Clinical Policy: Buprenorphine-Naloxone (Suboxone, Bunavail, Zubsolv)
Reference Number: PA.CP.PMN.81
Effective Date: 01/18
Last Review Date: 01/19 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. 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.*
3. Dose meets one of the following (a, b, c, or d):
    a. Bunavail: dose does not exceed 12.6 mg/2.1 mg per day;
    b. Suboxone: dose does not exceed 24 mg/6 mg per day;
    c. Zubsolv: dose does not exceed 17.1 mg/4.2 mg per day.
    d. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

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. Member is responding positively to therapy;
3. If request is for a dose increase, new dose meets one of the following (a, b, c, or d):
    a. Bunavail: does not exceed 12.6 mg/2.1 mg per day;

b. Suboxone: does not exceed 24 mg/6 mg per day;
c. Zubsolv: does not exceed 17.1 mg/4.2 mg per day.
d. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

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*);
Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

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
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): hypersensitivity to buprenorphine or naloxone

Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Buprenorphine-naloxone (Suboxone) sublingual (SL) or buccal dissolving film	Induction: Titrate to 8 mg/2 mg SL on Day 1 and 16 mg/4 mg SL on Day 2; then start maintenance treatment Maintenance: Target dose: buprenorphine 16 mg/naloxone 4 mg once daily; dosage should be adjusted in increments or decrements of 2 mg/ 0.5 mg or 4 mg/1 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 4 mg/1 mg to 24 mg/6 mg per day	24 mg/6 mg per day

Drug Name	Dosing Regimen	Maximum Dose
Buprenorphine-naloxone (Bunavail) buccal film	Maintenance: Target dose: buprenorphine 8.4 mg/naloxone 1.4 mg once daily; dosage should be adjusted in increments or decrements of 2.1 mg/ 0.3 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 2.1 mg/0.3 mg to 12.6 mg/2.1 mg per day	12.6 mg/2.1 mg per day
Buprenorphine-naloxone SL tablet	Maintenance: Target dose: buprenorphine 16 mg/naloxone 4 mg SL once daily; dosage should be adjusted in increments or decrements of 2 mg/ 0.5 mg or 4 mg/1 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 4 mg/1 mg to 24 mg/6 mg per day	24 mg/6 mg per day
Buprenorphine-naloxone (Zubsolv) SL tablet	Induction: Titrate to 5.7 mg/1.4 mg SL on Day 1 and 11.4 mg/2.9 mg SL on Day 2; then start maintenance treatment Maintenance: Target dose: buprenorphine 11.4 mg/naloxone 2.9 mg once daily; dosage should be adjusted in increments or decrements of 2.9 mg/ 0.71 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 2.9 mg/0.71 mg to 17.2 mg/4.2 mg per day	17.1 mg/4.2 mg per day

VI. Product Availability

Buprenorphine-naloxone (Suboxone)	Sublingual film: buprenorphine/naloxone 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, 12 mg/3 mg
Buprenorphine-naloxone (Bunavail)	Buccal film: buprenorphine/naloxone 2.1 mg/0.3 mg; 4.2 mg/0.7 mg, 6.3 mg/1 mg
Buprenorphine-naloxone	Sublingual tablet: buprenorphine/naloxone 2 mg/0.5 mg, 8 mg/2 mg
Buprenorphine-naloxone (Zubsolv)	Sublingual tablet: buprenorphine/naloxone 0.7 mg/0.18 mg, 1.4 mg/0.36 mg, 2.9 mg /0.71 mg, 5.7 mg/1.4 mg, 8.6 mg/2.1 mg, 11.4 mg/2.9 mg

VII. References

1. Suboxone Sublingual Film Prescribing Information. North Chesterfield, VA: Indivior Inc.; February 2018. Available at: https://www.suboxone.com/. Accessed October 23, 2018.
2. Bunavail Prescribing Information. Raleigh, NC: BioDelivery Sciences International, Inc.; February 2018. Available at: https://bdsi.com/bunavail/. Accessed October 23, 2018.
3. Zubsolv Prescribing Information. Morristown, NJ: Orexo US, Inc.; February 2018. Available at: https://www.zubsolv.com/. Accessed October 23, 2018.
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 October 23, 2018.

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	
1Q 2019 annual review: removed XDEA number (DATA2000 waiver) as a requirement since prescription use of these products is limited under the Drug Addiction Treatment Act; removed criteria related to participation in drug abuse counseling and urine drugs screens (e.g., submission of at least 2 negative random urine drug screens) to shift the responsibility of appropriate monitoring and use to the prescriber; removed requirement related to adherence to therapy on re-auth and added requirement for positive response to therapy; modified generalized dosing requirement to include specific max dose of each drug; references reviewed and updated.	01.19	