Clinical Policy: Methadone

Reference Number: OR.CP.PMN.161
Effective Date: 04.01.22
Last Review Date: 10.22 Revision Log
Line of Business: Medicaid – Trillium Oregon Health Plan

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Methadone hydrochloride is an opioid agonist.

FDA Approved Indication(s)
Methadone is 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.
  Limitation(s) of use:
  - 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 with long-acting opioids, reserve methadone for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
  - Methadone tablets are not indicated as an as-needed (prn) analgesic.
- For the detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- For the maintenance treatment of opioid addiction (heroin or other morphine-ike drugs), in conjunction with appropriate social and medical services.
  Limitation(s) of use:
  - Methadone products used for the treatment of opioid addiction in detoxification or maintenance programs are subject to the conditions for distribution and use required under 42 CFR 8.12.

****Methadone cannot be used for substance abuse treatment in a clinical setting outside of an approved methadone clinic****

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.

This policy is applicable to Methadone 5 mg and 10 mg tablets for pain management. It is the policy of Trillium Community Health Plan that Methadone is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Pain Management (must meet all)**:**

1. Prescribed for pain management for use around-the-clock (not prn);
2. Age ≥ 18 years;

3. Previous use of a short-acting narcotic analgesic with inadequate response *(See Appendix B);*
4. Member meets one of the following (a or b):
   a. Prescribed by or in consultation with a pain management specialist, an oncologist, or for use in palliative or hospice care;
   b. Failure of fentanyl patch and morphine sulfate ER (MS Contin®), unless both are contraindicated or clinically significant adverse effects are experienced;
5. Request does not exceed health plan approved daily quantity limit.

Approval duration: Duration of request or 6 months (whichever is less)

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Pain Management (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Prescribed for use around-the-clock (not prn);
4. Request does not exceed health plan approved daily quantity limit.

Approval duration: Duration of request or 6 months (whichever is less)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 3 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
prn: as-needed

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Short-acting opioid analgesics: codeine sulfate, hydromorphone, meperidine, morphine sulfate, oxycodone, tramadol, codeine/ acetaminophen (APAP), butalbital/APAP/caffeine/codeine, butalbital/aspirin/caffeine/codeine, hydrocodone/APAP, hydrocodone/ibuprofen, oxycodone/APAP, oxycodone/ibuprofen, tramadol/APAP	Varies	Not applicable

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Significant respiratory depression;
  - Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment;
  - Known or suspected gastrointestinal obstruction, including paralytic ileus;
  - Hypersensitivity to methadone.
- Boxed warning(s):
  - Addiction, abuse, and misuse;
  - Life-threatening respiratory depression;
  - Accidental ingestion;
  - Life-threatening QT prolongation;
  - Neonatal opioid withdrawal syndrome;
  - Cytochrome P450 interaction;
  - Risks from concomitant use with benzodiazepines or other CNS depressants;
  - Conditions for distribution and use of methadone products for the treatment of opioid addiction.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Pain Management	For opioid naïve patients: 2.5 mg PO every 8 to 12 hours To convert to Methadone tablets from another opioid: use available conversion factors to obtain estimated dose Titrate slowly with dose increases no more frequent than every 3 to 5 days	N/A

VI. Product Availability

Tablets: 5 mg and 10 mg

VII. References

1. Dolophine Prescribing Information. Eatontown, NJ: West-Ward Pharmaceuticals Corp.; June 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/006134s050lbl.pdf . Accessed July 28, 2022.
2. Methadone Prescribing Information. Eatontown, NJ: Hikma Pharmaceuticals USA Inc.; August 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=802ab399-479b-4271-a2a7-07aadde91cff&type=pdf. Accessed July 28, 2022.
3. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. JAMA. 2016;315(15):1624-1645.
4. The American Academy of Pain Medicine. The Evidence against Methadone as a "Preferred" Analgesic: A position statement from the American Academy of Pain Medicine. Available at: https://painmed.org/position-statements/?option=com_content&view=article&id=92;the-evidence-against-methadone-as-a-preferred-analgesic&catid=32;position-statements. Accessed July 28, 2022.
5. The American Academy of Pain Medicine. Clinical practice guidelines. Methadone for Pain Management: Improving Clinical Decision Making. Recommended Prescriber Practices from the American Academy of Pain Medicine. July 2016. Available at: http://www.painmed.org/library/clinical-guidelines/. Accessed July 28, 2022.
6. Manchikanti L, Kaye AM, Knezevic NN, et al. Responsible, Safe, and Effective Prescription of Opioids for Chronic Non-Cancer Pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines. Pain Physician. 2017 Feb;20(2S):S3-S92.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy TCHP.PHAR.1901 Methadone (Dolophine); no significant changes; references reviewed and updated.	12.20.21	01.06.22
4Q 2022 annual review: no significant changes; removed references to Dolophine as discontinued product; references reviewed and updated.	09.16.22	10.06.22

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

 Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.