Reference number(s)
7291-J

Post Limit Prior Authorization Buprenorphine-Naloxone

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/naloxone (brand unavailable)	buprenorphine and naloxone	sublingual tablets
Suboxone	buprenorphine and naloxone	sublingual films
Zubsolv	buprenorphine and naloxone	sublingual tablets

Indications

FDA-approved Indications

Buprenorphine and Naloxone Sublingual Tablet (Suboxone Tablet)

Buprenorphine and Naloxone Sublingual Tablets are indicated for the maintenance treatment of opioid dependence. Buprenorphine and Naloxone Sublingual Tablets should be used as part of a complete treatment plan that includes counseling and psychosocial support.

Suboxone Film

Suboxone sublingual film is indicated for treatment of opioid dependence. Suboxone sublingual film should be used as part of a complete treatment plan that includes counseling and psychosocial support.

Zubsolv

Zubsolv is indicated for treatment of opioid dependence. Zubsolv should be used as part of a complete treatment plan that includes counseling and psychosocial support.

Coverage Criteria

Opioid Use Disorder

Authorization may be granted when the requested drug is being prescribed for 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 ANY of the following: buprenorphine/naloxone 2 mg/0.5 mg, Suboxone (buprenorphine/naloxone) 2 mg/0.5 mg, Suboxone (buprenorphine/naloxone) 4 mg/1 mg, Suboxone (buprenorphine/naloxone) 12 mg/3 mg, Zubsolv (buprenorphine/naloxone) 0.7 mg/0.18 mg, Zubsolv (buprenorphine/naloxone) 1.4 mg/0.36 mg, Zubsolv (buprenorphine/naloxone) 2.9 mg/0.71 mg, or Zubsolv (buprenorphine/naloxone) 8.6 mg/2.1 mg.
- The patient requires a higher buprenorphine 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/naloxone 2 mg/0.5 mg, Suboxone (buprenorphine/naloxone) 2 mg/0.5 mg, Suboxone (buprenorphine/naloxone) 4 mg/1 mg, Suboxone (buprenorphine/naloxone) 12 mg/3 mg, Zubsolv (buprenorphine/naloxone) 0.7 mg/0.18 mg, Zubsolv (buprenorphine/naloxone) 1.4 mg/0.36 mg, Zubsolv (buprenorphine/naloxone) 2.9 mg/0.71 mg, or Zubsolv (buprenorphine/naloxone) 8.6 mg/2.1 mg.

Drug	1 Month Limit	3 Month Limit
buprenorphine/naloxone 8 mg/2 mg sublingual tablet	120 tablets / 25 days 4 tablets / day	360 tablets / 75 days 4 tablets / day
Suboxone 8 mg/2 mg sublingual film	120 films / 25 days	360 films / 75 days

Drug	1 Month Limit	3 Month Limit
	4 films / day	4 films / day
Zubsolv 5.7 mg/1.4 mg sublingual tablet	120 tablets / 25 days 4 tablets / day	360 tablets / 75 days 4 tablets / day
Zubsolv 11.4 mg/2.9 mg sublingual tablet	60 tablets / 25 days 2 tablets / day	180 tablets / 75 days 2 tablets /day

Duration of Approval (DOA)

- 7291-J: DOA: 12 months

References

1. Buprenorphine and Naloxone Sublingual Tablets [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; October 2024.
2. Suboxone Sublingual Film [package insert]. North Chesterfield, VA: Indivior, Inc.; May 2025.
3. Zubsolv [package insert]. Morristown, NJ: Orexo US, Inc.; May 2025.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed October 2, 2025.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 10/02/2025).
6. Clinical Pharmacology. 2025. Buprenorphine; naloxone. In Clinical Pharmacology. Elsevier. Retrieved October 2, 2025 from https://www.clinicalkey.com/pharmacology/monograph/3680?n=Buprenorphine;%20Naloxone
7. 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.
8. 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.
9. 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.
10. 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.