BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Policy

Opioid Dependence and Reversal Agents – Unified Formulary

Policy Number: 9.509
Version Number: 2.2
Version Effective Date: 9/1/2021

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

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

Policy

Reference Table:

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

* 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, MassHealth requires 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, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

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Procedure:

Approval Diagnosis:	Treatment of opioid dependence –buprenorphine/naloxone film,
Approval Criteria: **High Dose** **Suboxone®** (buprenorphine/naloxone film) > 24 mg/day and ≤ 32 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
Approval Criteria: **High Dose** **Suboxone®** (buprenorphine/naloxone film)* > 32 mg/day * A-rated generic available, both brand and A-rated generic require a PA	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)
Denial Criteria:	Cases that do not meet the approval criteria will be denied. If a request is denied and the prescriber has additional clinical documentation, a **new** prior authorization request must be submitted.
Brand Preferred over Generic:	• In addition to any prior authorization requirements that may be listed above, generic medications listed below have Brand name products that are included on the MassHealth Brand Name Preferred Over Generic List. Requests for generic versions require a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent prior to approval: ○ buprenorphine/naloxone film
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 may be approved for **1 year.** • <u>High Dose</u> (>32 mg/day for buprenorphine/naloxone may be approved for duration as determined by clinical reviewer
Recertification criteria	**buprenorphine/naloxone film** Recertifications will be reviewed to verify member is still not currently taking an opioid as indicated by claims • Members approved for **>24 mg/day to ≤ 32mg buprenorphine/naloxone film:** recertification may be issued for **1 year**

APPENDIX

Stability

Stability on a medication requiring a prior authorization is not a reason to bypass approval criteria

Grandfathering

Information is not applicable.

Additional Information

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.

***Members at ≥24 mg/day of buprenorphine/naloxone film**

Prescribing information for buprenorphine/naloxone film indicates that doses above 24 mg/day have not been demonstrated to provide any clinical advantage. However, the SAMHSA Treatment Improvement Protocol (TIP) for opioid treatment programs indicates that although most patients are likely to remain stable on 12 to 24 mg per day, some may need dosages up to 32 mg/day.

HIGH DOSE

Requests > 32 mg/day generic buprenorphine/naloxone film should be denied → Deny

Due to the "ceiling effect" of buprenorphine higher dosing offers little additional benefit and increases the potential for diversion. At 16 mg/day, mu-opioid receptor availability is decreased by 85- 92%, and 32 mg/day decreased receptor availability 94-98%.

OFF-LABEL USES—Buprenorphine and buprenorphine/naloxone

Pain Management

Buprenorphine/naloxone filmare not FDA-approved for pain management. These agents have a ceiling analgesic effect and analgesic effects last only 4 to 8 hours. There are less costly alternatives for use in pain management **→ Deny**

Depression
Buprenorphine/naloxone film, are not FDA-approved for depression. There are limited studies showing antidepressant activity of buprenorphine as no better than antidepressant activity associated with methadone→ **Deny**

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

Next Review Date

2/2022

Other Applicable Policies

References

Reference to Applicable Laws and Regulations, if Any

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