Clinical Policy: Buprenorphine (Subutex) SL tablets

Reference Number: AZ.CP.PMN.82
Effective Date: 06.27.18
Last Review Date: 07.20
Line of Business: Arizona Medicaid

Revision Log

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

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

FDA approved indication
Buprenorphine sublingual tablets (Subutex®) are indicated for the treatment of opioid dependence and is preferred for induction. Buprenorphine should be used as part of a complete treatment plan that includes counseling and psychosocial support.

Limitation of use: this policy is for buprenorphine sublingual tablets only and not for other dosage formulations of buprenorphine.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Arizona Complete Health that buprenorphine sublingual tablets are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Opioid Dependence

1. Diagnosis of Opioid Dependence
2. Pregnant or nursing woman in a Medication Assisted therapy (MAT) program with one of the following ICD-10 codes:
    a. O09.91 - Supervision of high risk pregnancy, 1st trimester
    b. O09.92 - Supervision of high risk pregnancy, 2nd trimester
    c. O09.93 - Supervision of high risk pregnancy, 3rd trimester
    d. O09.90 - Supervision of high risk pregnancy - use for post-partum nursing mothers.

OR

3. Documentation of failure, contraindication, or clinically significant adverse effects experienced with Suboxone. (See General Information for more details about adverse effects.)

4. Dose does not exceed 24mg (3 tablets) per day

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): AZ.CP.PMN.53 for Arizona Medicaid.

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. Documentation of positive response to therapy
3. One of the following conditions is met:
    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;
    c. Member is still pregnant or nursing;
    d. Confirmation that prescriber is evaluating random drug screens.
4. If request is for a dose increase, new dose does not exceed 24 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): AZ.CP.PMN.53 for Arizona Medicaid.

III. 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 policy – CP.PMN.53.

B. Pain Management

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: General Information

- Brand name Subutex (buprenorphine) is no longer on the market.
- 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.
- Buprenorphine 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.

- Use of naloxone may cause symptoms of opioid withdrawal to include: restlessness, irritability, body aches, dizziness, weakness, diarrhea, stomach pain, nausea, fever, chills, and runny nose in the absence of a cold.
- An adverse effect is an undesired harmful effect resulting from the medication. An allergy is an adverse drug reaction mediated by an immune response such as rash, hives, and the swelling of lips, tongue, and throat.
- Adverse effects of buprenorphine can include: nausea, vomiting, constipation, muscle cramps and aches, cravings, insomnia, irritability, and fever.
- The Drug Addiction Treatment Act of 2000 (DATA 2000) limits office-based use of buprenorphine (Subutex) to physicians who meet special training criteria and can provide appropriate services.
- 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

Appendix C: Therapeutic Alternatives

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Buprenorphine HCl/Naloxone HCl Dihydrate Sublingual 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 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
Suboxone oral Dissolving Film (buprenorphine-naloxone)	**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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Opioid dependence	Induction Adults: 8 mg sublingually (SL) on Day 1 and 16 mg SL on Day 2; then the patient 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.	24 mg/day

Product Availability
Buprenorphine sublingual tablets: 2 mg, 8 mg

VI. References

1. 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 June 8, 2020.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: http://www.clinicalpharmacology-ip.com/
3. Buprenorphine Prescribing Information. Eatontown, NJ: Hikma Pharmaceuticals USA Inc.; April 2019. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed June 8, 2020.
4. AHCCCS Pharmacy Updates June 2018 https://www.azahcccs.gov/PlansProviders/Downloads/PharmacyUpdates/BuprenorphineMATUpdate6272018.pdf
5. Subutex Prescribing Information. North Chesterfield, VA: Reckitt Benckiser HealthCare (UK) Ltd. Available at: https://www.suboxone.com/content/pdfs/SUBUTEX_Prescribing_Information.pdf Accessed June 8, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template Added references Annual Review – no clinical changes	9/18	
Added buprenorphine/naloxone SL tab under therapeutic alternatives, updated logo; updated numbering from AZ.CP.PHAR.10.11.9 to AZ.CP.PMN.82 to align with Corporate numeration.	07.19	07.19
2020 annual review: no significant changes; added Subutex as brand reference to align with Corp criteria; references reviewed and updated.	07.20	7.20

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.