

Pharmacy Policy

Buprenorphine and Naloxone Products

Policy Number: 9.504

Revision Number: R1

Version Effective Date: 1/22/2021

Product Applicability	All Plan+ Products
<p>Well Sense Health Plan</p> <p><input checked="" type="checkbox"/> New Hampshire Medicaid</p>	<p>Boston Medical Center HealthNet Plan</p> <p><input type="checkbox"/> MassHealth - MCO</p> <p><input type="checkbox"/> MassHealth - ACO</p> <p><input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct</p> <p><input type="checkbox"/> Senior Care Options</p>

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

Prior Authorization Policy

Products Affected:

- **Suboxone® SL film (greater than 24mg per day)***
- **buprenorphine-naloxone SL tablets (Suboxone® SL tablets)**
- **Bunavail® (buprenorphine-naloxone buccal films)**
- **Zubsolv® (buprenorphine-naloxone SL tablets)**
- **buprenorphine SL tablets (Subutex® SL tablets)**
- **Belbuca® (buprenorphine buccal film)**
- **Butrans® 7.5mcg (buprenorphine transdermal patch)**
- **buprenorphine transdermal patch 5mcg, 10mcg, 15mcg, 20mcg (generic for Butrans®)**
- **Sublocade™ (buprenorphine extended release subcutaneous injection)**

* Please note: Suboxone SL film and tablet formulations and buprenorphine/naloxone formulations at doses of 24mg 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	None

* 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.

Criteria	
Required Medical Information	<p>Suboxone SL film and tablets, generic buprenorphine/naloxone SL films and tablets (>24 mg to 32mg per day), Preferred</p> <ol style="list-style-type: none"> 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 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 <p>buprenorphine SL tablets (Subutex®) Preferred</p> <ol style="list-style-type: none"> 1. A diagnosis of opioid dependence; AND 2. One of the following: <ol style="list-style-type: none"> a. An adverse reaction or contraindication to naloxone; OR b. Attestation that the member is pregnant; OR c. Both of the following: <ol style="list-style-type: none"> 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 3. For doses greater than 24 mg to 32 mg per day, both of the following: <ol style="list-style-type: none"> a. An inadequate response to 24 mg of buprenorphine daily and that there is a high risk for relapse; AND b. A dose taper was tried and failed in the previous 3 months or was not attempted due to a high risk of relapse <p>Bunavail®(buprenorphine-naloxone buccal films) Non Preferred</p> <p>Zubsolv® (buprenorphine-naloxone SL tablets) Non Preferred</p> <ol style="list-style-type: none"> 1. A diagnosis of opioid dependence; AND 2. A trial and failure of 2 Preferred products required prior to Non-Preferred products (see Appendix B) 3. For doses greater than 24 mg to 32 mg per day, both of the following: <ol style="list-style-type: none"> a. An inadequate response to 24 mg of buprenorphine daily and that there is a high risk for relapse; AND b. A dose taper was tried and failed in the previous 3 months or was not attempted due to a high risk of relapse <p>Belbuca™ (buprenorphine buccal film) Non Preferred</p> <ol style="list-style-type: none"> 1. Diagnosis of moderate to severe chronic pain; AND Trial and failure of 2 Preferred products is required prior to Non-Preferred products (see Appendix C); OR 2. Attestation that prescriber wants to avoid using a full opioid agonist <p>buprenorphine transdermal patch 5mcg, 10mcg, 15mcg and 20 mcg (branded generic for Butrans®)</p>

* 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.

	<p>Preferred</p> <ol style="list-style-type: none"> 1. Diagnosis of moderate to severe chronic pain; AND 2. Attestation that prescriber wants to avoid using a full opioid agonist <p>Butrans 7.5mcg Non Preferred</p> <ol style="list-style-type: none"> 3. Diagnosis of moderate to severe chronic pain; AND 4. A trial and failure of 2 Preferred products is required prior to Non-Preferred products (see Appendix C); OR 5. Attestation that prescriber wants to avoid using a full opioid agonist <p>Sublocade™ (buprenorphine extended release subcutaneous injection)</p> <ol style="list-style-type: none"> 1. A diagnosis of opioid dependence; AND 2. Member has been initiated on treatment with a transmucosal buprenorphine containing product for a minimum of 7 days; AND 3. Clinical rationale why member cannot continue with a transmucosal buprenorphine containing product; AND 4. 4. Provider agrees that member will be tapered off of transmucosal buprenorphine containing products
Age Restriction	Belbuca, Butrans: 18 years or older
Prescriber Restriction	None
Coverage Duration	<p>Sublocade</p> <p>Initial: 6 months</p> <p>Reauthorization: 12 months</p> <p>1 year</p>
Quantity Limit	See Appendix below
Other criteria	<p>Sublocade Reauthorization:</p> <ol style="list-style-type: none"> 1. Provider attestation that continuation of therapy is clinically appropriate; AND 2. The member will not receive supplemental trans-mucosal buprenorphine containing products while receiving Sublocade therapy

Appendix A – Quantity Limitations

Medication Name	Strength	Quantity Limitation
Suboxone® (buprenorphine/naloxone) sublingual film	2/0.5 mg; 4/1mg	3 films per day
	8/2 mg	3 films per day
	12/3mg	2 films per day
buprenorphine/naloxone sublingual tablet	All	3 tablets per day
Zubsolv®	1.4/3.6mg, 5.7/1.4mg, 8.6/2.1mg	2 tablets per day
	11.4/2.9mg	1 tablet per day

* 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.

buprenorphine HCL	All	3 tablets per day
Bunavail™ buccal film	2.1/0.3mg	1 film per day
	4.2/0.7mg	3 films per day
	6.3/1mg	2 films per day
Belbuca™ buccal film	All	2 films per day
Butrans® patch buprenorphine patch (branded generic for Butrans®)	All	1 patch per 7days
Sublocade	All	1 vial of 100mg (0.5mL) per 30 days 1 vial of 300mg (1.5mL) per 30 days

Appendix B – Opiate Dependence Treatment

Preferred	Non-Preferred
buprenorphine (generic for Subutex)	Bunavail
buprenorphine/naloxone (generic for Suboxone)	Zubsolv
Suboxone	

Appendix C – Long Acting Opioids

Preferred	Non-Preferred
buprenorphine patch	Belbuca
Embeda	Butrans
fentanyl patch	
hydromorphone ER	
morphine ER	
morphine sulfate	
oramorph	
oxycodone	
oxymorphone ER	

Applicable Coding:

Code	Medication
Q9991	Sublocade 100mg
Q9992	Sublocade 300mg

* 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.

Clinical Background Information and References

- 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.
- Subutex[®] (buprenorphine sublingual tablets). [Package insert]. Richmond, VA: Reckitt Benckiser Pharmaceuticals, Inc.; June 2005.
- Suboxone[®] (buprenorphine/naloxone sublingual tablets). [Package insert]. Richmond, VA: Reckitt Benckiser Pharmaceuticals, Inc.; Sept 2006.
- Suboxone[®] (buprenorphine/naloxone sublingual film. [Package insert]. Richmond, VA: Reckitt Benckiser Pharmaceuticals, Inc.; April 2014
- Zubsolv[®] (buprenorphine/naloxone sublingual tablets). [Package insert] New York, NY: Orexo; Feb 2018
- Weaver MF, Hopper JA. Treatment of opioid abuse and dependence. UpToDate[®], available at <https://www.uptodate.com>, accessed August 2015
- Bunavail[®] (buprenorphine/naloxone buccal film). [Package insert] BioDelivery Sciences International, Inc., Raleigh, NC; Feb 2018
- 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.
- 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
- PL Detail-Document, Naloxone for Opioid Overdose: FAQs. Pharmacist's Letter/Prescriber's Letter. July 2015.
- Evzio (naltrexone hydrochloride) [prescribing information]. Richmond, VA: Kaleo, Inc.; April 2014
- 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.
- 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, NH DHHS

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. Added language that	1/1/2021	P&T Committee, NH DHHS

* 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.

Policy Revisions History

	transmucosal buprenorphine therapy will be stopped after starting Sublocade. Probuphine moved to NF, removed from policy. Trial/fail requirements updated to reflect NH PDL. Appendices B and C added for preferred drugs		
1/22/2021	Policy updated to remove PA requirement for Suboxone SL film 16-24mg per day dosing	1/22/2021	P&T Committee, NH DHHS

Next Review Date

2021

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.

* 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.