluation should be used as part of an overall treatment plan (1-6).
Methadone is a long acting opioid whose duration of analgesic action (typically 4 to 8 hours) approximates that of morphine and has an elimination half-life that is substantially longer (typically 8 to 59 hours). Methadone’s pharmacokinetic properties, coupled with high inter-patient variability in its absorption, metabolism, and relative analgesic potency necessitate a cautious and highly individualized approach to prescribing. The complexities associated with methadone dosing can contribute to cases of iatrogenic overdose, particularly during treatment initiation and dose titration. Studies indicate that methadone-related fatalities were primarily related to respiratory depression during initial treatment along with poly-substance use (8-11).

Safety and effectiveness in patients under the age 18 has not been established (1).

Related policies

Policy

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

Opioids may be considered **medically necessary** in patients 18 and older who require buprenorphine (with or without naloxone) for the treatment of opioid dependence or currently taking methadone for the treatment of opioid dependence or chronic pain.

Opioids are considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age

18 years of age or older

Diagnosis

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

1. Currently taking buprenorphine (with or without naloxone) for the treatment of opioid dependence
   a. Patient receiving other opioids must have **ONE** of the following:
      i. Patient is being started on a opioid addiction treatment medication
         1) Patients currently on opioid therapy must be tapered off within 30 days
ii. Patient has a recent injury, accident or surgery requiring inpatient admission, emergency department visit or ambulatory surgery visit
   2) Patients currently on opioid therapy must be tapered off within 30 days

2. Currently taking methadone for the treatment of opioid dependence or pain
   a. Patients currently on opioid therapy must be tapered off within 30 days

   AND ALL of the following:
   1. NO dual therapy with another opioid addiction medication

Prior – Approval Renewal Requirements
None

Policy Guidelines
Pre - PA Allowance
None

Prior - Approval Limits
Duration
30 day taper of the requested opioid narcotic
MD to provide medication requested and quantity for 30 days
IF PA medication NOT to exceed PA limits based on 30 days

Prior – Approval Renewal Limits
None

Rationale
Summary
The maintenance treatment of opioid dependence use is limited under the Drug Addiction Treatment Act (DATA) to limited to physicians who meet certain qualifying requirements, have notified the Secretary of Health and Human Services (HHS), and have a unique identification number on each prescription. They have the potential for misuse, abuse, and diversion. Patient
use should be monitored as part of counseling and psychosocial support during treatment and precautions taken against potential abuse. As with other opioids, physical dependence, respiratory depression, and overdose may also occur; hence monitoring and frequent patient evaluation should be used as part of an overall treatment plan. Safety and effectiveness in pediatric patients under the age of 18 has not been established (1-4).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of opioids and opioid dependence medications while maintaining optimal therapeutic outcomes.

References
4. Oxycodone [package insert], North Wales, PA: Teva Pharmaceuticals; October 2015.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>December 2016</td>
<td>Addition to PA and Annual review</td>
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<tr>
<td>May 2017</td>
<td>Addition of methadone to criteria</td>
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<tr>
<td>July 2017</td>
<td>Methadone requirement changing to only patients currently on opioid therapy must be tapered off within 30 days</td>
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<tr>
<td>September 2017</td>
<td>Annual review</td>
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March 2018
Annual editorial review
Removal of the requirement of patient will be monitored during therapy for signs and symptoms of abuse / misuse as well as compliance and the potential diversion to others

March 2019
Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.