BOSTON MEDICAL CENTER HEALTHNet PLAN

bmchp.org | 888-566-0008

WELL SENSE HEALTH PLAN

wellsense.org | 877-957-1300

Pharmacy Medical Necessity Policy

Opioid Dependence and Reversal Agents – Unified Formulary

Policy Number: 9.509
Version Number: 2.3
Version Effective Date: 1/1/2022

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth ACO ☒ MassHealth MCO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit

Note: Disclaimer and audit information is located at the end of this document.

Policy

Reference Table:

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

Drugs that Require PA	No PA
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 is required. **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 is required.

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.

Approval Criteria (Under QL):

buprenorphine SL tablet ≤ 24 mg/day	1. Diagnosis of treatment of opioid dependence; **AND** 2. Clinical rationale for prescribing buprenorphine instead of buprenorphine/naloxone documented as **ONE** of the following: a. Medical records documenting naloxone allergy; **OR** b. Current pregnancy (request must include anticipated date of delivery); **OR** c. Member is breastfeeding; **OR** 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	1. Diagnosis of treatment of opioid dependence; **AND** 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
Duration of Authorization	If request meets **ALL CURRENT** criteria, approval durations are as follows: • New Start – buprenorphine sublingual tablet: ○ Due to naloxone allergy or hepatic impairment: may be approved for **up to 1 year.** ○ Due to breastfeeding: may be approved for **up to 6 months**. ○ Due to pregnancy, may be approved for **up to 10 months or up to 1 month past anticipated date of delivery, whichever is sooner.**

.

	• Requests for Bunavail® (≤ 12.6 mg/day), buprenorphine/naloxone sublingual tablet (≤ 24 mg/day), or Zubsolv® (≤ 17.2 mg/day) may be approved for **1 year.**

Approval Criteria High Dose (Over QL):

High Dose - QL buprenorphine SL tablet buprenorphine/naloxone SL tablet **Suboxone®** (buprenorphine/naloxone film)	1. Diagnosis of treatment of opioid dependence 2. **ONE** of the following: a. Requested dose is greater than 24mg/day and less than or equal to 32mg/day; **AND** i. Documentation of **ONE** of the following: 1. This is the lowest effective dose for this member; **OR** 2. Complete treatment plan **OR** b. Requested dose is greater than 32mg/day; **AND** i. Clinical rationale why member requires dosing greater than 32mg/day
High Dose – QL **Zubsolv®** (buprenorphine/naloxone tablet)	1. Diagnosis of treatment of opioid dependence 2. **ONE** of the following: a. Requested dose is greater than 17.2/4.3 mg/day and less than or equal to 22.8/5.8 mg/day; **AND** i. Documentation of **ONE** of the following: 1. This is the lowest effective dose for this member; **OR** 2. Complete treatment plan **OR** **3.** Requested dose is greater than 22.8/5.8 mg/day; **AND** i. Clinical rationale why member requires dosing greater than 22.8/5.8 mg/day
High Dose – QL **Bunavail®** (buprenorphine/naloxone buccal film)	1. Diagnosis of treatment of opioid dependence 2. **ONE** of the following: a. Requested dose is greater than 12.6/2.1 mg/day and less than or equal to 16.8/2.8 mg/day; **AND** i. Documentation of **ONE** of the following: 1. This is the lowest effective dose for this member; **OR** 2. Complete treatment plan b. Requested dose is greater than 16.8/2.8 mg/day; **AND** i. Clinical rationale why member requires dosing greater than 16.8/2.8 mg/day
Duration of Authorization	If request meets **ALL CURRENT** criteria, approval durations are as follows: • <u>High Dose</u> (> 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®) may be approved for **1 year.** • High Dose (>32 mg/day for buprenorphine/naloxone and buprenorphine/naloxone sublingual tablet, >22.8 mg/day for Zubsolv®, or >16.8 mg/day for Bunavail®) may be approved for duration as determined by clinical reviewer.

Responsibility and Accountability

Policy History

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	Policy created to align with MH Unified Formulary Policy	1/1/2021	P&T Committee
2/11/2021	Annual policy review, no changes	6/1/2021	P&T Committee
5/13/2021	Policy updated to reflect 3/1/21 changes from MH	7/1/2021	P&T Committee
7/23/2021	Updated policy to reflect changes dated 6/16/21 from MH: Formatting, adding * definition to reference table	9/1/2021	P&T Committee
10/1/2021	Updated policy, MH UPPL: The four agents include: Bunavail® (buprenorphine/naloxone buccal film), buprenorphine sublingual tablet, buprenorphine/naloxone sublingual tablet, and Zubsolv® (buprenorphine/naloxone tablet).	1/1/2022	P&T Committee

Next Review Date

2/2022

Other Applicable Policies

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: Indivior Pharmaceuticals; October 2019.
3. Zubsolv (buprenorphine/naloxone) [prescribing information]. Morristown, NJ: Orexo; October 2019.
4. Buprenorphine HCl/Naloxone HCl Sublingual Tablets [prescribing information]. North Wales, PA: Teva Pharmaceuticals; September 2017.
5. Suboxone Sublingual Tablets, Subutex AMCP Dossier (2010). Reckitt Benckiser Pharmaceuticals.

Reference to Applicable Laws and Regulations, if Any

Buprenorphine products – Regulations

- The Drug Addiction and Treatment Act of 2000 (DATA 2000) allows specially trained physicians to use schedule III, IV, and V medicines to treat opioid dependence. For more information visit http://www.buprenorphine.samhsa.gov or call 1-866-287-2728.

- For physicians with a valid waiver, DEA issues a unique identification number (UIN) similar to the physician's registration number in which the first alpha location is replaced with an "X" (i.e., BC1234567 becomes XC1234567). Verification of a physician's waiver for prescribing Suboxone or Buprenorphine can be made by calling Substance Abuse and Mental Health Services Administration (SAMHSA) at 301-443-0457. This can also be performed using the SAMHSA pharmacist look-up tool online (available: **https://www.samhsa.gov/bupe/lookup-form**). As of 7/15/19, we are no longer verifying the waiver status of providers in our review.