Reference number(s)
2328-HJ

Quantity Limit; Post Limit Prior Authorization Buprenorphine Sublingual Tablets

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
buprenorphine (brand unavailable)	buprenorphine	sublingual tablets

Indications

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.

Initial Quantity Limit

Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength.

If the patient is requesting more than the initial quantity limit, 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.

Initial Limit Quantity

Drug	1 Month Limit
buprenorphine sublingual tablets 2 mg	90 tablets / 25 days
buprenorphine sublingual tablets 8 mg	120 tablets / 25 days

Duration Limit

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.

Drug	Duration Limit (per 3 months)
buprenorphine sublingual tablets	30-day supply

Coverage Criteria

Opioid Use Disorder

Authorization may be granted when the requested drug is being prescribed for induction therapy and/or subsequent maintenance therapy for the treatment of opioid use disorder when ONE of the following criteria is met:

- The patient is pregnant OR breastfeeding. [ACTION REQUIRED: Documentation is required for approval.]
- The patient has an intolerance to naloxone. [ACTION REQUIRED: Documentation is required for approval.]
- The patient has moderate or severe liver impairment. [ACTION REQUIRED: Documentation is required for approval.]

Quantity Limits Apply

Post Limit Quantity

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.

Drug	1 Month Limit	3 Month Limit
buprenorphine sublingual tablets 2 mg	90 tablets / 25 days 3 tablets / day	270 tablets / 75 days 3 tablets / day
buprenorphine sublingual tablets 8 mg	120 tablets / 25 days 4 tablets / day	360 tablets / 75 days 4 tablets / day

Duration of Approval (DOA)

- 2328-HJ: DOA: 12 months

References

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4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 10/02/2025).
5. Cunningham C, Edlund MJ, Fishman M, et al. The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 focused update. American Society of Addiction Medicine. January 2020. 1-91.
6. Clinical Pharmacology. 2025. Buprenorphine. In Clinical Pharmacology. Elsevier. Retrieved October 2, 2025 from https://www.clinicalkey.com/pharmacology/monograph/1224?n=Buprenorphine
7. U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration (SAMHSA). TIP 63: Medications for Opioid Use Disorder - A Treatment Improvement Protocol. https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP21-02-01-002.pdf. Accessed November 5, 2025.
8. Meek JY, Nobel L; American Academy of Pediatrics. Policy Statement: Breastfeeding and the use of human milk. Pediatrics. 2022;150 (1):1-15.
9. Weimer MB, Herring AA, Kawasaki SS, et. al. ASAM Clinical Considerations: Buprenorphine Treatment of Opioid Use Disorder for Individuals Using High-Potency Synthetic Opioids. *J Addict Med.* 2023;17(6):632-639.
10. Substance Abuse and Mental Health Services Administration. Listening Session: Use of High Dose Buprenorphine for the Treatment of Opioid Use Disorder. December 11, 2023. U.S. Department of Health and Human Services.

11. Food and Drug Administration. (2024, December 27). Modifications to labeling of buprenorphine-containing transmucosal products for the treatment of opioid dependence (Docket No. FDA–2024–N–5381). Federal Register, 89(248), 105613–105617.