

Methadone

Medical policy no. 65.10.00.50

Effective: November 1, 2019

Note:

- For non-preferred agents in this class/category, patients must have had an inadequate response or have had a documented intolerance due to severe adverse reaction or contraindication to at least TWO* preferred agents.
*If there is only one preferred agent in the class/category documentation of inadequate response to ONE preferred agent is needed
- If a new-to-market drug falls into an existing class/category, the drug will be considered non-preferred and subject to this class/category prior authorization (PA) criteria

Related medical policies:

- Analgesics: Opioid Agonists (medical policy no. 65.10.00)**

Background:

The opioid agonists is a class of medications that is reserved for the treatment of severe pain that cannot be managed by non-pharmacologic therapies or other pharmacologic treatments. Methadone is a long-acting opioid agonist that has strong binding affinity to mu-opioid receptors, meaning that it can be used to provide analgesia or for the treatment of opioid use disorder.

Medical necessity

Drug	Medical Necessity
Methadone	<p>Methadone prescriptions require prior authorization.</p> <p>Methadone may be considered medically necessary when approved under prior authorization by the clinical criteria or by one of the exceptions listed below.</p> <p>Note: This criteria does not apply to methadone dispensed from an opiate treatment program.</p>

Clinical policy:

Clinical Criteria	
Treatment of chronic non-cancer pain	<p>For initial prescriptions for patients with a diagnosis of chronic non-cancer pain, providers must submit the following documentation:</p> <ol style="list-style-type: none"> ONE of the following (a or b) is met: <ol style="list-style-type: none"> Continuation of current methadone therapy for severe chronic non-cancer pain; OR Recent history of failure within the last 12 months, contraindication, or intolerable adverse effects to ALL generic long-acting opioids; Dose less than or equal to 20 mg per day;

	<ul style="list-style-type: none"> ○ For doses greater than 20 mg per day, documentation of clinical benefit at previous doses and clear clinical rationale that the patient is likely to benefit from further dose increases is required, and the criteria under Policy 65.10.00 for Maximum Daily Morphine Equivalent (MME) applies; ○ For use in combination with any other opioid prescription, MME will be calculated as part of the prior authorization criteria, and if the dose exceeds 120 MME per day, the criteria under Policy 65.10.00 for Maximum Daily Morphine Equivalent (MME) applies; <p>If ALL of the criteria is met, the request may be approved for 3 months.</p> <p>Reauthorization requests may be approved for 6 months if patient continues to meet all of the initial criteria and demonstrates clinically meaningful improvements in pain and/or function.</p>
<p>Pain related to cancer, hospice, palliative, or end-of-life care</p>	<p>For patients with a diagnosis or pharmacy claim for active cancer treatment, hospice, palliative care, or end-of-life care:</p> <p>Expedited authorization can be used to authorize methadone prescriptions.</p> <ul style="list-style-type: none"> ○ The pharmacy may submit the claim with the EA code 85000000540 to override the quantity limit and days supply; <ul style="list-style-type: none"> • [this EA does not override the 120 MME limit]; ○ By indicating “CANCER PAIN”, “HOSPICE”, “PALLIATIVE CARE”, OR “END OF LIFE CARE” the provider acknowledges that the patient has a medically necessary need that requires the prescribed opioid and it is documented in the medical record; ○ If the medical condition is provided to the pharmacy telephonically documentation must include the criteria met, who provided verification of the criteria, and the date the verification was provided. Example: a prescription should state, “cancer pain”, “hospice care”, or “palliative care” diagnosis provided by Jane Doe at provider’s office on MM/DD/YYYY;

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
Methadone	20 mg per day

Coding:

HCPCS Code	Description
S0109	Methadone, oral, 5 mg
J1230	Injection, methadone hcl, up to 10 mg

References

1. Dolophine Tablets [package insert]. Columbus, OH: Roxane Laboratories, Inc.; April 2015.
2. Methadone Injection [package insert]. Rockford, IL: Mylan Institutional LLC; January 2013
3. Methadone Oral Solution [package insert]. Columbus, OH: Roxane Laboratories, Inc.; April 2015.
4. Methadone Intensol Concentrate [package insert]. Columbus, OH: Roxane Laboratories, Inc.; April 2015.
5. Methadose Concentrate [package insert]. Hazelwood, MO: Mallinckrodt Inc.; October 2009.
6. Methadose Tablets [package insert]. Hazelwood, MO: Mallinckrodt Inc.; April 2014.
7. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.;
http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed June 2015.
8. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed June 2015.
9. FDA News Release. *SAMHSA and FDA Join to Educate the Public on the Safe Use of Methadone*. Food and Drug Administration Website.
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149572.htm> Accessed June 2015.
10. Medication-Assisted Treatment for Substance Use Disorders. *Follow Directions: How to Use Methadone Safely*. Division of Pharmacologic Therapies Website. <http://www.dpt.samhsa.gov/methadonesafety/> Accessed June 2015.
11. DEA Methadone Fact Sheet. http://www.justice.gov/dea/druginfo/drug_data_sheets/Methadone.pdf. Accessed June 2015.
12. Methadose Dispersible [package insert]. Hazelwood, MO: Mallinckrodt Inc.; December 2014.

History

Date	Action and Summary of Changes
09.18.2019	Updated to match other opioid policies
07.30.2019	Updated to include MME limit due to changes in 65.10.00
10.21.2015	New Policy