Clinical Policy: Buprenorphine-Naloxone (Suboxone, Bunavail, Zubsolv)

Reference Number: PA.CP.PMN.81
Effective Date: 01/18
Last Review Date: 08/17 Revision Log

Description
Buprenorphine-naloxone (Suboxone®, Bunavail®, and Zubsolv®) is a partial opioid agonist.

FDA approved indication
Suboxone, Bunavail, and Zubsolv are indicated for the treatment of opioid dependence.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness ® that Suboxone (*tablets*), Bunavail, and Zubsolv/generic are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Opioid Dependence (must meet all)**:**

1. Diagnosis of opioid dependence;
2. Prescriber has an "X" DEA number (DATA2000 waiver);
3. If request is for buprenorphine/naloxone (Suboxone) sublingual *tablets*, Bunavail, or Zubsolv, documented clinically significant adverse effects or contraindications to buprenorphine/naloxone (Suboxone) *film**;
    a. Note*: *Suboxone **film** does not require a prior authorization unless the daily dose exceeds quantity limits.*
4. Dose does not exceed the FDA approved maximum recommended dose for the requested agent.
5. Doses exceeding quantity limits will be reviewed to ensure the following conditions are met:
    a. Documentation of participation in a drug abuse counseling program;
    b. Submission of a recent urine drug test that is positive for buprenorphine and norbuprenorphine, while consistent with prescribed controlled substances

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Opioid Dependence (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria, , or the Continuity of Care Policy applies (*see PA.LTSS.PHAR.01*);

2. If request is for a dose increase, new dose does not exceed the FDA approved maximum recommended dose for the requested agent.
3. Doses exceeding quantity limits will be reviewed to ensure the following conditions are met:
    a. Documentation of participation in a drug abuse counseling program;
    b. Submission of a recent urine drug test that is positive for buprenorphine and norbuprenorphine, while consistant with prescribed controlled substances

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy, or the Continuity of Care Policy applies (*see PA.LTSS.PHAR.01*);
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: Duration of request or 12 months (whichever is less)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Pain management;

B. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
DATA: Drug Addiction Treatment Act
DEA: Drug Enforcement Administration
FDA: Food and Drug Administration

V. Dosage and Administration

Drug Name	Dosing Regimen*	Maximum Dose
Dissolving film		
Buprenorphine-naloxone (Suboxone)	Sublingual or buccal: Target dose: buprenorphine 16 mg/naloxone 4 mg once daily; dosage should be adjusted in increments/decrements of buprenorphine 2 mg/naloxone 0.5 mg or buprenorphine 4 mg/naloxone 1 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 4/1 mg buprenorphine/naloxone to 24/6 mg buprenorphine/naloxone per day	24 mg/6 mg per day

Buprenorphine-naloxone (Bunavail)	Buccal: Usual dose: buprenorphine 8.4 mg/naloxone 1.4 mg once daily; dosage should be adjusted in increments/decrements of buprenorphine 2.1 mg/naloxone 0.3 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 2.1/0.3 mg buprenorphine/naloxone to 12.6/2.1 mg buprenorphine/naloxone per day	12.6 mg/2.1 mg per day
Sublingual tablet		
Buprenorphine-naloxone	Sublingual: Target dose: Buprenorphine 16 mg/naloxone 4 mg once daily; dosage should be adjusted in increments/decrements of buprenorphine 2 mg/naloxone 0.5 mg or buprenorphine 4 mg/naloxone 1 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: Buprenorphine 4 to 24 mg/naloxone 1 to 6 mg once daily	24 mg/6 mg per day
Buprenorphine-naloxone (Zubsolv)	Sublingual: Target dose: Buprenorphine 11.4 mg/naloxone 2.9 mg once daily; dosage should be progressively adjusted in increments/decrements of 2.9 mg/0.71 mg or lower buprenorphine/naloxone to a level that holds the patient in treatment and suppresses opioid withdrawal signs and symptoms; usual range: 2.9 mg/0.71 mg buprenorphine/naloxone to 17.2 mg/4.2 mg buprenorphine/naloxone per day	17.1 mg/4.2 mg per day

**For maintenance treatment in patients with opioid dependence*

VI. Product Availability

Drug	Availability
Buprenorphine-naloxone (Suboxone)	Sublingual film: 2 mg buprenorphine with 0.5 mg naloxone, 4 mg buprenorphine with 1 mg naloxone, 8 mg buprenorphine with 2 mg naloxone and 12 mg buprenorphine with 3 mg naloxone

Buprenorphine-naloxone (Bunavail)	Buccal film: 2.1 mg buprenorphine/0.3 mg naloxone; 4.2 mg buprenorphine/0.7 mg naloxone and 6.3 mg buprenorphine/1 mg naloxone
Buprenorphine-naloxone	Sublingual tablet: 2 mg buprenorphine with 0.5 mg naloxone and 8 mg buprenorphine with 2 mg naloxone
Buprenorphine-naloxone (Zubsolv)	Sublingual tablet: 0.7 mg buprenorphine/0.18 mg naloxone; 1.4 mg buprenorphine/0.36 mg naloxone; 2.9 mg buprenorphine/0.71 mg naloxone; 5.7 mg buprenorphine/1.4 mg naloxone; 8.6 mg buprenorphine/2.1 mg naloxone; and 11.4 mg buprenorphine with 2.9 mg naloxone

VII. Workflow Document

N/A

VIII. References

1. Suboxone Prescribing Information. Richmond, VA: Indivior Inc.; February 2017. Available at: https://www.suboxone.com/. Accessed March 23, 2017.
2. Bunavail Prescribing Information. Raleigh, NC: BioDelivery Sciences International, Inc.; Available at: https://bunavail.com/. Accessed March 23, 2017.
3. Zubsolv Prescribing Information. Morristown, NJ: Orexo US, Inc.; December 2016. Available at: https://www.zubsolv.com/. Accessed March 23, 2017.
4. 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 (US); 2004. (Treatment Improvement Protocol (TIP) Series, No. 40.) Available from: https://www.ncbi.nlm.nih.gov/books/NBK64245/. Accessed March 23, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Removed PA requirement for Suboxone (film), updated counseling and urine drug test language.	04.09.18	