Pharmacy Medical Necessity Guidelines: Opioid Dependence Medications

Effective: March 20, 2017

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

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

Fax Numbers:
RXUM: 617.673.0988

**Note:** For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

**OVERVIEW**

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**
Suboxone, Zubsolv, and Bunavail (buprenorphine/naloxone) are indicated for the treatment of opioid dependence. Prescription use of these products is limited under the Drug Addiction Treatment Act.

**Note:** There is no prior authorization needed for these drugs if obtained by the provider and provided to the Member during a visit. The prior authorization only applies if the drug will be prescribed and picked up by the Member at the pharmacy.

No prior authorization required for generic buprenorphine/naloxone tablets.

**COVERAGE GUIDELINES**
The plan may authorize coverage of Suboxone film, Zubsolv tablets, and Bunavail buccal film (buprenorphine/naloxone) for Members, when the following criteria are met:

1. Documented diagnosis of opioid dependence

2. Documentation the Member cannot take generic buprenorphine/naloxone tablets

**LIMITATIONS**
1. Suboxone, Zubsolv, and Bunavail (buprenorphine/naloxone) will not be approved for any other diagnosis than those listed above in the criteria.
2. If criteria are met, the approval will be authorized for a period of **12 months**.

**CODES**
None

**REFERENCES**

APPROVAL HISTORY
March 9, 2010: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- November 9, 2010: Added Suboxone Film 2mg / 0.5mg and 8mg / 2mg with a QL of 90 films per 30 days.
- May 10, 2011: Added Documented diagnosis of opioid dependence, The requesting physician is certified to prescribe buprenorphine for opioid dependence and has been granted a special DEA waiver and prefix code (X DEA number), in accordance with DATA 2000 and Documented psychosocial support. Examples of psychosocial support include, but not limited to, the following; Documentation of participation in counseling, Substance-abuse specific support, Treatment that incorporates treatment planning and compliance, Taper schedule and/or previous taper attempts, Relapse prevention, Coping skills, Positive lifestyle adjustments. Added: Doses up to 24mg per day of Suboxone may initially be approved for up to 6 months. After initial approval and required supporting documents, coverage may be extended up to 1 year and Doses of Suboxone greater than 24mg per day, but not exceeding 32mg per day, may be approved for up to 6 months. Doses greater than 24mg per day will require a taper schedule and/or previous taper attempts or reasons why not indicated. Added “Suboxone tablet doses greater than 32mg per day and Suboxone film doses greater than 24mg per day will not be approved” and “Suboxone will not be approved for any other diagnosis than those listed above in the criteria”.
- September 13, 2011: Removed the criteria requiring documented participation is psychosocial support and documented adherence to treatment plan. Removed the Notes section: Doses up to 24mg per day of Suboxone may initially be approved for up to 6 months. After initial approval and required supporting documents, coverage may be extended up to 1 year. Doses of Suboxone greater than 24mg per day, but not exceeding 32mg per day, may be approved for up to 6 months. Doses greater than 24mg per day will require a taper schedule and/or previous taper attempts or reasons why not indicated. Added limitation that if criteria are met the approval will be authorized for a period of 12 months.
- June 12, 2012: Administrative change: updated "Administrative Process (Internal Use Only)” field to LPN/RN.
- August 14, 2012: Added note regarding submission of X DEA number.
- January 15, 2013: Added Suboxone Film 4mg / 1mg with a QL of 90 films per 30 days and 12mg / 3mg with a QL of 60 films per 30 days.
May 14, 2013: Added generic buprenorphine HCl / naloxone HCl sublingual tablets to the criteria and removed limitation #1: The following quantity limitations apply to coverage of Suboxone (buprenorphine HCl / naloxone HCl). Suboxone tablet doses greater than 32mg per day and Suboxone film doses greater than 24mg per day will not be approved. Please refer to the Pharmacy Medical Necessity Guidelines for Drugs with Quantity Limitations and submit a formulary exception request for those Members requiring higher quantities.

- **Suboxone 8mg / 2mg** - 120 sublingual tablets per 30 days
- **Suboxone 2mg / 0.5mg** - 90 sublingual tablets per 30 days
- **Suboxone Film 12mg / 3mg** - 60 films per 30 days
- **Suboxone Film 8mg / 2mg** - 90 films per 30 days
- **Suboxone Film 4mg / 1mg** - 90 films per 30 days
- **Suboxone Film 2mg / 0.5mg** - 90 films per 30 days

October 15, 2013: Added Zubsolv tablets (buprenorphine HCl / naloxone HCl) to the criteria.

November 4, 2014: Changed the name of the criteria to Opioid Dependence Medications and added Bunavail buccal tablets (buprenorphine HCl / naloxone HCl) to the criteria.

October 1, 2015: Administrative update: Added the following note: There is no prior authorization needed for these drugs if obtained by the provider and provided to the Member during a visit. The prior authorization only applies if the drug will be prescribed and picked up by the Member at the pharmacy.

November 10, 2015: Add criterion #3 "Documentation the Member cannot take the generic buprenorphine/naloxone."

January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.

October 18, 2016: No changes

March 14, 2017: removed the requirement documenting the prescriber has been granted an “X” DEA number.

**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 CareLinkSM 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.

**Provider Services**