Reference number(s)
REG 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 Limit Quantity

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, then the claim will reject with a message indicating that the quantity limit is exceeded.

Drug	1 Month Limit
Buprenorphine Sublingual Tablets	90 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

90 tablets / 25 days or 270 tablets / 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.

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Duration of Approval (DOA)

- 2328-HJ: DOA: 12 months

References

1. Buprenorphine sublingual tablets [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; September 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed November 5, 2024.
3. Micromedex ® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 11/05/2024).
4. 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.
5. 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, 2024.
6. Meek JY, Nobel L; American Academy of Pediatrics. Policy Statement: Breastfeeding and the use of human milk. Pediatrics. 2022;150 (1):1-15.

Document History

Written by: UM Development (CF/JH)

Date Written: 10/2017

Revised: 11/2017, 04/2018 (non-clinical change to question order and denial reasons); (JG) 07/2018 (no clinical changes); (CF) 11/2018 (no clinical changes), 11/2019 (opioid dependence updated to opioid use disorder); (DS) 11/2020 (no clinical changes; clarified limits do not accumulate), 11/2021 (no clinical changes); (DRS) 11/2022 (no clinical changes), (DFW) 11/2023 (no clinical changes), 11/2024 (added use for intolerance to naloxone and liver impairment and documentation requirements)

Reviewed: Medical Affairs: (DNC) 10/2017, 11/2017; (CHART) 11/27/2019, 02/27/2020 (FYI for CPO rec – opioid use disorder), 12/03/2020, 12/02/2021, 12/01/2022, 11/30/2023, 11/21/2024

External Review: 10/2017, 08/2018, 02/2019, 02/2020, 02/2021, 02/2022, 03/2023, 02/2024, 02/2025

CRITERIA FOR APPROVAL

Reference number(s)
REG 2328-HJ

1	Is the requested drug being prescribed for induction therapy and/or subsequent maintenance therapy for the treatment of opioid use disorder? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Is the patient pregnant or breastfeeding? ACTION REQUIRED: If yes, then prescriber MUST submit chart notes that show the patient is pregnant or breastfeeding. _____ [If Yes, then go to 3. If No, then go to 4.] Tech Note: Leave response as answered by prescriber. Verification of chart notes will be addressed in the next question.	Yes	No
3	Have chart notes showing the patient is pregnant or breastfeeding been submitted to CVS Health? *ACTION REQUIRED: Submit supporting documentation* [If Yes, then go to 8. If No, then no further questions.] Tech Note: If the PA is worked over the phone, then the prescriber still MUST submit physical chart notes.	Yes	No
4	Does the patient have an intolerance to naloxone? ACTION REQUIRED: If yes, then prescriber MUST submit chart notes that show the patient has an intolerance to naloxone. _____ [If Yes, then go to 5. If No, then go to 6.] Tech Note: Leave response as answered by prescriber. Verification of chart notes will be addressed in the next question.	Yes	No
5	Have chart notes showing the patient has an intolerance to naloxone been submitted to CVS Health? *ACTION REQUIRED: Submit supporting documentation* [If Yes, then go to 8. If No, then no further questions.] Tech Note: If the PA is worked over the phone, then the prescriber still MUST submit physical chart notes.	Yes	No
6	Does the patient have moderate or severe liver impairment? ACTION REQUIRED: If yes, then prescriber MUST submit chart notes that show the patient has moderate or severe liver impairment. _____ [If Yes, then go to 7. If No, then no further questions.]	Yes	No

	Tech Note: Leave response as answered by prescriber. Verification of chart notes will be addressed in the next question.		
7	Have chart notes showing the patient has moderate or severe liver impairment been submitted to CVS Health? *ACTION REQUIRED: Submit supporting documentation* [If Yes, then go to 8. If No, then no further questions.]	Yes	No
	Tech Note: If the PA is worked over the phone, then the prescriber still MUST submit physical chart notes.		
8	Does the patient require more than the plan allowance of 90 tablets per month? [No further questions]	Yes	No
	RPh Note: If yes, then deny and enter a partial approval for 90 tablets / 25 days or 270 tablets / 75 days of buprenorphine.		

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan only covers more of this drug (additional quantities) when you meet the criteria for additional quantities. Your plan covers up to 90 tablets per 30 days and one 30 day supply every 90 days. We reviewed the information we had. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Post limit criteria not met]
2.	Go to 3	Go to 4	
3.	Go to 8	Deny	We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan only covers more of this drug (additional quantities) when you meet the criteria for additional quantities. Your plan covers up to 90 tablets per 30

			days and one 30 day supply every 90 days. We reviewed the information we had. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Post limit criteria not met]
4.	Go to 5	Go to 6	
5.	Go to 8	Deny	We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan only covers more of this drug (additional quantities) when you meet the criteria for additional quantities. Your plan covers up to 90 tablets per 30 days and one 30 day supply every 90 days. We reviewed the information we had. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Post limit criteria not met]
6.	Go to 7	Deny	We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan only covers more of this drug (additional quantities) when you meet the criteria for additional quantities. Your plan covers up to 90 tablets per 30 days and one 30 day supply every 90 days. We reviewed the information we had. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Post limit criteria not met]
7.	Go to 8	Deny	We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan only covers

			more of this drug (additional quantities) when you meet the criteria for additional quantities. Your plan covers up to 90 tablets per 30 days and one 30 day supply every 90 days. We reviewed the information we had. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Post limit criteria not met]
8.	Deny	[PA Approved for 12 months. Approve 90 tablets per 25 days or 270 tablets per 75 days]. Approve, 12 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (90 tablets per 30 days). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial]