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

Reference Number: CP.CPA.276
Effective Date: 03.01.18
Last Review Date: 02.18
Line of Business: Commercial

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 (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 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. 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.CPA.09 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.CPA.09 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.CPA.09 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

Appendix C: General Information

- The Drug Addiction Treatment Act of 2000 (DATA 2000), limits office-based use of Suboxone and Subutex to physicians who meet special training criteria and can provide appropriate services.
- Under the Drug Addiction Treatment Act (DATA) codified at 21 U.S.C. 823(g), prescription use of Zubsolv in the treatment of opioid dependence is limited to physicians who meet certain qualifying requirements, and who have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe this product for the treatment of opioid dependence and have been assigned a unique identification number that must be included on every prescription.
- Pharmacists who seek information to verify whether or not physicians have valid waivers can check: http://www.buprenorphine.samhsa.gov/bwns_locator/index.html OR 1-866-BUP-CSAT OR email at info@buprenorphine.samhsa.gov
- Subutex contains only buprenorphine and is intended for use at the beginning of treatment for drug abuse. Suboxone contains both buprenorphine and the opiate antagonist naloxone and is intended to be the formulation used in maintenance treatment of opiate addiction.
- The difference in bioavailability of Zubsolv compared to Suboxone tablet requires a different tablet strength to be given to the patient. One Zubsolv 5.7/1.4 mg sublingual

tablet provides equivalent buprenorphine exposure to one Suboxone 8/2 mg sublingual tablet.

- Because of the potential for naloxone to precipitate withdrawal in both mother and fetus, pregnant women who are deemed to be appropriate candidates for buprenorphine treatment should be inducted and maintained on buprenorphine monotherapy (Subutex).
- Tramadol is a centrally-acting synthetic opioid analgesic. Concomitant use of buprenorphine with tramadol increases the risk of serotonin syndrome, CNS depression, and respiratory depression.
- Prescription Drug Monitoring programs (PDMPs) are databases of all controlled substance prescriptions dispensed in a particular state. PDMP databases should be used to confirm opioid abstinence. The California PDMP, known as CURES (Controlled Substance Utilization Review and Evaluation System) encourages judicious prescribing including use of the CURES system before prescribing controlled substances. For more information visit http://oag.ca.gov/cures or http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm

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
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

Drug Name	Dosing Regimen	Maximum Dose
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

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 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
New policy created - Policy split from CP.CPA.276 Buprenorphine, Buprenorphine plus Naloxone (retired). - Initial: removed requirement that member is not using concurrent opioid medications (including tramadol).	11.08.17	02.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
- Re-auth: added requirement related to absence/presence of opioid use since last approval; - Modified initial/continued approval duration from LOB to 12 months due to potential for abuse. - Added pain management as a diagnosis for which coverage is not authorized. - References reviewed and updated.		

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.