Clinical Policy: Buprenorphine (Subutex)

Reference Number: PA.CP.PMN.82
Effective Date: 01/18
Last Review Date: 01/19 Revision Log

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 Pennsylvania Health and Wellness ® 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. Member meets one of the following conditions (a, b, or c):
   a. Member is pregnant or breastfeeding;
   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);
3. Request meets one of the following (a or b):
   a. Dose does not exceed 24 mg per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 5 days for induction therapy; 12 months or duration of request (whichever is less) for other conditions

B. Other diagnoses/indications

1. Refer to PA.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 Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria, , or the Continuity of Care Policy applies (*see PA.LTSS.PHAR.01*); ***Note: Subutex will not be renewed for pregnancy unless there is documentation supporting that member is pregnant again*
2. Member is responding positively to therapy;
3. If request is for a dose increase, must meet one of the following (a or b):

a. New dose does not exceed 24 mg per day;
b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

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 the Continuity of Care Policy applies (*see PA.LTSS.PHAR.01*);
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to PA.CP.PMN.53 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 – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
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®)	**Opiate agonist dependence** • DAY 1 DOSING: First induction dose buprenorphine; naloxone 2 mg/0.5 mg or 4 mg/1 mg SL film; may titrate in 2 or 4 mg increments of buprenorphine, at approximately 2-hour increments, under supervision, up to a total dose of buprenorphine/naloxone 8 mg/2 mg SL film. • DAY 2 DOSING: A single daily dose of buprenorphine; naloxone up to 16 mg/4 mg SL film is recommended. • DAY 3 DOSING AND BEYOND: Progressively adjust dose in increments or decrements of 2 mg/0.5 mg or 4 mg/1 mg to a level that holds the patient in treatment and	24/6 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	suppresses opioid withdrawal signs and symptoms.	

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

- Contraindication(s): History of hypersensitivity to buprenorphine
- Boxed warning(s): none reported

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.	24 mg/day
	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.	

VI. Product Availability

Sublingual tablets: 2 mg and 8 mg

VII. References

1. Buprenorphine Prescribing Information. Morgantown, WV: Mylan Pharmaceuticals Inc.; February 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed October 30, 2018.
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 October 30, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Revised counseling and urine drug screen requirements.	04.09.18	
1Q 2019 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; removed "member is allergic to naloxone" as an approvable condition for Subutex since it's covered by "member has experienced clinically significant adverse effects or has contraindication(s) to Suboxone"; removed requirement related to adherence to therapy on re-auth and added requirement for positive response to therapy; added clarification to continued therapy that for induction therapy, re-auth is not permitted and members must be initial approval criteria; no significant changes; references reviewed and updated.	01.19	