Pharmacy Medical Necessity Guidelines: Buprenorphine/Naloxone Medications (Zubsolv®)

Effective: January 1, 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

FDA-APPROVED INDICATIONS

Buprenorphine/naloxone is indicated for the treatment of opioid dependence. It should be used as part of a complete treatment plan to include counseling and psychosocial support.

- Generic buprenorphine/naloxone sublingual tablets and generic buprenorphine/naloxone sublingual film are the preferred buprenorphine/naloxone products. They are covered up to the quantity limit of 32mg/day for the first six months of therapy.

COVERAGE GUIDELINES

The plan may authorize coverage of a non-preferred buprenorphine/naloxone product for Members when **ALL** of the following criteria are met and limitations do not apply:

1. Member has a diagnosis of opioid dependence

AND

2. Provider documentation with rationale for not using the preferred buprenorphine/naloxone products (generic sublingual tablet and film):
   a) Allergic or hypersensitivity reaction to the generic buprenorphine/naloxone tablet and film
   b) Adverse reaction that cannot be managed with either the generic tablet or generic film

LIMITATIONS

- Approval duration will be for one year for Members who meet the criteria and do not exceed the quantity limit.
- Approval duration will be for 6 months for Members who meet criteria but exceed the quantity limit.
- Requests for quantities that exceed the quantity limit will be reviewed according to the Drugs with Quantity Limitations criteria.
- The quantity limit for Members initiating or re-initiating therapy will allow up to the equivalent of 32 mg/day of Suboxone film/tablet for the initial 6 months.
- After the initial 6 months of therapy, quantities are limited so as to not exceed the recommended dose for maintenance treatment. The recommended maintenance dose according to FDA-approved prescribing information is:
  - 16 mg buprenorphine/day for generic buprenorphine/naloxone sublingual tablets and film
  - 11.4 mg buprenorphine/day for Zubsolv

Buprenorphine/Naloxone Product	Strength (buprenorphine/ naloxone)	Restriction (maintenance dosing)
Zubsolv sublingual tablets	11.4 mg/ 2.9 mg	PA/QL: one tablet per day
Zubsolv sublingual tablets	8.6 mg/ 2.9 mg	PA/QL: one tablet per day
Zubsolv sublingual tablets	5.7 mg/ 1.4 mg	PA/QL: two tablets per day
Zubsolv sublingual tablets	2.9 mg/ 0.71 mg	PA/QL: two tablets per day
Zubsolv sublingual tablets	1.4 mg/ 0.36 mg	PA/QL: two tablets per day
Zubsolv sublingual tablets	0.7 mg/ 0.18 mg	PA/QL: two tablets per day

The Drug Addiction Treatment Act of 2000 (DATA 2000) limits practitioners to no more than 100 patients in their individual practice for whom they are treating for opioid dependency with Schedule III, IV, and

V opioid medications or combinations of such medications that have been specifically approved by the Food and Drug Administration (FDA) for that indication. The limit is per individual practitioner and is not per group practice. For the first year, practitioners are limited to 30 patients.

CODES

None

REFERENCES

1. Buprenorphine HCl/Naloxone HCl Sublingual Tablets [prescribing information]. Elizabeth, NJ: Actavis Elizabeth; January 2024.
2. Center for Substance Abuse Treatment (2004). "Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction." *Treatment Improvement Protocol (TIP) series 40, Substance Abuse and Mental Health Services Administration*. Accessed at http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf.
3. Fitzgerald, W.L. (2008). "Medication-assisted treatment for opioid dependence: Adhering to requirements for buprenorphine dispensing." *University of Tennessee Advanced Studies in Pharmacy*, 5:250-255.
4. Kleber, H., Weiss, R., Anton Jr., R., George, T., Greenfield, S., Kosten, T., O'Brien, C., Rounsaville, B., Strain, E., Ziedonis, D., Hennessy, G., Connery, H.S. (2008). *Practice Guideline for the Treatment of Patients with Substance Use Disorders*, second edition. American Psychiatric Association.
5. Suboxone sublingual film (buprenorphine/naloxone) [prescribing information]. North Chesterfield, VA: Indivior Pharmaceuticals; March 2023.
6. Zubsolv (buprenorphine/naloxone) [prescribing information]. Morristown, NJ: Orexo; May 2025.

APPROVAL HISTORY

October 11, 2022: Reviewed by the Pharmacy and 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. December 2025 E-Vote: Effective January 1, 2026, removed Bunavail from limitation section due to product discontinuation.

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