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

Effective: January 14, 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

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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.

Risk Evaluation and Mitigation Strategy (REMS): To mitigate the risk of accidental overdose, misuse, and abuse and to inform prescribers, pharmacists, and patients of risks associated with buprenorphine-containing products, the FDA-approved REMS program includes a Medication Guide, Elements to Assure Safe Use (letters, brochures, appropriate use checklist), and an Implementation System.

- 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.

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 dependency

AND

2. The Member's treatment plan includes ongoing participation in a structured drug addiction treatment program and/or counseling

AND

3. 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 32 mg/day 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
    - 8.4 mg buprenorphine /day for Bunavail
    - 11.4 mg buprenorphine /day for Zubsolv

Buprenorphine/Naloxone Product	Strength (buprenorphine/ naloxone)	Restriction (maintenance dosing)
Bunavail buccal film	6.3 mg / 1 mg	PA/QL: one film per day
Bunavail buccal film	4.2 mg / 0.7 mg	PA/QL: two films per day
Bunavail buccal film	2.1 mg / 0.3mg	PA/QL: one film per day
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

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. Bunavail (buprenorphine and naloxone) [prescribing information]. Raleigh, NC: BioDelivery Sciences International Inc; October 2019.
2. Suboxone sublingual film (buprenorphine/naloxone) [prescribing information]. North Chesterfield, VA: IndiviorPharmaceuticals; October 2019.
3. Zubsolv (buprenorphine/naloxone) [prescribing information]. New York, NY: Orexo; October 2019.
4. Buprenorphine HCl/Naloxone HCl Sublingual Tablets [prescribing information]. Elizabeth, NJ: Actavis Elizabeth; February 2018.
5. Buprenorphine/Naloxone. Lexi-Drugs [database online]. Hudson, OH: Lexicomp Inc; 2014. http://online.lexi.com. Accessed November 12, 2014.
6. 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 buprenorphine.samhsa.gov/Bup_Guidelines.pdf.
7. Drug Addiction Treatment Act of 2000. Accessed at buprenorphine.samhsa.gov/data.html.
8. 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.
9. 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.
10. Suboxone Sublingual Tablets, Subutex AMCP Dossier (2010). Reckitt Benckiser Pharmaceuticals.
11. U.S. Department of Justice (2004). "Buprenorphine: Potential for abuse." *U.S. Department of Justice Intelligence Bulletin*.

APPROVAL HISTORY

December 9, 2014: Reviewed by the Pharmacy and Therapeutics Committee. Updated to include Bunavail; micro-tapering included as rationale for using a non-preferred product; provider attestation

of engagement in induction protocols, medication review of online monitoring programs, pill counts, urine drug screens, services for other addictions, and patient contracts.

Subsequent endorsement date(s) and changes made:

1. October 16, 2015: Updated table to include new Zubsolv strengths.
2. November 10, 2015: Updated limitation section to include new quantity limit of 32 mg buprenorphine/day for 6 months for Together Members initiating or re-initiating therapy with buprenorphine/naloxone, which is then reduced to the recommended maintenance dose. Removed the following criteria: Provider has a unique X-DEA number; Provider is not using buprenorphine-containing products to concurrently treat more than 100 patients; Structured induction protocol (new starts); Review of Member-specific medication usage through State Online Prescription Monitoring Program(s); Periodic pill counts; Services to address other addictions; Member-signed contracts; 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 a long-acting opioid agent or a short-acting opioid agent with a cumulative of 30 or more days. Modified the following criteria from Member is actively involved in a substance abuse treatment program to ongoing participation in a structured drug addiction treatment program and/or counseling; Urine drug screens with each visit to consistent evaluation with toxicology screens (must document date of last screen within the last 60 days). Specified the recommended maintenance dose for each medication (16 mg buprenorphine/day for generic buprenorphine/naloxone sublingual tablets and for Suboxone Film, 8.4 mg buprenorphine /day for Bunavail, 11.4 mg buprenorphine /day for Zubsolv).
3. December 8, 2015: Removed criteria pertaining to consistent evaluation with toxicology screens.
4. January 1, 2016: Administrative change to rebranded template.
5. February 14, 2017: No changes.
6. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
7. June 12, 2018: No changes.
8. 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. Administrative changes made to template.
9. February 12, 2019: Removed "Film Formulations may be approved if there is documentation of concern with child safety with use of generic tablets" from the limitation section of the MNG, as it is addressed in the criteria.
10. September 10, 2019: Effective 9/16/19, updated MNG to indicate that generic buprenorphine/naloxone film is a preferred formulation. Effective 1/1/2020, updated the approval criteria for nonpreferred products to remove microtapering and child safety as clinical rationale for approval of a nonpreferred agent.
11. January 14, 2020: 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