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

Reference Number: CP.PMN.81
Effective Date: 09.01.17
Last Review Date: 02.18
Line of Business: Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

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

## FDA Approved Indication(s)

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

## Policy/Criteria

*Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Bunavail, Suboxone, and Zubsolv 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 Suboxone *film*;
3. Dose does not exceed:
   a. Bunavail: 12.6 mg/2.1 mg per day;
   b. Suboxone: 24 mg/6 mg per day;
   c. Zubsolv: 17.1 mg/4.2 mg per day.

**Approval duration: 12 months**

**B. Other diagnoses/indications**

1. Refer to 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 Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. One of the following conditions is met (a or b):
   a. Member has NOT received an opioid analgesic since last approval;

b. Prescriber submits documentation acknowledging that the use of opioid during the last approval period was due to legitimate diagnosis of pain;

4. If request is for a dose increase, new dose does not exceed:
   a. Bunavail: 12.6 mg/2.1 mg per day;
   b. Suboxone 24 mg/6 mg per day;
   c. Zubsolv: 17.1 mg/4.2 mg per day.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   **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 – 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*
N/A

## 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<br>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 |
| 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 | 12.6 mg/2.1 mg per day |

| Drug Name | Dosing Regimen | Maximum Dose |
|---|---|---|
| | withdrawal symptoms; usual range: 2.1 mg/0.3 mg to 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<br>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

| Drug Name | 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. Richmond, VA: Indivior Inc.; February 2017. Available at: https://www.suboxone.com/. Accessed November 8, 2017.
2. Bunavail Prescribing Information. Raleigh, NC: BioDelivery Sciences International, Inc.; April 2015. Available at: https://bunavail.com/. Accessed November 8, 2017.
3. Zubsolv Prescribing Information. Morristown, NJ: Orexo US, Inc.; September 2017. Available at: https://www.zubsolv.com/. Accessed November 8, 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 November 8, 2017.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy split from CP.PMN.23 buprenorphine-naloxone (Suboxone) and buprenorphine (Subutex)<br>Initial: removed age requirement since not an absolute contraindication; combined criteria for Suboxone film and non-PDL buprenorphine-naloxone tablet/film into one set since they share the same basic requirements. Re-auth: added max dose. Updated references. | 03.17 | 08.17 |
| 1Q18 annual review:<br>- Removed XDEA number (DATA2000 waiver) as a requirement since prescription use of these products is limited under the Drug Addiction Treatment Act.<br>- 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.<br>- 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<br>- References reviewed and updated. | 11.08.17 | 02.18 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.