

Pharmacy Medical Necessity Guidelines: Opioid Dependence Medications

Effective: July 20, 2020

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
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan 		<p>Fax Numbers: RXUM: 617.673.0988</p>	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

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 and films.

COVERAGE GUIDELINES

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

1. Documented diagnosis of opioid dependence
- AND**
2. Documentation the Member cannot take generic buprenorphine/naloxone tablet or film

LIMITATIONS

- Zubsolv, and Bunavail (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**.
- The plan does not authorize coverage of **non-covered** Suboxone film medications through this Prior Authorization program. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives and submit a formulary exception request to the plan as indicated.
- Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception but will be considered on an individual basis for prior authorization.

CODES

None

REFERENCES

1. Appropriate Use Recommendations for Suboxone® Sublingual Film, Suboxone Sublingual Tablet and Subutex Sublingual Tablet. Reckitt Benckiser Pharmaceuticals, Inc.; September 2010.
2. Bunavail (buprenorphine/naloxone) buccal film [package insert]. Raleigh, NC: BioDelivery Sciences International, Inc.; February 2018.
3. Bridge TP, Fudala PJ et al. Safety and health policy considerations related to the use of buprenorphine/naloxone as an office-based treatment for opiate dependence. *Drug Alcohol Depend.* 2004;70(2 Suppl): S79-85.
4. Johnson RE, McCagh JC. Buprenorphine and naloxone for heroin dependence. *Curr Psychiatry Rep.* 2000 Dec; 2(6):519-26.
5. Kaur AD, McQueen A, Jan S. Opioid drug utilization and cost outcomes associated with the use of buprenorphine-naloxone in patients with a history of prescription opioid use. *J Manag Care Pharm.* 2008 Mar; 14(2):186-94.
6. Mammen K, Bell J. The clinical efficacy and abuse potential of combination buprenorphine-naloxone in the treatment of opioid dependence. *Expert Opin Pharmacother.* 2009 Oct; 10(15):2537-44.
7. Orman JS, Keating GM. Buprenorphine/naloxone: a review of its use in the treatment of opioid dependence. *Drugs.* 2009; 69(5):577-607.
8. Raisch DW, Fye CL, Boardman KD, Sather MR. Opioid dependence treatment, including buprenorphine/naloxone. *Ann Pharmacother.* 2002 Feb; 36(2):312-21.
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10. Suboxone (buprenorphine and naloxone) sublingual film [package insert]. North Chestefield, VA: Indivior, Inc.; February 2018.
11. Subramaniam GA, Warden D, Minhajuddin A et al. Predictors of abstinence: National Institute of Drug Abuse multisite buprenorphine/naloxone treatment trial in opioid-dependent youth. *J Am Acad Child Adolesc Psychiatry.* 2011 Nov; 50(11):1120-8.
12. Stimolo C, Favero VD, Zecchinato G et al. Safety and tolerability of the switch from buprenorphine to buprenorphine/naloxone in an Italian addiction treatment centre. *Clin Drug Investig.* 2010;30 Suppl 1:27-31.
13. Strain EC, Harrison JA, Bigelow GE. Induction of opioid-dependent individuals onto buprenorphine and buprenorphine/naloxone soluble-films. *Clin Pharmacol Ther.* 2011 Mar;89(3):443-9.
14. Weiss RD, Potter JS, Fiellin DA et al. Adjunctive counseling during brief and extended buprenorphine-naloxone treatment for prescription opioid dependence: a 2-phase randomized controlled trial. *Arch Gen Psychiatry.* 2011 Dec; 68(12):1238-46.
15. Woody GE, Poole SA, Subramaniam G et al. Extended vs short-term buprenorphine-naloxone for treatment of opioid-addicted youth: a randomized trial. *JAMA.* 2008 Nov 5; 300(17):2003-11.
16. Zubsolv (buprenorphine and naloxone) sublingual tablet [package insert]. Morristown, NJ: Orexo US, Inc.; September 2017.

APPROVAL HISTORY

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

Subsequent endorsement date(s) and changes made:

1. November 9, 2010: Added Suboxone Film 2mg / 0.5mg and 8mg / 2mg with a QL of 90 films per 30 days.
2. 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".

3. September 13, 2011: Removed the criteria requiring documented participation in 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.
4. June 12, 2012: Administrative change: updated "Administrative Process (Internal Use Only)" field to LPN/RN.
5. August 14, 2012: Added note regarding submission of X DEA number.
6. 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.
7. 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.
8. Suboxone 8mg / 2mg - 120 sublingual tablets per 30 days
9. Suboxone 2mg / 0.5mg - 90 sublingual tablets per 30 days
10. Suboxone Film 12mg / 3mg - 60 films per 30 days
11. Suboxone Film 8mg / 2mg - 90 films per 30 days
12. Suboxone Film 4mg / 1mg - 90 films per 30 days
13. Suboxone Film 2mg / 0.5mg - 90 films per 30 days
14. October 15, 2013: Added Zubsolv tablets (buprenorphine HCl / naloxone HCl) to the criteria.
15. 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.
16. 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.
17. November 10, 2015: Add criterion #3 "Documentation the Member cannot take the generic buprenorphine/naloxone."
18. January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
19. October 18, 2016: No changes
20. March 14, 2017: removed the requirement documenting the prescriber has been granted an "X" DEA number.
21. April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
22. October 17, 2017: No Changes
23. October 16, 2018: No Changes
24. January 8, 2019: Added "Film formulations may be approved if there is documentation of concern with child safety with the use of generic tablets" to the limitation section.
25. May 7, 2019: Effective October 1, 2019 move Suboxone film to not covered for all Tufts Health Plan Large Group Plans. Added the limitation which states Suboxone film is non-covered, and should be reviewed under the Non-Covered Drugs with Suggested Alternatives MNG.
26. March 10, 2020: Administrative update to clarify that generic buprenorphine-naloxone films are covered, and no longer require a prior authorization. Removed the limitation note: "Film formulations may be approved if there is documentation of concern with child safety with the use of generic tablets", because the generic films are covered.
27. April 14, 2020: Added the generic buprenorphine/naloxone films as a trial option.
28. July 14, 2020: Added the following limitation: Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception but will be considered on an individual basis for prior authorization.

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.