

PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 9/21/2017  
LAST REVIEW DATE: 11/19/2020  
LAST CRITERIA REVISION DATE: 11/19/2020  
ARCHIVE DATE:

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## DOLOPHINE (methadone hcl) oral tablet (brand and generic) METHADONE (methadone hcl) oral tablet and liquid (brand and generic)

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Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy).

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to [Pharmacyprecert@azblue.com](mailto:Pharmacyprecert@azblue.com). **Incomplete forms or forms without the chart notes will be returned.**

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**Criteria:**

- **Criteria for initial therapy:** Dolophine or Methadone (brand and generic) for **pain** is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:
1. Individual is 18 years of age or older
  2. A confirmed diagnosis of **ONE** of the following:
    - a. cancer related pain
    - b. pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options such as **Short Acting Narcotics** and **non-opioid therapy** are ineffective, not tolerated, or inadequate
  3. **For pain:** Failure, contraindication, or intolerance to at least **2 medications** listed below:
    - a. Morphine Extended Release (brand or generic)
    - b. Embeda ER capsule
    - c. Nucynta ER tablet
    - d. Oxycodone ER tablet (brand or generic)
    - e. Fentanyl transdermal
  4. Coordination of care will be performed between different prescribers for **ALL** controlled substances
  5. **For non-cancer pain:** A **treatment plan**, including:
    - a. Pain intensity (scales or ratings)
    - b. Functional status (physical and psychosocial)
    - c. Patient's goal of therapy (level of pain acceptable and/or functional status)
    - d. Current non-pharmacological treatment
  6. **For non-cancer pain:** For **morphine equivalent dosing (MED) greater than 180mg/day:**
    - a. A dosing schedule to bring individual to a lower dosage of MED less than 180mg/day (titration schedule required)
  7. **For non-cancer pain:** Physician-patient **pain management contract** must be provided
  8. **For non-cancer pain:** Documentation must be included for **random urine or blood tests** twice a year
  9. **For non-cancer pain:** Documentation of **PDMP reviewed** by the prescriber every time a prescription for controlled substance is provided
  10. **For non-cancer pain:** **One pharmacy (and another 24-hour closest pharmacy)** must be selected for all the controlled substances prescription services (limitation may vary by specific member's benefit plan\*)
  11. **For non-cancer pain:** Individual has been evaluated and must **not** have an active addiction to illicit substances or prescription drugs or a drug seeking behavior

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12. **For pain:** There is **NO** concomitant use with benzodiazepines-ex. clonazepam, lorazepam, diazepam etc. **OR** there is a treatment plan to taper use and to coordinate care among all prescribers
13. **For pain:** There are **NO** contraindications.
- Contraindications include:
    - Significant respiratory depression
    - Acute or severe bronchial asthma
    - Known or suspected gastrointestinal obstruction, including paralytic ileus
    - Hypersensitivity to morphine
    - Simultaneous use of monoamine oxidase inhibitors (MAOI) or use within 14 days

### **Initial approval duration:**

- Dolophine or Methadone will be approved at the requested dosage for 6 months for pain not related to cancer
- Dolophine or Methadone will be approved at the requested dosage for 12 months for pain related to cancer
- For non-cancer pain, one pharmacy (and another 24-hour closest pharmacy) must be selected for all the controlled substances prescription services (limitation may vary by specific member's benefit plan\*)

- **Criteria for continuation of coverage (renewal request):** Dolophine (brand and generic) or Methadone (brand and generic) is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:

- Individual's pain is controlled with these products
- There is documentation that coordination of care is being performed between different prescribers for **ALL** controlled substances
- The condition has not progressed or worsened while on therapy and no development of severe side effects like:
  - Apnea, dyspnea, epistaxis, hemoptysis, hyperventilation, hypoxia, upper respiratory infection etc.
  - Confusion/speech disturbance
  - Dehydration
  - Atrial fibrillation/arrhythmia/chest pain
  - Ascites
- For non-cancer pain:** A **treatment plan**, including:
  - Pain intensity (scales or ratings)
  - Functional status (physical and psychosocial)
  - Patient's goal of therapy (level of pain acceptable and/or functional status)
  - Current non-pharmacological treatment
- For non-cancer pain:** Physician-patient **pain management contract** must be provided

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6. **For non-cancer pain:** Documentation must be included for random urine or blood tests twice a year
7. **For non-cancer pain:** Documentation of PDMP reviewed by the prescriber every time a prescription for controlled substance is provided
8. **For non-cancer pain:** One pharmacy (and another 24-hour closest pharmacy) must be selected for all the controlled substances prescription services (limitation may vary by specific member's benefit plan\*)
9. **For non-cancer pain:** Individual has been evaluated and must **not** have an active addiction to illicit substances or prescription drugs or a drug seeking behavior
10. There is **NO** concomitant use with benzodiazepines-ex. clonazepam, lorazepam, diazepam etc. OR there is a treatment plan to taper use and to coordinate care among all prescribers

### Renewal duration:

- Dolophine or Methadone will be approved at the requested dosage for 12 months for pain not related to cancer
- Dolophine or Methadone will be approved at the requested dosage for 12 months for pain related to cancer
- For non-cancer pain, one pharmacy (and another 24-hour closest pharmacy) must be selected for all the controlled substances prescription services (limitation may vary by specific member's benefit plan\*)

\*For Qualified Health Plans (QHP) for Individuals/Families and Small Groups:

"**Narcotics Designated Network Program**" is a program that requires certain members taking narcotic medications to obtain prescriptions for all covered narcotic medications from one designated eligible physician or other provider and to obtain all covered narcotic medications from one network pharmacy designated by BCBSAZ and/or the PBM.

- **Patients should be tapered off or lower the dosage if any of the following apply: See "Definitions" section for Tapering guidelines**
  - The patient has committed serious or repeated drug seeking behavior
  - The patient makes no progress toward therapeutic goals
- **For all patients receiving more than 200 mg morphine or equivalent per 24 hours: See "Definitions" section for Tapering guidelines**
  - Taper patient to a lower dosage
  - Provide a Naloxone prescription to avoid side effects
  - Initiate/augment non-opioid treatments
  - Provide GH/Case management support to help with the taper

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### Description:

- Methadone is FDA-approved for detoxification and maintenance treatment of opioid addiction.

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- o 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) (Prescribing information: DOLOPHINE<sup>®</sup>, 2017; methadone oral solution, 2016; METHADOSE<sup>®</sup>, 2016).
- o Most long-acting opioids are associated with boxed warnings regarding the potential for abuse and misuse, life-threatening respiratory depression, neonatal opioid withdrawal syndrome, an interaction with alcohol, and accidental ingestion risks. DOLOPHINE and methadone products have additional boxed warnings regarding life-threatening QT prolongation.

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 extended-release opioid formulations, reserve Arymo ER (morphine sulfate) and Morphabond ER (morphine sulfate) 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. Arymo ER (morphine sulfate) and Morphabond (morphine sulfate) are not indicated as an as needed (PRN) analgesic.

Pain is a subjective episode described as an unpleasant, multi-dimensional, sensory, and emotional experience associated with actual or potential tissue damage or described in relation to such damage. The perception of pain is further influenced by physical, psychological, social, cultural, and hereditary factors. Persistent pain will often require treatment with regularly scheduled analgesics and supplemental analgesics for breakthrough periods.

Chronic pain can be defined as any pain that persists beyond the anticipated time of normal tissue healing, which is generally assumed to be three months. Chronic pain may be caused by numerous medical conditions and syndromes with widely divergent pathophysiology.

Opioid analgesic medications relieve a wide variety of pain syndromes and are generally accepted for the treatment of severe acute pain and chronic pain related to active cancer. In contrast, the use of chronic opioid therapy to treat other types of chronic pain not associated with malignancy remains controversial. There is a large amount of clinical experience with opioids for the treatment numerous pain syndromes, yet there are limited data on the safety and efficacy of long-term opioid therapy for chronic non-cancer pain.

There are many agents available with brand and generic options for the treatment of pain. Several agents are available as both immediate- (or short-) acting and long-acting formulations. There are clinically meaningful differences in potency, time to onset, elimination and duration of action among the various compounds.

Long-acting opioids are more convenient than short-acting opioids for the treatment of chronic pain conditions, although there is no reliable evidence of their superiority. There is no reliable comparative evidence demonstrating that one long-acting opioid is more effective than another opioid analgesic, including immediate-acting or other long-acting formulations.

Specific central nervous system (CNS) opiate receptors and endogenous compounds with morphine-like activity have been identified throughout the brain and spinal cord and are likely to play a role in the expression and

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perception of pain. Opioid receptors have also been identified within the peripheral nervous system (PNS). The primary site of therapeutic action of opioids is within the CNS. Opioid agonists are thought to reduce pain by acting primarily through interaction with opioid mu-receptors located in the brain, spinal cord, and smooth muscle. Opioid agonists produce respiratory depression by direct action on the brain stem respiratory center.

All opioids have the potential to cause respiratory depression, abuse and physical dependence. None have been proven to be safer than another. One method employed by manufacturers to mitigate abuse of opioids has been formulating products that are difficult to extract the main opioid ingredient from the original form. No opioid formulation or reformulation prevents use of large dosage units which is the most common method of abuse. There is concern that use of abuse deterrent formulations may shift use to other opioids, including heroin.

Providers should individualize treatment of pain in every case, using non-opioid analgesics, opioids on an as needed basis, combination products, and when appropriate chronic opioid therapy in a progressive comprehensive plan of pain management.

The World Health Organization's (WHO) guidelines for cancer pain management recommends a three-stepped approach with consideration for the type of pain and response to therapy. Initial therapy includes non-opioid analgesics such as non-steroidal anti-inflammatory drugs (NSAIDs). For mild to moderate pain, oral combinations of acetaminophen and NSAIDs with opioids are recommended. For moderate to severe pain, opioid analgesics are recommended. Titration of dose and frequency is individualized to the patient's response and development of adverse effects. For patients with inadequate pain relief and intolerable opioid-related toxicity/adverse effects, a switch to an alternative opioid may be an option for obtaining symptomatic relief.

The National Comprehensive Cancer Network (NCCN) 2015 Clinical Practice Guideline in Oncology: Adult Cancer Pain outlines numerous steps in managing opioid medications in cancer pain that can be adapted for non-cancer pain management. Examples of some of the recommendations include: use short-acting opioid medications for titration, for persistent pain initiate regular schedule of opioid with a rescue dose as needed, calculate opioid dose increase based on the total 24-hour dose (around the clock/scheduled and as needed doses), when possible, use the same short-acting and long-acting opioid formulation, and simplify regimen for improved adherence.

In theory, opioids have no maximum or ceiling dose; however recent guidelines suggest close evaluation of individuals using large doses of opioid medications to identify unique opioid related adverse effects. Morphine is a full opioid agonist and is relatively selective for the mu-opioid receptor, although it can bind to other opioid receptors at higher doses.

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### **Definitions:**

### **CDC Recommendations for Opioid Prescribing for Chronic Pain:**

#### **A. Determining when to initiate or continue opioids for chronic pain**

1. Opioids are not first-line or routine therapy for chronic pain
2. Establish and measure goals for pain and function
3. Discuss benefits and risks and availability of non-opioid therapies with patient

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### B. Opioid selection, dosage, duration, follow-up, and discontinuation

1. Use immediate-release opioids when starting
2. Start low and go slow - Use caution at any dose and avoid increasing to high dosages
3. When opioids are needed for acute pain, prescribe no more than needed
  - Do NOT prescribe ER/LA opioids for acute pain
4. Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if opioids cause harm or are not helping

### C. Assessing risk and addressing harms of opioid use

1. Evaluate risk factors for opioid-related harms
2. Check CSPMP for high dosages and prescriptions from other providers at the beginning of the treatment and at least quarterly while on the opioid treatment
3. Use urine drug testing to identify prescribed substances and undisclosed use
4. Avoid concurrent benzodiazepine and opioid prescribing
5. Arrange treatment for opioid use disorder if needed

### Prescriber Education:

- Guidelines for Prescribing Opioids for Chronic Pain  
[https://www.cdc.gov/drugoverdose/pdf/TurnTheTide\\_PocketGuide-a.pdf](https://www.cdc.gov/drugoverdose/pdf/TurnTheTide_PocketGuide-a.pdf)  
[http://www.agencymeddirectors.wa.gov/Files/FY16-288SummaryAMDGOpioidGuideline\\_FINAL.pdf](http://www.agencymeddirectors.wa.gov/Files/FY16-288SummaryAMDGOpioidGuideline_FINAL.pdf)  
[https://www.cdc.gov/drugoverdose/pdf/Guidelines\\_Factsheet-a.pdf](https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf)
- Checklist for prescribing opioids for chronic pain  
[https://www.cdc.gov/drugoverdose/pdf/PDO\\_Checklist-a.pdf](https://www.cdc.gov/drugoverdose/pdf/PDO_Checklist-a.pdf)
- Tapering Opioids for Chronic Pain  
[https://www.cdc.gov/drugoverdose/pdf/Clinical\\_Pocket\\_Guide\\_Tapering-a.pdf](https://www.cdc.gov/drugoverdose/pdf/Clinical_Pocket_Guide_Tapering-a.pdf)
- Non-Opioid Treatments  
[https://www.cdc.gov/drugoverdose/pdf/nonopioid\\_treatments-a.pdf](https://www.cdc.gov/drugoverdose/pdf/nonopioid_treatments-a.pdf)
- Assessing Benefits and Harms of Opioid  
[https://www.cdc.gov/drugoverdose/pdf/Assessing\\_Benefits\\_Harms\\_of\\_Opioid\\_Therapy-a.pdf](https://www.cdc.gov/drugoverdose/pdf/Assessing_Benefits_Harms_of_Opioid_Therapy-a.pdf)
- Calculating Total Daily Dose of Opioids for Safer Dosage  
[https://www.cdc.gov/drugoverdose/pdf/calculating\\_total\\_daily\\_dose-a.pdf](https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf)
- Checking Controlled Substances Prescription Monitoring Program (CSPMP)  
<https://arizona.pmpaware.net/login>  
<https://pharmacypmp.az.gov/>
- Educational Webinar Series for Prescribers  
<https://www.cdc.gov/drugoverdose/pdf/COCA-webinar-series-allslides-a.pdf>  
<https://www.cdc.gov/drugoverdose/prescribing/trainings.html>  
<http://www.coperems.org/>
- CDC Guideline for Prescribing Opioids for Chronic Pain  
<https://www.cdc.gov/drugoverdose/prescribing/clinical-tools.html>

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- Washington State Opioid Taper Plan Calculator  
[www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf](http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf)
- Tapering Long-Term Opioid Therapy in Chronic Non-Cancer Pain  
[www.mayoclinicproceedings.org/article/S0025-6196\(15\)00303-1/fulltext](http://www.mayoclinicproceedings.org/article/S0025-6196(15)00303-1/fulltext)
- UpToDate  
[https://www.uptodate-com.mwu.idm.oclc.org/contents/overview-of-the-treatment-of-chronic-non-cancer-pain?source=search\\_result&search=non-cancer%20pain&selectedTitle=1~150](https://www.uptodate-com.mwu.idm.oclc.org/contents/overview-of-the-treatment-of-chronic-non-cancer-pain?source=search_result&search=non-cancer%20pain&selectedTitle=1~150)

**Sustained release (SR) and extended release (ER) and controlled release (CR) formulation:**

A dose form where active drug is released slowly over a prolonged period of time thereby allowing for less frequent administration throughout the day  
Also known as long-acting formulation

**Immediate release formulation:**

A dose form where active drug is released quickly over a short period of time and usually requires more frequent/multiple administration throughout the day  
Also known as short-acting formulation

**Opioid Risk Assessment Tool:**

Score each that applies	Female	Male
Family history of substance abuse		
Alcohol	1	3
Illegal drugs	2	3
Rx drugs	4	4
Personal history of substance abuse		
Alcohol	3	3
Illegal drugs	4	4
Rx drugs	5	5
Age between 16-45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disorders		
ADD,OCD, Bipolar, Schizophrenia	2	2
Depression	1	1
Total score		
Assessment of risk		
Low risk for abuse	< 3	
Moderate risk for abuse	4-7	
High risk for abuse	≥ 8	
Definitions of risk		
Low = unlikely to abuse		
Moderate = as likely will as will not abuse		
High = likely to abuse		



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**Resources:**

Dolophine (methadone). Package Insert. Revised by manufacturer 10/2019. Accessed 06-15-20.

Methadone. Package Insert. Revised by manufacturer 12/2018. Accessed 06-15-20.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.

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