

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

(buprenorphine sublingual tablets)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

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 apply.

QUANTITIES FOR APPROVAL

For pregnant patients: 90 tablets per 25 days* OR 270 tablets per 75 days*

For non-pregnant patients: 21 tablets per 75 days*

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

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.
5. U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration (SAMHSA). TIP 40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction - A Treatment Improvement Protocol. https://www.ncbi.nlm.nih.gov/books/NBK64245/pdf/Bookshelf_NBK64245.pdf. Accessed October 2017.
6. U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration (SAMHSA). TIP 43: Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Program. <http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf>. Accessed October 2017.
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.
8. Medication Assisted Treatment for Substance Use Disorders – Informational Bulletin. <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-07-11-2014.pdf>. Accessed October 2017.
9. Eidelman AI, Schanler RJ; American Academy of Pediatrics Section on Breastfeeding. Breastfeeding and the use of human milk. *Pediatrics*. 2012;129 (3):827-843.