Pharmacy Medical Necessity Guidelines: Buprenorphine Sublingual Tablets

Effective: July 10, 2018

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<th>Prior Authorization Required</th>
<th>Type of Review – Care Management</th>
<th>Not Covered</th>
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<th>Pharmacy (RX) or Medical (MED) Benefit</th>
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This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

**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

**LIMITATIONS**

1. Approval duration will be limited to one year. Subsequent approvals will require documentation the member continues to meet all coverage criteria.

**CODES**

None

**REFERENCES**


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

Subsequent endorsement date(s) and changes made:
- June 9, 2015: Dosing criteria removed.
- January 1, 2016: Administrative change to rebranded template.
- 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.”
- February 14, 2017: Removed the requirement that the provider have a unique X-DEA number.
- May 9, 2017: Administrative update, adding Tufts Health RITogether to the template.
- July 11, 2017: No changes.
- July 10, 2018: 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. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). 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.
This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink SM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.