Clinical Policy: Methadone for Management of Pain

Description

Methadone is a potent synthetic opiate agonist of the phenylheptylamine class and is structurally unrelated to morphine. Methadone is the most frequently used agent in medically supervised opiate withdrawal and maintenance programs. Methadone is an effective analgesic but is considered a second-line agent in the treatment of severe, chronic pain. Methadone is useful in patients who have developed tolerance to other opiate agonists or have developed intractable side effects due to opiate therapy. Equianalgesic dosing of chronic methadone and other opiate agonists is unclear. Benefits of methadone in the treatment of chronic pain include lack of active metabolites, high bioavailability following oral administration, and low cost.

FDA Approved Indication(s)

All edits are based on FDA labeling as published by the manufacturer

Brand

Multiple Medication classes are included in this edit

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that buprenorphine/naloxone or buprenorphine is medically necessary for members meeting the following criteria:

Initial Approval Criteria:
methadone oral tablet, dispersible tablet, or oral solution

A. Indication of methadone is for the treatment of long term chronic pain requiring long term therapy (must meet all);

   1. Diagnosis of moderate to severe chronic pain;

   2. Failure of at least TWO non-opioid ancillary treatments (such as non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen, anticonvulsants, antidepressants, etc.) at maximum tolerated doses, unless contraindicated;
3. Member must have trialed and failed monotherapy with an immediate release agent;
4. Member has tried and failed all preferred long acting opioids

AND

B. Total daily dose ≤ 60mg;

OR

C. Total daily dose > 60mg; and
D. Member not opiate naïve; and
E. Member tried methadone with total daily dose ≤ 60mg with suboptimal pain relieving effect and therefore this is a dose increase; or
F. Member has intractable side effects or tolerance to pain relieving effects of other opiate medication and equianalgesic conversion from other opiate suggests starting dose of methadone > 60mg (Appendix A).

Approval duration: 6 months

Continued Approval (must meet all criteria as applicable):
A. Indication for methadone continues to be pain management
B. Member not experiencing severe adverse reactions to methadone

Approval duration: 6 months
Appendix A: Equinagesic Conversion Chart

<table>
<thead>
<tr>
<th>Opioid Agonist</th>
<th>Oral/Rectal mg</th>
<th>IV/SC mg</th>
<th>IV to PO</th>
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</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>30</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>20</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>7.5</td>
<td>1.5</td>
<td>5</td>
</tr>
<tr>
<td>Codeine</td>
<td>200</td>
<td>120 (IM)</td>
<td>N/A</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>30</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Oxymorphone</td>
<td>10</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Fentanyl¹</td>
<td>N/A</td>
<td>100 mcg/single dose</td>
<td></td>
</tr>
<tr>
<td>Methadone²</td>
<td>1-20</td>
<td>1-10</td>
<td>1.5</td>
</tr>
<tr>
<td>Codeine</td>
<td>200</td>
<td>130</td>
<td>1.5</td>
</tr>
</tbody>
</table>

Equianalgesic dose (route) current opioid = Equianalgesic dose (route) Desired opioid

24hr dose (route) current opioid = 24hr dose (route) Desired opioid

These are NOT suggested starting doses; these are doses of opioids that produce approximately the same amount of analgesia. Titration to clinical response is necessary. Recommended doses do not apply to patients with renal or hepatic insufficiency. Elderly patients generally require lower doses, titrated slowly to the desired effect or intolerable side effects.

CONVERTING TO/FROM FENTANYL PATCH
1mg/h fentanyl transdermal = 2mg total oral morphine/day
25mcg/h fentanyl transdermal = 9 tabs per day of:
Oxycodone 5mg/APAP 325mg, Hydrocodone 7.5mg/APAP 325mg, Codeine 30mg/APAP
(PercoceT) (LoritabT) (TyloxT)

PREVENTING CROSS TOLERANCE
When converting from one opioid to another decrease the equianalgesic dose by 25-50% to allow for incomplete cross-tolerance between different opioids. (may need to titrate rapidly to an analgesic dose within the first 24 hrs).

OPIOIDS NOT RECOMMENDED FOR USE

Naproxene SHOULD NOT BE USED in elder adults or patients with renal failure because of CNS toxic metabolites. Contraindicated with MAOls.

Mixed agonist/antagonist (pentazocine, butorphanol, nalbuphine): compete with opioids leading to withdrawal, analgesic ceiling effect, high risk of psychomimetic adverse effects.

Propoxyphene: no better than placebo. Toxic metabolites at high doses.

OPIOIDS SPECIAL PRECAUTIONS

Methadone Variable pharmacodynamic and pharmacokinetic effects complicate the use of methadone for analgesia. Symptoms of overdose may be delayed 3-7 days after starting or increasing Methadone. Escalate methadone off 4-7 days.

References:
2. University of Texas Geriatric Equianalgesic Conversion Table.

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>New Policy</td>
<td>7/15</td>
<td>7/15</td>
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<tr>
<td>Reformatted policy to be consistent with pharmacy medical necessity format</td>
<td>10/15</td>
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<tr>
<td>Added Appendix A, Equianalgesic Table</td>
<td></td>
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<tr>
<td>Added detail to long term chronic therapy for initial therapy criteria A</td>
<td>9/16</td>
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<td>Added that methadone has step therapy through all other preferred long acting opioids.</td>
<td>7/2017</td>
<td>7/2017</td>
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<tr>
<td>Annual Review – No updates needed</td>
<td>7/2018</td>
<td>7/2018</td>
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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional
organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.
For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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