Clinical Policy: Buprenorphine (Subutex)

Reference Number: PA.CP.PMN.82
Effective Date: 01/18
Last Review Date: 09/17 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. Prescriber has an "X" DEA number (DATA2000 waiver);
3. Member meets one of the following conditions (a, b, c, or d):
   a. Member is pregnant or breastfeeding;
   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);
4. Dose does not exceed 24 mg per day.
5. Doses exceeding quantity limits will be reviewed to ensure the following conditions are met:
   a. Documentation of participation in a drug abuse counseling program;
   b. Submission of a recent urine drug test that is positive for buprenorphine and norbuprenorphine, while consistent with prescribed controlled substances

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. If request is for a dose increase, new dose does not exceed 24 mg per day.
3. Doses exceeding quantity limits will be reviewed to ensure the following conditions are met:
    a. Documentation of participation in a drug abuse counseling program;
    b. Submission of a recent urine drug test that is positive for buprenorphine and norbuprenorphine, while consistent with prescribed controlled substances

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*);
2. Refer to PA.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 – PA.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
Revised counseling and urine drug screen requirements.	04.09.18	