Reference number(s)
7290-J

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.

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 ALL of the following criteria are met:

- The requested drug is being used as part of a complete program for the treatment of opioid use disorder. [NOTE: Complete treatment programs may include the following: behavioral therapies (e.g., individual therapy, group counseling, family behavior therapy, cognitive behavioral therapy, motivational enhancement, motivational incentives, mutual support), medical history,

physical exam, and screening laboratory tests as needed (e.g., HIV and hepatitis C screening), diversion control protocols such as observed dosing, pill counts, testing for buprenorphine's metabolite (nor-buprenorphine), random urine testing for opioids and other illicit substances, use of the Prescription Drug Monitoring Program (PDMP) if available in state.]
- The request is NOT for buprenorphine sublingual tablet 2 mg.
- The patient meets ONE of the following: is pregnant or breastfeeding, has an intolerance to naloxone, has moderate or severe liver impairment. [ACTION REQUIRED: Documentation is required for approval.]
- The patient requires a higher stabilization dose due to exposure to high-potency synthetic opioids (HPSO) or pregnancy.

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.

No additional quantities are available for buprenorphine sublingual tablet 2 mg.

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

Duration of Approval (DOA)

- 7290-J: 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).

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6. 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.
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 4, 2025.
8. Medication Assisted Treatment for Substance Use Disorders – Informational Bulletin. http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-07-11-2014.pdf. Accessed November 12, 2025.
9. Meek JY, Nobel L; American Academy of Pediatrics. Policy Statement: Breastfeeding and the use of human milk. Pediatrics. 2022;150 (1):1-15.
10. 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.
11. 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.
12. 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.