

# **PRIOR AUTHORIZATION CRITERIA**

## **Buprenorphine sublingual tablets (Subutex®)**

### **POLICY**

#### **FDA-APPROVED INDICATIONS**

Buprenorphine sublingual tablets are indicated for the treatment of opioid dependence and are preferred for induction. Buprenorphine sublingual tablets should be used as part of a complete treatment plan to include counseling and psychosocial support.

Under the Drug Addiction Treatment Act (DATA) codified at 21 U.S.C. 823(g), prescription use of this product in the treatment of opioid dependence is limited to physicians who meet certain qualifying requirements, and who have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe this product for the treatment of opioid dependence and have been assigned a unique identification number that must be included on every prescription.

#### **COVERAGE CRITERIA**

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being used as part of a complete program for the treatment of opioid dependence [Note: Complete treatment programs may include the following: A) Behavioral therapies (e.g., individual therapy, group counseling, family behavior therapy, cognitive behavioral therapy, motivational enhancement, motivational incentives), B) Medical history, physical exam, and screening laboratory tests as needed (e.g., HIV and hepatitis C screening), C) Diversion control protocols such as observed dosing, pill counts, testing for buprenorphine's metabolite (nor-buprenorphine), D) Random testing for heroin and other drugs of abuse, E) Use of the Prescription Drug Monitoring Program (PDMP) if available in state.]  
**AND**
  - The patient is pregnant or breastfeeding **AND**
  - The requested drug is being prescribed for induction therapy and/or subsequent maintenance therapy for opioid dependence treatment**OR**
  - The requested drug is being prescribed for INDUCTION THERAPY for transition from opioid use to opioid dependence treatment

#### **Quantity limits:**

Buprenorphine 2mg: Quantity Limit is 12 tablets per day

Buprenorphine 8mg: Quantity Limit is 3 tablets per day

**Approval Length:** 12 months

#### **REFERENCES**

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4. U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration (SAMHSA). <https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine>. Accessed October 2017.

Initial Criteria: 2018

Totally Revised Criteria Date: 7/2019

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7. American Society of Addiction Medicine National Practice Guideline For the Use of Medications in the Treatment of Addiction Involving Opioid Use. <http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24>. Accessed October 2017.
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