Clinical Policy: Medication Assisted Treatment of Opioid Addiction

Reference Number: OH.PHAR.PPA.40
Effective Date: 01.01.2020
Last Review Date: 11.2021
Line of Business: Medicaid

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

Description

Buprenorphine injection **(Sublocade®)** is a partial opioid agonist.

CENTRAL NERVOUS SYSTEM AGENTS: MEDICATION ASSISTED TREATMENT OF OPIOID ADDICTION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BUNAVAIL® buccal film BUPRENORPHINE/NALOXONE SL tablets/films Clonidine SUBOXONE® SL film (buprenorphine/naloxone) Vivitrol†† ZUBSOLV® SL tablets (buprenorphine/naloxone)	Sublocade†††	BUPRENORPHINE SL tablets (generic of Subutex®)† Lucemyra

†Use restricted to pregnancy or breastfeeding; or contraindication to preferred products.
†† Vivitrol may be billed by the pharmacy if it is not dispensed directly to the patient. If not administered by the pharmacist, the drug must be released only to the administering provider or administering provider's staff, following all regulations for a Prescription Pick-Up Station as described by the Ohio Board of Pharmacy
††† Sublocade may be billed by the pharmacy if it is not dispensed directly to the patient. If not administered at the pharmacy, the drug must be released only to the administering provider or administering provider's staff, following all applicable regulations.

FDA Approved Indication(s)

- Subutex is indicated for the treatment of opioid dependence
- Bunavail, Suboxone, Zubsolv are indicated for the treatment of opioid dependence
- Vivitrol is indicated for the prevention of relapse to opioid dependence, following opioid detoxification
- Sublocade is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.

• Lucemyra (lofexidine) is indicated for the treatment of opioid agonist withdrawal symptoms to facilitate abrupt opioid discontinuation

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

* No PA required for short-acting, buprenorphine containing, oral agents. However buprenorphine (Subutex®) is restricted to women of childbearing age unless member has an allergy to a preferred product.

It is the policy of health plans affiliated with Centene Corporation® that Sublocade, Subutex, Bunavail, Suboxone and Zubsolv are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Sublocade (must meet all)**:**

1. Diagnosis of opioid dependence;
2. Currently established on a dose of at least 8mg of oral buprenorphine for at least 7 days;
3. Medical justification supports inability to continue to use oral formulation and Vivitrol;
4. Urine drug screen result obtained within the last 7 days with no illicit substances or non-prescribed therapies detected (initially). Subsequent authorization dependent upon UDS results indicating compliance to treatment plan;
5. Provider will attest that the patient is receiving or planning to receive counseling;
6. The physician has reviewed OARRS within 7 days prior to the PA request. If the patient has received controlled substances since the previous authorization:
    a. The physician has coordinated with all other prescribers of controlled substances and has determined that the patient should continue treatment; and
    b. If the patient has received other controlled substances for 84 or more continuous days, the physician has consulted with a board-certified addictionologist or addiction psychiatrist who has recommended the patient receive substance abuse treatment (consultation not necessary if the prescriber is a board-certified addictionologist or addiction psychiatrist)
7. Dose does not exceed 300mg per month in the first 60 days and 100mg thereafter. Providers may request a maintenance dose increase beyond 100mg by submitting additional clinical documentation supporting the need for a higher dose
8. Re-authorization requires adherence to specified treatment plan inclusive of adherence to counseling, OARRS and urine drug screening requirements

Approval duration:

1. Initial authorization: 30 days

2. Subsequent authorization: Length of approval depends upon member status and compliance to treatment plan. Not to exceed 180 days

B. Subutex (must meet all):

1. Diagnosis of opioid dependence;
2. Age ≥ 16 years;
3. Member meets one of the following conditions (a, b, or c):
   a. Member is pregnant;
   b. Member has experienced clinically significant adverse effects or contraindication(s) to buprenorphine/naloxone (e.g., Suboxone);
   c. Request is for induction therapy (treatment duration of ≤ 5 days);
4. Dose does not exceed 16 mg per day
5. If request is for dose exceeding 16 mg per day, all of the following must be met (a and b):
   a. Dose does not exceed 24 mg per day
   b. Prescriber submits documentation with rationale for dose increase

Approval duration:

1. Induction therapy: 5 days
2. Maintenance therapy: Duration of request or 12 months (whichever is less)

C. Bunavail, Suboxone, Zubsolv (must meet all):

1. Diagnosis of opioid dependence;
2. Age ≥ 16 years;
3. Dose does not exceed:
   a. Bunavail: 8.4 mg per day
   b. Suboxone: 16mg per day
   c. Zubsolv: 11.4 mg per day
4. If request is for dose exceeding those stated in criteria 4 above, all of the following must be met (a and b):
   a. Dose does not exceed the following: Bunavail (12.6 mg per day), Suboxone (24 mg per day), or Zubsolv (17.1 mg per day)
   b. Prescriber submits documentation with rationale for dose increase

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

D. Lucemyra (lofexidine) (must meet all):

1. Diagnosis of opioid agonist withdrawal due to opioid dependence or opioid use disorder;
2. Age ≥ 18 years;
3. Patient is currently undergoing or is scheduled to undergo abrupt opioid discontinuation;
4. Provider provides documentation/support for why a taper plan (such as with buprenorphine or methadone) cannot be used;

5. Member meets at least one of the following:
   a. Therapeutic failure of maximal dose of clonidine (due to intolerable adverse effects) or inability to reach maximal dose of clonidine due to adverse effects;
   b. Documented history of intolerance to clonidine (ex: hypotension, bradycardia)
   c. Contraindication to clonidine as specified by FDA labeling
   d. Lofexidine has already been initiated in an inpatient setting

6. Dose does not exceed 2.88mg (16 tablets) per day

Approval duration: 14 days

II. Diagnoses/Indications for which coverage is NOT authorized:

A. 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 policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
MAT: medication-assisted treatment
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
buprenorphine-naloxone (Suboxone®) sublingual (SL) or buccal dissolving film, SL tablet	**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
Bunavail® (buprenorphine-naloxone) 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/	12.6 mg/2.1 mg per day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	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	
Zubsolv® (buprenorphine-naloxone) 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

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindications(s):
  - Sublocade: hypersensitivity to buprenorphine or any other ingredients in Sublocade
  - Suboxone, Bunavail, Zubsolv, Subutex: hypersensitivity to buprenorphine or naloxone

- Boxed warning(s):
  - Sublocade: risk of serious harm or death with intravenous administration; available only through a restricted program called the Sublocade REMS Program
  - Suboxone, Bunavail, Zubsolv, Subutex: none reported

IV. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Buprenorphine (Sublocade®)	Two monthly initial doses of 300 mg subcutaneously followed by 100 mg monthly maintenance doses	300 mg per month
Buprenorphine (Subutex®)	**Induction** Adults: 8 mg sublingually (SL) on Day 1 and 16 mg SL on Day 2; then the patient	24 mg/day

Drug Name	Dosing Regimen	Maximum Dose
	should start maintenance treatment. **Maintenance** The maintenance dose is generally in the range of 4 mg to 24 mg buprenorphine per day depending on the individual patient. The recommended target dose is 16 mg. 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.	

V. Product Availability

Drug Name	Availability
Buprenorphine (Subutex®)	Sublingual tablets: 2mg,8mg
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	Sublingual tablet: buprenorphine/naloxone 2 mg/0.5 mg, 8 mg/2 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 (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
Buprenorphine (Sublocade®)	Subcutaneous Injection: 100 mg/0.5 mL and 300 mg/1.5 mL provided in a prefilled syringe with a 19 Gauge 5/8-inch needle

VI. References

Refer to package insert

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.2019	
Added criteria point: Provider will attest that the patient is receiving or planning to receive counseling for Sublocade. Updated preferred/non-preferred chart	11.21	

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.