



Clinical Policy: Buprenorphine-Naloxone (Suboxone, Bunavail, Zubsolv)  
 Reference Number: CP.PMN.XX  
 Effective Date: 09/17  
 Last Review Date: 08/17  
 Line of Business: Medicaid

[Coding Implications](#)  
[Revision Log](#)

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See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**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 (~~including which may include~~ office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that [Suboxone, Bunavail, and Zubsolv/generic Subutex](#) are **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. ~~Buprenorphine/naloxone film (Suboxone)~~Opioid Dependence** (must meet all):

1. Diagnosis of opioid dependence;
2. Age ≥ 16 years;
3. Prescriber has an “X” DEA number (DATA2000 waiver);
4. Member will participate in drug abuse counseling program while on therapy;
5. Random urine drug screens will be obtained while on therapy;
5. If request is for buprenorphine/naloxone (Suboxone) sublingual ~~tablets, Bunavail, or Zubsolv, documented clinically significant adverse effects or contraindications to buprenorphine/naloxone (Suboxone) film;~~
6. Dose does not exceed the FDA approved maximum recommended dose for the requested agent.

6. Prescribed dose of Suboxone film does not exceed 24 mg per day and health plan approved daily quantity limit.

**Approval duration: 12 months**

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**B. ~~Non-PDL buprenorphine/naloxone tablet/film (Zubsolv, Bunavail, generic buprenorphine/naloxone)~~** (must meet all):

1. Diagnosis of opioid dependence;
2. Age ≥ 16 years;
3. Prescriber has an “X” DEA number (DATA2000 waiver);
4. Member will participate in drug abuse counseling program while on therapy;
5. Random urine drug screens will be obtained while on therapy;
6. Contraindication or intolerance to Suboxone film;
7. Prescribed dose does not exceed the FDA approved dose and health plan approved daily quantity limit for the requested agent.

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~~Approval duration: 12 months~~

~~C.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. ~~Member is e~~Currently receiving ~~this~~ medication via Centene benefit or member has previously met initial approval criteria;
2. ~~Evidence of a~~Adherence to buprenorphine/naloxone ~~or buprenorphine per pharmacy claims records~~ as evidenced by pharmacy claims history;
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 was due to legitimate diagnosis of pain;
4. Submission of at least TWO negative random urine drug screens since last approval;
5. Documentation of participation in a drug abuse counseling program since last approval;
- ~~5-7.If request is for a dose increase, new dose does not exceed the FDA approved maximum recommended dose for the requested agent, must be submitted.~~

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**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
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:**

~~A.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*  
DATA: Drug Addiction Treatment Act  
DEA: Drug Enforcement Administration  
FDA: Food and Drug Administration

**V. Dosage and Administration**

Drug Name	Dosing Regimen*	Maximum Dose
<i>Dissolving film</i>		

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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
<i>Sublingual tablet</i>		
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	17.1 mg/4.2 mg per day

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	buprenorphine/naloxone to 17.2 mg/4.2 mg buprenorphine/naloxone per day	
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*\*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. Buprenorphine-Suboxone Prescribing Information. Elizabeth, NJ: Richmond, VA: Actavis Elizabeth LLC/Indivior Inc.; November-February 2017. Available at: <https://www.suboxone.com/https://dailymed.nlm.nih.gov/dailymed/>. Accessed March 23, 2017.~~
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- ~~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.~~
- ~~2. Buprenorphine/naloxone and buprenorphine Monographs. Clinical Pharmacology. Accessed July 2016. <http://www.clinicalpharmacology-ip.com>~~
- ~~3. Substance Abuse and Mental Health Services Administration. Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. 2004 Printing. [http://buprenorphine.samhsa.gov/Bup\\_Guidelines.pdf](http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf). Accessed July 2016.~~

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PMN.23 buprenorphine-naloxone (Suboxone) and buprenorphine (Subutex)  <u>Initial: removed age requirement per new template update 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.</u> <u>Re-auth: added max dose.</u> <u>Updated references.</u>	03/17	08/17

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**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

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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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**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.

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