BOSTON MEDICAL CENTER HEALTHNet PLAN

WELL SENSE HEALTH PLAN

bmchp.org | 888-566-0008 wellsense.org | 877-957-1300

Pharmacy Policy

Buprenorphine and Naloxone Products

Policy Number: 9.504
Version Number: 2.1
Version Effective Date: 7/1/2021

Product Applicability ☐ **All Plan[+] Products**

Well Sense Health Plan
☐ New Hampshire Medicaid

Boston Medical Center HealthNet Plan
☐ MassHealth - MCO
☐ MassHealth - ACO
☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct
☐ Senior Care Options

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

Prior Authorization Policy

Products Affected:

- **Suboxone® SL film/Buprenorphine-Naloxone SL film (greater than 24mg per day)***
- **buprenorphine-naloxone SL tablets (Suboxone® SL tablets)**
- **buprenorphine SL tablets (Subutex® SL tablets)**
- **buprenorphine transdermal patch 5mcg, 7.5mcg, 10mcg, 15mcg, 20mcg (generic for Butrans®)**

*** Please note: Suboxone SL film at doses of 16mg or less is covered without a prior authorization.*

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None
Required Medical Information	**Suboxone SL film/Buprenorphine-Naloxone SL film (>24 mg to 32mg per day)** 1. A diagnosis of opioid dependence; AND 2. An inadequate response to 24 mg of buprenorphine daily and that there is a high risk for

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	relapse; AND 3. A dose taper was tried and failed in the previous 3 months or was not attempted due to a high risk of relapse **buprenorphine-naloxone SL tablets** 1. A diagnosis of opioid dependence; AND 2. Intolerance to the sublingual film formulation of Suboxone® that is not expected to occur with the requested medication. 3. For doses greater than 24 mg to 32 mg per day both of the following: a. An inadequate response to 24 mg of buprenorphine daily and that there is a high risk for relapse b. A dose taper was tried and failed in the previous 3 months or was not attempted due to a high risk of relapse **buprenorphine SL tablets (Subutex®)** 1. A diagnosis of opioid dependence; AND 2. One of the following: a. An adverse reaction or contraindication to naloxone; OR b. Attestation that the member is pregnant; OR c. Both of the following: i. The member is currently breastfeeding; and ii. The member is stable and the prescriber assesses the patient to be at minimal risk of abusing buprenorphine or other drugs of abuse **buprenorphine transdermal patch 5mcg, 7.5mcg, 10mcg, 15mcg and 20 mcg** Documentation of the following: 1. Diagnosis of moderate to severe chronic pain; AND 2. An intolerance to a trial of morphine extended release tablet; AND 3. An inadequate response to at least a 2-week trial of, intolerance or contraindication to a non-narcotic agent at the maximum tolerated dose; OR 4. Prescriber wants to avoid using a full opioid agonist
Prescriber Restriction	None
Coverage Duration	1 year
Quantity Limit	See Appendix below

Appendix A – Quantity Limitations

Medication Name	Strength	Quantity Limitation
Suboxone® (buprenorphine/naloxone) sublingual film	2/0.5 mg	12 films per day
	4/1 mg	6 films per day
	8/2 mg	3 films per day
	12/3mg	2 films per day
buprenorphine/naloxone sublingual tablet	2/0.5 mg	12 tablets per day
	8/2 mg	3 tablets per day
buprenorphine transdermal patch	All	1 patch per 7 days

Applicable Coding:

Clinical Background Information and References

1. Center for Substance Abuse Treatment. Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction. Rockville (MD): Substance Abuse and Mental Health Services Administration (SAMHSA); DHHS Publication No. (SMA) 04-3939.2004.
2. Subutex® (buprenorphine sublingual tablets). [Package insert]. Richmond, VA: Reckitt Benckiser Pharmaceuticals, Inc.; June 2005.
3. Suboxone® (buprenorphine/naloxone sublingual tablets). [Package insert]. Richmond, VA: Reckitt Benckiser Pharmaceuticals, Inc.; Sept 2006.
4. Suboxone® (buprenorphine/naloxone sublingual film. [Package insert]. Richmond, VA: Reckitt Benckiser Pharmaceuticals, Inc.; April 2014
5. Zubsolv® (buprenorphine/naloxone sublingual tablets). [Package insert] New York, NY: Orexo; Feb 2018
6. Weaver MF, Hopper JA. Treatment of opioid abuse and dependence. UpToDate®, available at https://www.uptodate.com, accessed August 2015
7. Bunavail® (buprenorphine/naloxone buccal film). [Package insert] BioDelivery Sciences International, Inc., Raleigh, NC; Feb 2018
8. Soyka M. Buprenorphine-naloxone buccal soluble film for the treatment of opioid dependence: current update. Expert Opin Drug Deliv. 2015 Feb;12(2):339-47.
9. American Association of Poison Control Centers. Joint Position Statement on Expanding Access to Naloxone. October 7, 2014. Available at http://www.acmt.net/_Library/Press_Releases/Naloxone_Clinical_Toxicology_Release_10_08_14.pdf
10. PL Detail-Document, Naloxone for Opioid Overdose: FAQs. Pharmacist's Letter/Prescriber's Letter. July 2015.
11. Evzio (naltrexone hydrochloride) [prescribing information]. Richmond, VA: Kaleo, Inc.; April 2014
12. The ASAM National Practice Guidelines for the use of medications in the treatment of addiction involving opioid use. June 2015 Available at http://www.asam.org/quality-practice/guidelines-and-consensus-documents/npg/complete-guideline. Accessed on August 19, 2016.
13. Probuphine (buprenorphine) [prescribing information]. Princeton, NJ: Braeburn Pharmaceuticals Inc; May 2016.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
9/10/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
9/10/2020	9.153 Buprenorphine and Naloxone Products Policy retired, new policy created. Changed requirement for pregnancy from documentation to attestation. Belbuca, Butrans, Probuphine, Sublocade, Zubsolv moving to NF for 2021, removed from policy.	1/1/2021	P&T Committee
1/21/2021	Policy updated to remove PA requirement for Suboxone SL film 16-24mg per day dosing	1/21/2021	P&T Committee
2/11/2021	Annual policy review, updated policy to reflect generic availability of buprenorphine 7.5mcg patch	6/1/2021	P&T Committee
4/12/2021	Aligned quantity limits to be equivalent to 24 mg buprenorphine. Removed reference to buprenorphine SL tabs (subutex) QL since no QL in place	4/12/2021	P&T Committee
6/15/2021	Updated policy to include generic Suboxone SL film	7/1/2021	P&T Committee

Next Review Date

2/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.