Pharmacy Medical Necessity Guidelines: Buprenorphine Sublingual Tablets

Effective: April 14, 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

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Buprenorphine sublingual tablets are indicated for the treatment of opioid dependence and is preferred for induction. Buprenorphine sublingual tablets should be used as part of a complete treatment plan to include counseling and psychosocial support.

Under the Drug Addiction Treatment Act (DATA) codified at 21 U.S.C. 823(g), prescription use of this product in the treatment of opioid dependence is limited to physicians who meet certain qualifying requirements, and who have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe this product for the treatment of opioid dependence and have been assigned a unique identification number that must be included on every prescription.

COVERAGE GUIDELINES

The plan may authorize coverage of buprenorphine sublingual tablets for Members, when **all** the following criteria are met:

1. Documented diagnosis of opioid dependence

AND

2. Documentation of one of the following:
   a) The Member is currently pregnant or nursing

   OR

   b) The provider submitted documentation of an allergic or hypersensitivity reaction to buprenorphine/naloxone or the naloxone component of buprenorphine/naloxone

AND

3. The Member has not filled prescriptions within the last six months for buprenorphine/naloxone treatment concurrent with **one** of the following, unless the provider clinically justifies the use of the opioid agent due to a recent surgery or adjustment period:
   a) A long-acting opioid agent
   b) A short-acting opioid agent with a cumulative supply of 30 or more days

Upon Renewal

1. Documentation that the Member continues to meet all the coverage criteria.

LIMITATIONS

1. Approval duration will be limited to one year.

CODES

None

REFERENCES

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APPROVAL HISTORY

July 8, 2014: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. June 9, 2015: Dosing criteria removed.
2. January 1, 2016: Administrative change to rebranded template.
3. May 10, 2016: Updated the length of approval to one year. Removed limitation #4 "Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria."
4. February 14, 2017: Removed the requirement that the provider have a unique X-DEA number
5. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
6. July 11, 2017: No changes.
7. July 10, 2018: No changes.
8. June 11, 2019: Administrative changes made to template.
9. April 14, 2020: No changes.

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.