Clinical Policy: Buprenorphine-Naloxone (Bunavail, Suboxone)

Reference Number: HIM.PA.35
Effective Date: 02.01.17
Last Review Date: 02.18
Line of Business: Health Insurance Marketplace Revision Log

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

Description

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

FDA Approved Indication(s)

Bunavail and Suboxone 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 Suboxone *and Bunavail** 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. Member meets (a or b):
   a. Request is for Suboxone;
   b. Request is for Bunavail for MHS Indiana member;
3. If request is for buprenorphine/naloxone (Suboxone) sublingual *tablets*, documented clinically significant adverse effects or contraindications to Suboxone *film*;
4. Dose does not exceed Suboxone 24 mg/6 mg per day.

Approval duration: 12 months

**Note: With the exception of MHS Indiana, Bunavail is a non-formulary agent for all HIM plans. For MHS Indiana only, Bunavail is a formulary agent that requires a prior authorization.*

B. Other diagnoses/indications

1. Refer to HIM.PHAR.21 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 Suboxone 24 mg/6 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 HIM.PHAR.21if 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 – HIM.PHAR.21 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

V. References

1. Suboxone Prescribing Information. Richmond, VA: Indivior Inc.; February 2017. Available at: http://www.suboxone.com/. Accessed November 8, 2017.
2. 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
Converted to new template. Clinical changes made to criteria: -Initial: added a requirement for diagnosis of opioid dependence; removed age requirement; modified generalized FDA approved limit to specific max dose; -Continued: modified to allow use of opioid since last approval if prescriber submits documentation	12.16	02.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
acknowledging that the use of opioid during the last approval was due to legitimate diagnosis of pain; added max dose requirement. Updated references.		
1Q18 annual review - Removed XDEA number (DATA2000 waiver) as a requirement since prescription use of this product 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. - Added Bunavail as an option for MHS Indiana members only since it is a MHS Indiana formulary agent that requires a PA. - Removed requirement related to adherence to therapy on re-auth and added requirement for positive response to therapy - 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.

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.