Opioid Dependence and Reversal Agents
Bunavail (buprenorphine/naloxone buccal film)
Buprenorphine sublingual tablet
Suboxone (buprenorphine/naloxone film)
Zubsolv (buprenorphine sublingual tablet)
Effective 11/01/2022

Plan	☐ MassHealth ☒ MH UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions			

Overview

No PA	Drugs that Require PA
Sublocade® (buprenorphine extended-release injection) PD	Bunavail® (buprenorphine/naloxone buccal film) †
Suboxone® # (buprenorphine/naloxone film) PD ≤ 24 mg/day †§	buprenorphine sublingual tablet †
Vivitrol® (naltrexone injection)	buprenorphine/naloxone sublingual tablet†
	Suboxone® (buprenorphine/naloxone film) PD > 24 and ≤ 32 mg/day, > 90 days †*§
	Suboxone® (buprenorphine/naloxone film) PD > 32 mg/day †*§
	Zubsolv® (buprenorphine/naloxone tablet) †

* Available as an A-rated generic, both brand and A-rated generic require PA

† Any of these agents will require a PA if it's determined that the member is stable (60 days of therapy within the last 90) on opioid dependence therapy and has a claim for a long-acting opioid (for any length of time) or a short-acting opioid for > seven days within the last 30 days

PD Preferred Drug. In general, A trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. **Please note, for non-preferred buprenorphine products, a trial with Sublocade® is not required prior to approval of a non-preferred agent.**

§Brand Preferred over generic equivalents. In general, A trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

Coverage Guidelines

Approval of the requested medication will be granted if the member meets the following drug specific criteria:

Buprenorphine SL tablet ≤ 24 mg/day
Prescriber provides documentation of **ALL** of the following:

1. The member has a diagnosis of opioid dependence
2. Clinical rationale for prescribing buprenorphine instead of buprenorphine/naloxone documented as **ONE** of the following:
    a. Medical records documenting naloxone allergy
    b. Current pregnancy (request must include anticipated date of delivery)
    c. Member is breastfeeding
    d. Prescriber documents desire to avoid buprenorphine/naloxone therapy due to moderate to severe hepatic impairment (i.e., Child-Pugh B to C)

Buprenorphine/naloxone SL tablet ≤ 24 mg/day
Zubsolv® (buprenorphine/naloxone tablet) ≤ 17.2/4.3 mg/day
Bunavail® (buprenorphine/naloxone buccal film) ≤ 12.6/2.1 mg/day
Prescriber provides documentation of **ALL** of the following:

1. The member has a diagnosis of opioid dependence
2. Medical records documenting an adverse reaction to Suboxone (buprenorphine/naloxone film) that is allergic in nature, or cannot be expected or managed during the course of buprenorphine therapy *(See Appendix B – Buprenorphine/naloxone film trials)*

Approvable High Dose:
Buprenorphine SL tablet > 24 mg/day and ≤ 32 mg/day
Buprenorphine/naloxone SL tablet > 24 mg/day and ≤ 32 mg/day
Suboxone® (buprenorphine/naloxone film) > 24 mg/day and ≤ 32 mg/day
Zubsolv® (buprenorphine/naloxone tablet) > 17.2/4.3 mg/day and ≤ 22.8/5.8 mg/day
Bunavail® (buprenorphine/naloxone buccal film) > 12.6/2.1 mg/day and ≤ 16.8/2.8 mg/day
Prescriber provides documentation of **ALL** of the following:

1. Individual drug PA criteria must be met first
2. **ONE** of the following:
    a. This is the lowest effective dose for this member
    b. Complete treatment plan

Approvable High Dose:
Buprenorphine SL tablet > 32 mg/day
Buprenorphine/naloxone SL tablet > 32 mg/day
Suboxone® (buprenorphine/naloxone film) > 32 mg/day
Zubsolv® (buprenorphine/naloxone tablet) > 22.8/5.8 mg/day
Bunavail® (buprenorphine/naloxone buccal film) > 16.8/2.8 mg/day

Prescriber provides documentation of **ALL** of the following:

1. Individual drug PA criteria must be met first
2. Clinical rationale why member requires dosing greater than 32 mg/day (for Zubsolv, dosing is > 22.8/5.8 mg/day or for Bunavail, dosing is > 16.8/2.8 mg/day)

Continuation of Therapy

Reauthorization may be granted with physician attestation of continuation of therapy. Pharmacy claims will be verified to member is still not currently taking an opioid.

Limitations

1. Initial approvals will be granted for the following:
   If request meets **ALL CURRENT** criteria, approval durations are as follows:
   a. New Start – buprenorphine sublingual tablet:
      - Due to naloxone allergy or hepatic impairment: up to **1 year.**
      - Due to breastfeeding: up to **6 months.**
      - Due to pregnancy, up to **10 months or up to 1 month past anticipated date of delivery**, whichever is sooner.

   b. Requests for Bunavail® (≤ 12.6 mg/day), buprenorphine/naloxone sublingual tablet (≤ 24 mg/day), or Zubsolv® (≤ 17.2 mg/day): **1 year.**
   c. High Dose: > 24 mg/day to ≤ 32 mg/day for buprenorphine/naloxone film and buprenorphine/naloxone sublingual tablet, >17.2 mg/day to ≤ 22.8 mg/day for Zubsolv® or > 12.6 mg/day to ≤ 16.8mg/day for Bunavail®: **1 year.**
   d. High Dose: > 32 mg/day for buprenorphine/naloxone and buprenorphine/naloxone sublingual tablet, Zubsolv® > 22.8 mg/day or Bunavail® >16.8 mg/day: **3 months**
2. Reauthorizations will be granted for the following:
   a. Bunavail®, buprenorphine tablet, buprenorphine/naloxone film, buprenorphine/naloxone tablet, and Zubsolv®: **1 year**
   b. Buprenorphine tablet due to pregnancy: treat as New Start
   c. Buprenorphine tablet due to breastfeeding: for **3 months.**
   d. Members approved for ≤ 24 mg/day of buprenorphine tablet (due to ADR, allergy or hepatic impairment), or buprenorphine/naloxone sublingual tablet, ≤ 17.2 mg/day of Zubsolv® or ≤ 12.6 mg/day of Bunavail®: **1 year**
   e. Members approved for > 24 mg/day to ≤ 32mg buprenorphine tablet (due to ADR or allergy), buprenorphine/naloxone film or tablet, >17.2 mg/day of Zubsolv® or >12.6 mg/day of Bunavail®: **1 year**

Appendices

Appendix A: Buprenorphine New Starts

Allergy

- Bioavailability for naloxone in combination with buprenorphine following sublingual administration is estimated between 0% and 10%. Naloxone is eliminated rapidly with a mean elimination half-life of 1.1 hours.
- In a comparative study, adverse event profiles were similar for subjects treated with 16 mg Suboxone® (buprenorphine/naloxone) or 16 mg Subutex® (buprenorphine).
- Medical records documenting naloxone allergy are required.
- Complete requests may be approved

Pregnancy

- Methadone is the standard of care in U.S. for treating pregnant women with opioid dependence.
- For new requests, documentation of anticipated date of delivery must be submitted. If initial request does not include anticipated date of delivery and prescriber cannot be contacted for the information, request can be approved for 1 month while asking for anticipated date of delivery on external comment.
- Complete requests may be approved for up to 10 months or up to 1 month past anticipated date of delivery, whichever is sooner.

Breast-feeding

- Use of high doses of sublingual buprenorphine in pregnant women showed that buprenorphine passes into the mother's milk. Breast-feeding is therefore not advised in mothers treated with buprenorphine.
- If provider states that member is breast-feeding and does not want to use naloxone → Approve may be granted 6 months.

Hepatic Impairment

- Prescribing information for Suboxone® film notes that due to differences in pharmacokinetics and the inability to adjust the separate doses of buprenorphine and naloxone within each combination dosing unit, buprenorphine/naloxone therapy should be avoided in patients with severe hepatic impairment and may not be appropriate in patients with moderate hepatic impairment. No dose adjustment is required in patients with mild hepatic impairment.
- If a provider requests buprenorphine tablets for a member with moderate to severe hepatic impairment (i.e., Child-Pugh B to C) and would like to avoid the use of combination buprenorphine/naloxone for this reason → Approval may be granted

Induction Therapy

- It is recommended that patients dependent upon long-acting opioids initiate therapy with buprenorphine tablets (without naloxone).
- The SAMHSA Treatment Improvement Protocol (TIP) Manual 43 recommends 2 days of induction with buprenorphine in these patients.
- Requests for buprenorphine for induction therapy for members dependent upon long-acting opioids approval may be granted for a maximum of 5 days.

Members will be required to transition to Suboxone® film after induction, unless prior authorization criteria are met for a non-preferred formulation.

Appendix B: Buprenorphine/naloxone film trials

Allergic reaction to buprenorphine/naloxone film

Requests documenting an allergic reaction to buprenorphine/naloxone film will be reviewed for specific reaction.

- If medical records document that the member had anaphylaxis, angioedema, itching, rash or difficulty breathing, and it can be definitively traced to the buprenorphine/naloxone film use, this should not be rechallenged → **Approval may be granted.**
    - Medical records of details of allergic reaction MUST be provided documenting time course of reaction being documented, i.e. compare dates of claims or documented buprenorphine/naloxone film use to onset and occurrence of reaction.

***Members at ≥24 mg/day of buprenorphine/naloxone film or generic buprenorphine/naloxone sublingual tablets**

Approvals maybe be considered on a case by case basis when the following is met:

- Provider requesting Bunavail® (buprenorphine/naloxone buccal film), buprenorphine/naloxone tablet or Zubsolv® (buprenorphine/naloxone tablet) and notes increased cravings or withdrawal symptoms after a trial with buprenorphine/naloxone film for a member already at 24 mg/day
- Provider should be contacted, and member specific factors would preclude further dose increase.

References

1. Sublocade (buprenorphine extended-release) [prescribing information]. North Chesterfield, VA: Indivior Inc; March 2018
2. 30. Buprenorphine sublingual tablets [prescribing information]. Morgantown, WV: Mylan; February 2018.
3. Suboxone sublingual film (buprenorphine/naloxone) [prescribing information]. Richmond, VA: Indivior; February 2018.
4. Zubsolv (buprenorphine/naloxone) [prescribing information]. Morristown, NJ: Orexo US; February 2018.
5. Bunavail (buprenorphine/naloxone) [prescribing information]. Raleigh, NC: BioDelivery Sciences International Inc; February 2018

Review History

02/20/19 – Reviewed
11/18/20 – Reviewed P&T
11/17/2021 – Reviewed and Updated for Nov P&T; separated out CommExch vs. MH and combined Bunavail, Suboxone, Zubsolv criteria and Sublocade criteria; removed Probuphine to its own criteria; matched MH UPPL criteria effective 1/1/2022; Non-UPPL non-preferred products added to the guideline as reference in the reference table. The four agents include: Bunavail® (buprenorphine/naloxone buccal film), buprenorphine sublingual tablet, buprenorphine/naloxone sublingual tablet, and Zubsolv® (buprenorphine/naloxone tablet) added to UPPL Effective 01/01/2022.
11/16/2022 – Reviewed and updated for Nov P&T; matched MH. Clarified verbiage in Appendix and Limitations. No criteria changes. Effective 11/01/2022

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