Pharmacy Medical Necessity Guidelines: Buprenorphine Sublingual Tablets

Effective: November 10, 2026

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

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.

COVERAGE GUIDELINES

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

Initial Criteria:

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

   OR

   c) The provider submits documentation that the Member has moderate-to-severe hepatic impairment (i.e., Child-Pugh B or C)

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

Renewal Criteria:

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

LIMITATIONS

1. Approval duration will be limited to one year.
2. Buprenorphine sublingual tablet will not be approved for the treatment of pain.

CODES

None

REFERENCES

1. Alto WA, O'Connor AB. Management of women treated with buprenorphine during pregnancy. *Am J Obstet Gynecol*. 2011 Oct;205(4):302-8.
2. Amato L, Minozzi S, Davoli M, et al. Psychosocial and pharmacological treatments versus pharmacological treatments for opioid detoxification. Cochrane Database Syst Rev. 2008 Jul 16; (3):CD005031.
3. Assadi SM, Hafezi M, Mokri A, et al. Opioid detoxification using high doses of buprenorphine in 24 hours: a randomized, double blind, controlled clinical trial. *J Subst Abuse Treat*. 2004:27(1):75-82.
4. Castells X, Kosten TR, Capellà D, et al. Efficacy of opiate maintenance therapy and adjunctive interventions for opioid dependence with comorbid cocaine use disorders: A systematic review and meta-analysis of controlled clinical trials. *Am J Drug Alcohol Abuse*. 2009;35(5):339-49.

5. Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004.
6. Connock M, Juarez-Garcia A, Jowett S, et al. Methadone and buprenorphine for the management of opioid dependence: a systematic review and economic evaluation. *Health Technol Assess*. 2007 Mar;11(9):1-171, iii-iv.
7. Fareed A, Vayalapalli S, Casarella J, et al. Effect of buprenorphine dose on treatment outcome. *J Addict Dis*. 2012;31(1):8-18.
8. Gowing L, Ali R, White JM. Buprenorphine for the management of opioid withdrawal. Cochrane Database Syst Rev. 2009 Jul 8;(3):CD002025.
9. Jones HE, Finnegan LP, Kaltenbach K. Methadone and buprenorphine for the management of opioid dependence in pregnancy. *Drugs*. 2012 Apr 16;72(6):747-57.
10. Mattick RP, Kimber J, Breen C, et al. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. Cochrane Database Syst Rev. 2008 Apr 16;(2):CD002207.
11. Minozzi S, Amato L, Vecchi S, Davoli M. Maintenance agonist treatments for opiate dependent pregnant women. Cochrane Database Syst Rev. 2008 Apr 16;(2):CD006318.
12. Soyka M, Kranzler HR, van den Brink W, et al. The World Federation of Societies of Biological Psychiatry (WFSBP) guidelines for the biological treatment of substance use and related disorders. Part 2: Opioid dependence. *World J Biol Psychiatry*. 2011 Apr;12(3):160-87.
13. Subutex [package insert]. Indivior Inc; North Chesterfield, VA: June 2022.
14. Tetrault JM, Fiellin DA. Current and potential pharmacological treatment options for maintenance therapy in opioid-dependent individuals. *Drugs*. 2012 Jan 22;72(2):217-28.
15. Wright NM, Sheard L, Adams CE, et al. Comparison of methadone and buprenorphine for opiate detoxification (LEEDS trial): a randomised controlled trial. *Br J Gen Pract*. 2011 Dec;61(593):e772-80.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. July 11, 2023: No changes.
2. April 9, 2024: Effective May 1, 2024, updated RxUM fax number.
3. November 4, 2025: No changes.
4. November 10, 2026: 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.

Provider Services