

QUANTITY LIMIT PRIOR AUTHORIZATION CRITERIA

BRAND NAME

(generic)

(buprenorphine sublingual tablets)

Status: CVS Caremark Criteria

Type: Quantity Limit; Post Limit 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.

INITIAL QUANTITY LIMIT*

Drug

1 Month Limit**

Buprenorphine sublingual tablets

90 tablets / 25 days

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

**If the patient is requesting more than the initial quantity limit, then the claim will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.*

DURATION LIMIT*

Drug

Duration Limit (per 3 months)

Buprenorphine sublingual tablets

30-day supply

**If the patient is requesting more than a cumulative 30-day supply within the past 3 months, then the claim will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.*

COVERAGE CRITERIA

- The requested drug will be covered with prior authorization when the following criteria are met:
 - The patient is pregnant or breastfeeding**AND**
 - Buprenorphine is being prescribed for induction therapy and/or subsequent maintenance therapy for opioid dependence treatment

Quantity limits apply.

POST LIMIT QUANTITY

90 tablets per 25 days* or 270 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

1. Buprenorphine sublingual tablets [package insert]. Elizabeth, NJ: Actavis Pharma, Inc, November 2016.
2. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed October 2017.
3. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed October 2017.
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. Eidelman AI, Schanler RJ; American Academy of Pediatrics Section on Breastfeeding. Breastfeeding and the use of human milk. *Pediatrics*. 2012;129 (3):827-843.