Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Opioid Dependence Medications

Effective: February 10, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Zubsolv (buprenorphine/naloxone) sublingual tablet is indicated for treatment of opioid dependence. Zubsolv (buprenorphine/naloxone) should be used as part of a complete treatment plan that includes counseling and psychosocial support.

Notes:

- There is no prior authorization needed for drugs used for maintenance of detoxification treatment 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 and films.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of **Zubsolv (buprenorphine/naloxone) sublingual tabs** for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of opioid dependence

AND

2. Documentation of an adverse reaction to buprenorphine/naloxone tablets or films that is allergic in nature, or cannot be expected or managed during the course of buprenorphine therapy

Limitations

- Zubsolv (buprenorphine/naloxone) will not be approved for any other diagnosis than those listed above in the criteria.
- If criteria are met, the approval will be authorized for a period of **12 months**.
- Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.

Codes

None

References

1. Zubsolv (buprenorphine and naloxone) sublingual tablet [package insert]. Morristown, NJ: Orexo US, Inc.; December 2025.

Approval and Revision History

February 14, 2023: Reviewed by the Pharmacy & Therapeutics Committee. Medical Necessity Guidelines will be effective 4/1/23.

Subsequent endorsement date(s) and changes made:

- February 13, 2024: No changes
- February 11, 2025: No changes

- February 10, 2026: No changes
- February 2026: Administrative update to remove CareLink from Medical Necessity Guideline template.

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.