Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Opioid Analgesics

Effective: October 1, 2023

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ 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

The plan has implemented a prior authorization program for methadone, buprenorphine containing products, and select long acting opioids, which have indications for managing chronic pain and are covered under pharmacy benefit.

Belbuca (buprenorphine) buccal film and **Butrans (buprenorphine) transdermal patch** 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.

Methadone intensol oral concentrate, oral solution, and tablets are indicated for treatment of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. Under the medical benefit, methadone may be covered as detoxification treatment of opioid addiction (heroin or other morphine-like drugs) and maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

Methadone injection is indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatment options are inadequate and temporary treatment of opioid dependence in patients unable to take oral medication.

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 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.

Per the Centers for Disease Control and Prevention (CDC), nonpharmacologic and nonopioid pharmacologic therapy is preferred for the treatment of chronic pain. Opioid therapy should be considered only if the expected benefits for pain and function are expected to outweigh the risks associated with opioid therapy.

Prior to initiating opioid therapy, it is recommended that prescribers establish realistic treatment goals with patients, including realistic goals for pain and function, and discuss the risks of opioid therapy. Clinicians should also consider how opioid therapy will be discontinued if benefits do not outweigh the risks. Opioid therapy should only be considered if there is a clinically significant improvement in pain and function that outweighs the risk to patient safety. Before starting and periodically during opioid therapy, providers should consider risk factors for opioid-related harm, and incorporate into the treatment plan strategies to decrease risk. This includes offering naloxone when there are factors present that increase the risk of opioid overdose (e.g., history of overdose, history of substance abuse disorder, higher opioid dosages [≥ 50 MME/day], concurrent benzodiazepine use).

Once opioids are initiated, providers should prescribe the lowest effective dose. Caution should be used when prescribing opioids at any dosage. Caution should be exercised when prescribing opioids at any dose, and clinicians should carefully reassess the evidence of individual benefits and risks when considering increasing the opioid dosage above 50 morphine milligram equivalents (MME) per day. Per the CDC, clinicians should avoid increasing an opioid dosage above 90 MME/day or carefully justify a decision to titrate a dosage above 90 MME/day, as the benefits of high dose opioids for chronic pain are not established.

Abstral (fentanyl citrate sublingual tablet), Actiq (fentanyl citrate oral transmucosal lozenge), Fentora (fentanyl citrate buccal tablet), Lazanda (fentanyl citrate nasal spray), Subsys (fentanyl sublingual spray), and oral fentanyl citrate are indicated for breakthrough pain, secondary to cancer.

Clinical Guideline Coverage Criteria

Buprenorphine for Pain

The plan may authorize coverage of **buprenorphine transdermal patch** or **Belbuca (buprenorphine) buccal film** for patients, when **all** the following criteria are met:

1. The patient has a documented diagnosis of chronic pain, or end of life pain requiring around the clock, long-term opioid treatment

AND

2. Alternative treatment options are inadequate (non-opioid analgesics and immediate release opioids)

Methadone

The plan may authorize coverage of **methadone** tablet, intensol oral concentrate, oral solution, and injection for patients, when **all** the following criteria are met:

1. The patient has a documented diagnosis of moderate to severe pain requiring continuous, around-the-clock treatment with an opioid analgesic

AND

2. The patient is not opioid-naïve

AND

3. **Non-cancer patients only:** The patient has had an ECG showing a normal QTc interval

AND

4. The patient meets one of the following:
   a. Has had an inadequate response, intolerance, or contraindication to two other long-acting opioid analgesics

   OR

   b. The provider submits a clinical rationale for the use of oral methadone over other long-acting opioid analgesics

AND

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

AND

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

AND

7. The provider has a plan in place to monitor the patient for misuse and addiction during therapy

AND

8. Injection only: Provider submit a clinical rationale for the use of the injection over the oral formulation

Long-Acting Opioids Requiring Prior Authorization

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

Initial Therapy:

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 patient has tried and failed a generic short acting opioid

AND

e. 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

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

AND

g. 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

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

Fentanyl Transmucosal Agents

The plan may authorize coverage of **Fentanyl Transmucosal Agents** for patients, when **all** the following criteria are met:

1. Patient is the following:
   a. 18 years of age or older

   OR

   b. The patient is 16 years of age or older if the request is for brand name Actiq (fentanyl transmucosal lozenge)

   AND

2. The patient has a diagnosis of breakthrough pain due to cancer

AND

3. The patient is currently receiving and is tolerant to at least one or more long-acting opioid analgesics with an average daily dose of at least 30 mg of oxycodone per day, or at least 8 mg of hydromorphone per day, or at least 60 mg of morphine per day, or at least 25mg of oxymorphone per day, or an equianalgesic daily dose of another opioid

Limitations

1. Prior authorization approvals for select long-acting opioids, where a single dosage form or FDA labeled daily dose exceeds 90 MME/day are still subject to review under the Drugs with Quantity Limitations MNG when applicable.
2. In Massachusetts, if prior authorization is approved for a non-abuse deterrent formulation, then coverage must be approved for the abuse deterrent formulation that is chemically equivalent.
3. In Rhode Island, PA on long acting opioids for initial fills still applies.
4. Methadose 40mg soluble oral tablets and Methadose oral concentrate are FDA approved for detoxification treatment and are not covered under the pharmacy benefit.
5. 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.
6. 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.
7. Coverage for select long-acting opioids where a single dosage form or FDA approved daily dose exceeds 90 MME will require prior authorization, and be limited as follows:

Drug	If Approved, Enter Auth for:	GPIs for Additional Authorization
Avinza* 120 mg (morphine sulfate beads ER 24 hr capsules)	Arymo, Embeda, and Morphabond	6510005510A6** 651000557002** 6510005510A7**
Duragesic* 50, 62.5, 75, 87.5, 100 mcg/hr (Fentanyl Patch)		
Hydromorphone ER 32 mg tablet (generic Exalgo)		
Hysingla ER 100 and 120 mg (hydrocodone ER tablet) **ADF**		
Kadian 50, 60, 70, 80, 100, 200 mg (morphine sulfate ER capsule)	Arymo, Embeda, and Morphabond	6510005510A6** 651000557002** 6510005510A7**
Morphine sulfate beads ER 24 hr capsules 120 mg (generic Avinza)	Arymo, Embeda, and Morphabond	6510005510A6** 651000557002** 6510005510A7**
Morphine sulfate ER 12 or 24 hr capsules 50, 60, 70, 80, 100, 200 mg (generic Kadian)	Arymo, Embeda, and Morphabond	6510005510A6** 651000557002** 6510005510A7**
Morphine sulfate ER tablets 60, 100, 200 mg (generic MS Contin)	Arymo, Embeda, and Morphabond	6510005510A6** 651000557002** 6510005510A7**
MS Contin* 60, 100, 200 mg (morphine sulfate ER tablet)	Arymo, Embeda, and Morphabond	6510005510A6** 651000557002** 6510005510A7**
Zohydro ER (hydrocodone ER capsule)	Hysingla ER	6510003010A8**

*Brand = Non-covered, with quantity limitations, ADF = Abuse Deterrent Formulation

Codes

None

References

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4. Butrans (buprenorphine) [prescribing information]. Stamford, CT: Purdue Pharma; June 2022.
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19. Xtampza ER (oxycodone) [prescribing information]. Cincinnati, OH: Patheon Pharmaceuticals; March 2021.

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, Updated overview sections with some updates from CDC recommendations for prescribing opioids for chronic pain. Added requirement that both non-opioid analgesics and immediate release opioids are required for buprenorphine containing products for pain. Added initial and reauthorization criteria for long-acting opioids, clarified that approval required a diagnosis of chronic pain, added initial criteria requirement requiring a trial with a short-acting opioid, 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 short acting 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.