PRIOR AUTHORIZATION CRITERIA

<table>
<thead>
<tr>
<th>BRAND NAME (generic)</th>
<th>DOLOPHINE (methadone hydrochloride tablets)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>METHADONE / METHADONE INTENSOL (methadone hydrochloride injection; oral solution; oral concentrate)</td>
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<tr>
<td></td>
<td>METHADOSE (methadone hydrochloride oral concentrate; dispersible tablets; tablets)</td>
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**Status:** CVS Caremark Criteria  
**Type:** Post Limit Prior Authorization

**POLICY**

**FDA-APPROVED INDICATIONS**

**Dolophine Tablets**

Dolophine 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.

**Limitations 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 Dolophine for use in patients for whom alternative analgesic treatment options (e.g., non-opioid analgesics or immediate-release opioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Dolophine is not indicated as an as-needed (prn) analgesic.
- Detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- Maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

**Methadone Injection**

- For the treatment of moderate to severe pain not responsive to non-narcotic analgesics.
- For use in temporary treatment of opioid dependence in patients unable to take oral medication.

Outpatient maintenance and outpatient detoxification treatment may be provided only by opioid treatment programs (OTPs) certified by the Federal Substance Abuse and Mental Health Services Administration (SAMHSA) and registered by the Drug Enforcement Administration (DEA). This does not preclude the maintenance treatment of a patient with concurrent opioid addiction who is hospitalized for conditions other than opioid addiction and who requires temporary maintenance during the critical period of hospitalization, or of a patient whose enrollment has been verified in a program which has been certified for maintenance treatment with methadone.

NOTE: INJECTABLE METHADONE PRODUCTS ARE NOT APPROVED FOR THE OUTPATIENT TREATMENT OF OPIOID DEPENDENCE. IN THIS PATIENT POPULATION, PARENTERAL METHADONE IS TO BE USED ONLY FOR PATIENTS UNABLE TO TAKE ORAL MEDICATION, SUCH AS HOSPITALIZED PATIENTS.

**Methadone Oral Solution**

Methadone Hydrochloride Oral Solution USP 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.

**Limitations 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 Hydrochloride Oral Solution USP for use in patients for whom alternative analgesic treatment options (e.g., non-opioid analgesics or immediate-release opioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Methadone Hydrochloride Oral Solution USP is not indicated as an as-needed (prn) analgesic.
- Detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
• Maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

**Methadone Intensol Oral Concentrate**

Methadone Hydrochloride Oral Solution USP 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.

**Limitations 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 Hydrochloride Oral Solution USP for use in patients for whom alternative analgesic treatment options (e.g., non-opioid analgesics or immediate-release opioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Methadone Hydrochloride Oral Solution USP is not indicated as an as-needed (prn) analgesic.
- Detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- Maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

**Methadose Concentrate**

- For detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- For maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

**Note**

Outpatient maintenance and outpatient detoxification treatment may be provided only by Opioid Treatment Programs (OTPs) certified by the Federal Substance Abuse and Mental Health Services Administration (SAMHSA) and registered by the Drug Enforcement Administration (DEA). This does not preclude the maintenance treatment of a patient with concurrent opioid addiction who is hospitalized for conditions other than opioid addiction and who requires temporary maintenance during the critical period of his/her stay, or of a patient whose enrollment has been verified in a program which has been certified for maintenance treatment with methadone.

**Methadose Dispersible**

- For detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- For maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

**Note** – Outpatient maintenance and outpatient detoxification treatment may be provided only by Opioid Treatment Programs (OTPs) certified by the Federal Substance Abuse and Mental Health Services Administration (SAMHSA) and registered by the Drug Enforcement Administration (DEA). This does not preclude the maintenance treatment of a patient with concurrent opioid addiction who is hospitalized for conditions other than opioid addiction and who requires temporary maintenance during the critical period of his/her stay, or of a patient whose enrollment has been verified in a program which has been certified for maintenance treatment with methadone.

**Methadose Tablets**

Methadose Oral Tablets (methadone hydrochloride tablets USP) 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.

**Limitations 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 Methadose for use in patients for whom alternative analgesic treatment options (e.g., non-opioid analgesics or immediate-release opioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Methadose is not indicated as an as-needed (prn) analgesic.
- Detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- Maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

**Conditions For Distribution And Use Of Methadone Products For The Treatment Of Opioid Addiction**

Code of Federal Regulations, Title 42, Sec 8

Methadone products when used for the treatment of opioid addiction in detoxification or maintenance programs, shall be dispensed only by opioid treatment programs (and agencies, practitioners or institutions by formal agreement with the program sponsor) certified by the Substance Abuse and Mental Health Services Administration and approved by the designated state authority. Certified treatment programs shall dispense and use methadone in oral form only and according to the treatment requirements stipulated in the Federal Opioid Treatment Standards (42 CFR 8.12). See below for important regulatory exceptions to the general requirement for certification to provide opioid agonist treatment.

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Failure to abide by the requirements in these regulations may result in criminal prosecution, seizure of the drug supply, revocation of the program approval, and injunction precluding operation of the program.

Regulatory Exceptions To The General Requirement For Certification To Provide Opioid Agonist Treatment:
During inpatient care, when the patient was admitted for any condition other than concurrent opioid addiction (pursuant to 21CFR 1306.07(c)), to facilitate the treatment of the primary admitting diagnosis.
During an emergency period of no longer than 3 days while definitive care for the addiction is being sought in an appropriately licensed facility (pursuant to 21CFR 1306.07(b)).

COVERAGE CRITERIA
Methadone will be covered with prior authorization when the following criteria are met:
- Methadone is NOT being prescribed for detoxification treatment or as part of a maintenance treatment plan for opioid/substance abuse or addiction
- The patient does NOT have any of the following: significant respiratory depression OR known or suspected paralytic ileus
- Methadone is being prescribed for pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate
- The patient can safely take the requested dose based on their current opioid use history
- The patient has been evaluated and will be monitored regularly for the development of addiction, abuse, or misuse of methadone

REFERENCES