

Effective: October 1, 2023

Guideline Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Non-Formulary <input type="checkbox"/> Step-Therapy <input type="checkbox"/> Administrative
Applies to:	
Commercial Products	
<input checked="" type="checkbox"/> Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988 <input checked="" type="checkbox"/> Tufts Health Plan Commercial products; Fax: 617-673-0988 CareLink SM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization	
Public Plans Products	
<input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988	

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Rules and Regulations for Pain Management, Opioid Use, and the Registration of Distributors of Controlled Substances in Rhode Island [R21-28-CSD]. These regulations apply to patients considered “initiates,” individuals who have not had an opioid in the last 30 days. Section 3.3 of the regulation limits the initial prescription to 20 doses and no more than 30 morphine milligram equivalents (MME) per day and prohibits the prescribing of long-acting or extended-release opioids; like methadone, for acute pain.

Short-acting opioid analgesics are indicated for the management of moderate to severe pain for which use of an opioid analgesic is appropriate.

Long-acting opioid analgesics 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.

Because of the risks of addiction, abuse, and misuse with opioids, even at doses recommended by clinical guidelines, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve long-acting opioids for use in patients for whom alternative treatment options (e.g., nonopioid analgesics, immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Long-acting agents are not indicated as an as-needed analgesic.

Clinical Guideline Coverage Criteria

Long-Acting Opioids Requiring Prior Authorization

The plan may authorize coverage of all **long-acting opioids** for patients, when **all** the following criteria are met:

Initial Criteria:

1. Both of the following:
 - a. The patient is diagnosed with sickle-cell, cancer-related, or end-of-life pain

AND

 - b. If requesting Oxycontin or oxycodone ER, has the Patient tried and failed or has a contraindication to Xtampza ER

OR
2. All of the following:
 - a. The patient has a diagnosis of chronic pain

AND

- b. The patient has had an inadequate response to a generic immediate release opioid

AND

- c. The patient signed a pain agreement consistent with the American Academy of Pain Management guidelines

AND

- d. The analgesic is prescribed by or in consultation with a pain specialist, addiction specialist, palliative care specialist, hematologist/oncologist, physiatrist, rheumatologist or headache specialist (board certified) OR there is a plan for the patient to be referred to a pain specialist, addiction specialist, palliative care specialist, hematologist/oncologist, physiatrist, rheumatologist or headache specialist (board certified) OR rationale provided why the patient is not a candidate to see a specialist

AND

- e. The risks of opioid analgesics (e.g., tolerance, dependence, respiratory depression, cognitive impairment) have been discussed with the patient

AND

- f. The provider has a plan to monitor for signs of misuse, abuse, and addiction during therapy

AND

- g. For renewals, provider has a taper plan in place or has a rationale as to why a dose taper is not appropriate at this time.

AND

- h. If requesting Oxycontin or oxycodone ER, has the Patient tried and failed or has a contraindication to Xtampza ER

Reauthorization Criteria:

- 1. Both of the following:

- a. The patient is diagnosed with sickle-cell, cancer-related, or end-of-life pain

AND

- b. If requesting Oxycontin or oxycodone ER, the Patient has tried and failed, or has a contraindication to Xtampza ER

OR

- 2. All of the following:

- a. The patient has a diagnosis of chronic pain

AND

- b. The patient signed a pain agreement consistent with the American Academy of Pain Management guidelines

AND

- c. The analgesic is prescribed by or in consultation with a pain specialist, addiction specialist, palliative care specialist, hematologist/oncologist, physiatrist, rheumatologist or headache specialist (board certified) OR there is a plan for the patient to be referred to a pain specialist, addiction specialist, palliative care specialist, hematologist/oncologist, physiatrist, rheumatologist or headache specialist (board certified) OR rationale provided why the patient is not a candidate to see a specialist

AND

- d. The risks of use of a high dose schedule II, III, or IV analgesic use (e.g., tolerance, dependence, respiratory depression, cognitive impairment) have been discussed with the patient

AND

- e. The provider has a plan to monitor for signs of misuse, abuse, and addiction during therapy

AND

- f. The provider has a taper plan in place or has a rationale as to why a dose taper is not appropriate at this time.

AND

- g. If requesting Oxycontin or oxycodone ER, has the Patient tried and failed or has a contraindication to Xtampza ER

Initial Opioid Prescriptions

The plan may authorize coverage of **initial opioid prescriptions** over the quantity limit of 20 doses per fill or 30 morphine milligram equivalents (MME) per day when the following criteria are met:

- 1. The patient has a filled an opioid prescription in the last 30 days

OR

- 2. The patient meets one of the following:

- a. Diagnosis of cancer-associated pain
- b. Diagnosis of sickle cell anemia
- c. Is on palliative/nursing home care
- d. Is currently on chronic pain management

Limitations

1. The Plans will not authorize coverage for more than 30 MMEs per day if there is no documentation the patient has filled an opioid in the past 30 days.
2. Initial authorizations for all opioid analgesics will be for a duration of 6 months, with the exception of opioid analgesics requested for members with a diagnosis of sickle-cell, cancer-related, or end-of-life pain (these authorizations will be for a duration of twelve-months). Reauthorizations will be provided in twelve-month intervals. If no reauthorization criteria is listed, initial criteria must be met. Patients new to the plan stable on an opioid analgesic should be reviewed against Reauthorization Criteria.
3. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception but will be considered on an individual basis for prior authorization.

Codes

None

References

1. Rhode Island *Rules and Regulations for Pain Management, Opioid Use, and the Registration of Distributors of Controlled Substances in Rhode Island [R21-28-CSD]*.
2. DrugDex® System (database online). Greenwood Village, CO: Thomson Micromedex. Available at: micromedexsolutions.com.
3. Facts and Comparisons® (database online). St. Louis, MO: Wolters Kluwer Health, Inc. Available at: factsandcomparisons.com.
4. Micromedex® Healthcare Series [databased on the Internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc.; Updated periodically [cited 2016 March]. Available from: <http://www.micromedexsolutions.com>
5. The American Academy of Pain Management. Prescribing issue. Opioid agreement & contracts. URL : http://www.naddi.org/aws/NADDI/asset_manager/get_file/32898/opioidagreements.pdf Accessed 2016 March 28.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- October 11, 2022: Effective 1/1/23, updated long-acting opioid criteria to clarify criteria for sickle-cell, cancer-related, or end-of-life pain vs pain (Chronic), and clarified requests for Oxycontin/oxycodone ER must require trial and failure with, or contraindication to Xtampza ER.
- July 11, 2023: Effective October 1, 2023, Added initial and reauthorization criteria for long-acting opioids, and updated approval duration in the limitations section: 12 months for a diagnosis of sickle-cell, cancer-related, or end-of-life pain, 6 months for all other initial opioid requests, and 12 months upon reauthorization.
- September 12, 2023: Effective October 1, 2023, clarified requirement with generic immediate-release opioid for long-acting opioid criteria.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.