Clinical Policy: Buprenorphine (Subutex)
Reference Number: NH.PMN.24
Effective Date: 09/17
Last Review Date: 07/18 Revision Log
Line of Business: Medicaid

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

Description
Buprenorphine (Subutex®) is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor.

FDA approved indication
Subutex is indicated for the treatment of opioid dependence and is preferred for induction.

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 Subutex is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Opioid Dependence (must meet all)**:**

1. Diagnosis of opioid dependence;
2. Prescriber has an "X" DEA number (DATA2000 waiver);
3. Member will participate in drug abuse counseling program while on therapy;
4. Random urine drug screens will be obtained while on therapy;
5. Member meets one of the following conditions (a, b, c, or d):
   a. Member is pregnant;
   b. Member is allergic to naloxone;
   c. Member has documented genuine contraindication(s) or intolerance to Suboxone film;
   d. Request is for induction therapy (treatment duration of ≤ 5 days);
6. Dose does not exceed 24 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; ***Note: Subutex will not be renewed for pregnancy unless there is documentation supporting that member is pregnant again*
2. Adherence to buprenorphine 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;
6. If request is for a dose increase, new dose does not exceed 24 mg per day.

Approval duration: 12 months or duration of request (whichever is less)

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;

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

Indication	Dosing Regimen	Maximum Dose
Opioid dependence	<u>Induction</u> Adults: 8 mg sublingually (SL) on Day 1 and 16 mg SL on Day 2; then the patient should start maintenance treatment.	24 mg/day
	<u>Maintenance</u> The maintenance dose is generally in the range of 4 mg to 24 mg buprenorphine per day depending on the individual patient. Doses higher than this have not been demonstrated to provide any clinical advantage. The dosage of buprenorphine should be progressively adjusted in increments/decrements of 2 mg or 4	

	mg buprenorphine to a level that holds the patient in treatment and suppresses opioid withdrawal signs and symptoms.	

VI. Product Availability

Sublingual tablet: 2 mg and 8 mg

VII. Workflow Document

N/A

VIII. References

1. Buprenorphine Prescribing Information. Elizabeth, NJ: Actavis Elizabeth LLC; November 2016. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed March 23, 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 March 23, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PMN.23 buprenorphine-naloxone (Suboxone) and buprenorphine (Subutex) Initial: removed age requirement since not an absolute contraindication; modified 12-month approval duration for conditions other than induction to include "or duration of request (whichever is less)", if applicable (e.g., pregnancy). Re-auth: added a clarification that Subutex will not be renewed for pregnancy unless there is documentation that member is pregnant again; added max dose; modified 12-month approval duration to include "or duration of request (whichever is less)", if applicable (e.g., pregnancy) Updated references	03/17	08/17
Annual Review, No Changes	07/18	07/18

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.

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.