Pharmacy Medical Necessity Guidelines: Opioid Analgesics

Effective: October 19, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

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, 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 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.

COVERAGE GUIDELINES

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

1. The Member 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 or immediate release opioids)

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

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

AND

2. The member is not opioid-naïve

AND

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

AND

4. The member 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 Member 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 Member

AND

7. The provider has a plan in place to monitor the Member 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

The plan may authorize coverage of **select long-acting opioids,** where a single dosage form or FDA labeled daily dose exceeds 90 MME/day, for Members (see attached list in limitations section), when **all** the following criteria are met:

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

OR

2. The member has a diagnosis of pain

AND

3. All of the following:
   a. The Member signed a pain agreement consistent with the American Academy of Pain Management guidelines

AND

b. 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 member 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 member is not a candidate to see a specialist

AND

c. 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 member

AND

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

AND

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

LIMITATIONS

1. Coverage for buprenorphine containing products will be limited as follows:

Buprenorphine 5, 7.5, 10, 15, 20 mcg/hr transdermal patch	4 patches/30 days
Belbuca 150, 300, 450, 600, 750, 900 mcg buccal film	60 films/30 days

2. Coverage for methadone will be limited as follows:

Methadone intensol concentrate	2 ml/day
Methadone oral solution	5 mg/5 mL: 20 mL/day 10 mg/5 mL: 10 mL/day
Methadone tablet	5 mg: 4 tabs/day 10 mg: 2 tabs/day
Methadone injection	2 ml/day

3. 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	Quantity Limitation	If Approved, Enter Auth for:	GPIs for Additional Authorization
Arymo ER 60 mg (morphine sulfate ER tablet) **ADF**	3 tablets/day		
Avinza* 120 mg (morphine sulfate beads ER 24 hr capsules)	1 capsule/day	Arymo, Embeda, and Morphabond	6510005510A6** 651000557002** 6510005510A7**
Duragesic* 50, 62.5, 75, 87.5, 100 mcg/hr (Fentanyl Patch)	10 patches/30 days		
Embeda 50/2, 60/2.4, 80/3.2, 100/4 mg (morphine sulfate ER/naltrexone capsule) **ADF**	3 capsules/day		
Hydromorphone ER 32 mg tablet (generic Exalgo)	1 tablet/day		
Hysingla ER 100 and 120 mg (hydrocodone ER tablet) **ADF**	2 tablet/day		
Kadian 50, 60, 70, 80, 100, 200 mg (morphine sulfate ER capsule)	2 capsules/day	Arymo, Embeda, and Morphabond	6510005510A6** 651000557002** 6510005510A7**
MorphaBond 60 and 100 mg (morphine sulfate ER tablet) **ADF**	3 tablets/day		
Morphine sulfate beads ER 24 hr capsules 120 mg (generic Avinza)	1 capsule/day	Arymo, Embeda, and Morphabond	6510005510A6** 651000557002** 6510005510A7**

Morphine sulfate ER 12 or 24 hr capsules 50, 60, 70, 80, 100, 200 mg (generic Kadian)	2 capsules/day	Arymo, Embeda, and Morphabond	6510005510A6** 651000557002** 6510005510A7**
Morphine sulfate ER tablets 60, 100, 200 mg (generic MS Contin)	3 tablets/day	Arymo, Embeda, and Morphabond	6510005510A6** 651000557002** 6510005510A7**
MS Contin* 60, 100, 200 mg (morphine sulfate ER tablet)	3 tablets/day	Arymo, Embeda, and Morphabond	6510005510A6** 651000557002** 6510005510A7**
Zohydro ER (hydrocodone ER capsule)	2 tablets/day	Hysingla ER	6510003010A8**

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

4. 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.
5. 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.
6. In Rhode Island, PA on long acting opioids for initial fills still applies.
7. Methadose 40mg soluble oral tablets and Methadose oral concentrate are FDA approved for detoxification treatment and are not covered under the pharmacy benefit.
8. Authorizations will be limited to one year.
9. Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior authorization.

CODES

None

REFERENCES

1. Belbuca (buprenorphine) [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc.; October 2015.
2. Butrans (buprenorphine) [prescribing information]. Stamford, CT: Purdue Pharma; June 2014.
3. Centers for Disease Control and Prevention (CDC). Injury prevention & control: opioid overdose. URL: cdc.gov/drugoverdose/pubs/index.html#tabs-760094-4. March 16, 2016. Accessed 2016 March 28.
4. Chou R, Fanciullo GJ, Fine PG, et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *The Journal of Pain*. 2009;10:113-30.
5. Drug Facts and Comparisons® eAnswers [databased on the Internet]. St. Louis: Wolters Kluwer Health, Inc.; 2016 [cited 2016 March]. Available from: online.factsandcomparisons.com.
6. Methadone [prescribing information]. Mahwah, NJ: Glenmark Pharmaceuticals, Inc.; October 2018.Micromedex® Healthcare Series [databased on the Internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc.; Updated periodically [cited 2016 March]. Available from: micromedexsolutions.com
7. The American Academy of Pain Management. Prescribing issue. Opioid agreement & contracts. URL: naddi.org/aws/NADDI/asset_manager/get_file/32898/opioidagreements.pdf Accessed 2016 March 28.

APPROVAL HISTORY

September 18, 2018: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- January 18, 2019: Effective 4/1/19 added PA criteria and quantity limitation for methadone as well as update duration of therapy of MNG to one year.
- June 11, 2019: Clarified that methadone Intensol oral concentrate is the oral concentrate formulation covered with Prior Authorization under the pharmacy benefit.
- September 10, 2019 Effective January 1, 2020 select long-acting opioids, where a single dosage form or FDA approved daily dose exceeds 90 MME per day will require prior authorization. Added list of select medications to limitations section and criteria for applicable medications. Clarified methadone criteria to require inadequate response, intolerance, contraindication, or clinical rationale for the use of oral methadone over other long-acting opioid analgesics. Added the following limitations: 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. 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. In Rhode Island, PA on long acting opioids for initial fills still applies.

- October 15, 2019: Removed "malignant pain" from the criteria as an approvable diagnosis, and added sickle cell-related pain as an approvable diagnosis for long-acting opioids. Added palliative care specialist, physiatrist, rheumatologist, and headache specialist to the list of approvable specialists. Updated methadone criteria to indicate that the member should have had an ECG showing a normal QTc interval.
- July 14, 2020: Added the following limitation: Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior authorization.
- October 13, 2020: Updated methadone criteria to specify that a normal EKG is required for non-cancer patients.

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.

Provider Services