Reference number(s)
780-C

Initial Prior Authorization with Quantity Limit
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 for the requested drug 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 patient meets ONE of the following:
  - The requested drug is being prescribed for induction therapy and/or subsequent maintenance therapy for the treatment of opioid use disorder and the following criteria is met:
    - 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 requested drug is being prescribed for INDUCTION THERAPY for transition from opioid use to treatment of opioid use disorder.

Quantity Limits Apply

Induction therapy: 21 tablets / 75 days.

Induction therapy and/or subsequent maintenance therapy in a patient that is pregnant or breastfeeding, has an intolerance to naloxone or has moderate or severe liver impairment: 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.

Duration of Approval (DOA)

- 780-C:
  - Induction therapy: DOA: 3 months
  - Induction therapy and/or subsequent maintenance therapy in a patient that is pregnant or breastfeeding, has an intolerance to naloxone or has moderate or severe liver impairment: 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. Medication Assisted Treatment for Substance Use Disorders – Informational Bulletin. http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-07-11-2014.pdf. Accessed November 6, 2024.
7. 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 (JH)

Date Written: 07/2003

Revised: (NB) 02/2005, 02/2006; (SE) 03/2009,10/2009 (clarification); (CT) 12/2009; (KD) 04/2010 (added pregnancy information and Suboxone for induction); (SE) 07/2010 (added renewal criteria regarding use of other opioids/urine drug screen/changed duration of approval) 12-2009 (3), 07/2010 (added in QL question) 12-2009 (4), 09-2010 (removed QL and related question) 12-2009 (4); (CY) 03/2011 (added QL), 06/2011, 03/2012 (removed Suboxone, made separate document), 12/2012; (SE) 05/2013 (created commercial version), 09/2013; (CF) 09/2014, 05/2015 (added denial reasons), 09/2015; (CF/GB) 08/2016; (CF/JH) 01/2017 (no clinical changes), 04/2017 (added breastfeeding, clarified complete program question), 11/2017; (CF) 11/2018 (no clinical changes); 11/2019 (opioid dependence updated to opioid use disorder); (DS) 11/2020 (no clinical changes), 11/2021 (no clinical changes); (DRS) 11/2022 (no clinical changes), (DFW) 11/2023 (no clinical changes), 11/2024 (added maintenance use for intolerance to naloxone and liver impairment and documentation requirements)

Reviewed: Medical Affairs: 07/2003; (MM) 02/2005, 02/2006; (WLF) 03/2009, 12/2009, 04/2010; (KP) 07/2010, 07/2010, 06/2011, 11/2011, 03/2012; (DC) 12/2012; (KP) 10/2013; (LCB) 09/2014; (DNC) 09/2015, 04/2017, 11/2017, 02/2018; (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: 05/2005, 06/2006, 04/2009, 05/2010, 06/2010, 10/2010, 10/2011, 08/2012, 02/2013, 04/2014, 12/2014, 12/2015, 12/2016, 04/2017, 02/2018, 02/2019, 02/2020, 02/2021, 02/2022, 03/2023, 02/2024, 02/2025

CRITERIA FOR APPROVAL			
1	Is the requested drug being used as part of a complete program for the treatment of opioid use disorder? [Complete treatment programs may include	Yes	No

	the following: A) Behavioral therapies (e.g., individual therapy, group counseling, family behavior therapy, cognitive behavioral therapy, motivational enhancement, motivational incentives, mutual support), B) Medical history, physical exam, and screening laboratory tests as needed (e.g., HIV and hepatitis C screening), C) Diversion control protocols such as observed dosing, pill counts, testing for buprenorphine's metabolite (nor-buprenorphine), D) Random urine testing for opioids and other illicit substances, E) Use of the Prescription Drug Monitoring Program (PDMP) if available in state.] [If Yes, then go to 2. If No, then no further questions.]		
2	Is the requested drug being prescribed for induction therapy and/or subsequent maintenance therapy for the treatment of opioid use disorder in a patient that meets ONE of the following: A) is pregnant or breastfeeding, B) is intolerant to naloxone, C) has moderate or severe liver impairment? ACTION REQUIRED: If yes, then prescriber MUST submit chart notes that show the patient is pregnant or breastfeeding, has an intolerance to naloxone or has moderate or severe liver impairment. _____ [If Yes, then go to 3. If No, then go to 5.] 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 that the patient meets ONE of the following been submitted to CVS Health: A) is pregnant or breastfeeding, B) has an intolerance to naloxone, C) has moderate or severe liver impairment? *ACTION REQUIRED: Submit supporting documentation* [If Yes, then go to 4. 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 require more than the plan allowance of 90 tablets per month? [No further questions] RPh Note: If yes, then deny and enter a partial approval for 90 tablets / 25 days or 270 tablets / 75 days of buprenorphine.	Yes	No
5	Is the requested drug being prescribed for INDUCTION THERAPY for transition from opioid use to treatment of opioid use disorder? [If Yes, then go to 6. If No, then no further questions.]	Yes	No

6	Does the patient require more than the plan allowance of 21 tablets in a three month period for induction therapy? [No further questions] RPh Note: If yes, then deny and enter a partial approval for 21 tablets / 75 days of buprenorphine.	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug if you will be taking this drug as a part of a certain treatment plan. We have denied your request because you are not (or will not be) taking this drug as a part of a complete program for the treatment of opioid use disorder. We reviewed the information we had. Your request 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: Not a component of a regimen]
2.	Go to 3	Go to 5	
3.	Go to 4	Deny	Your plan only covers this drug for starting and continuing treatment of opioid use disorder when records showing you are A) pregnant or breastfeeding, B) cannot take naloxone, or C) have moderate or severe liver problems, have been sent to us. Your records must be provided and must show what your doctor tells us. We denied your request because we did not receive your records or the records did not show what your doctor has told us. We reviewed the information we had. Your request 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: Diagnosis/Documentation - Pregnant/Breastfeeding, Intolerance to Naloxone, Liver

			Impairment]
4.	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 – Pregnant or Breastfeeding, Intolerance to Naloxone, Liver Impairment]
5.	Go to 6	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are for starting treatment for opioid use disorder and starting and continuing treatment for opioid use disorder if you are pregnant or breastfeeding, cannot take naloxone, or have moderate or severe liver problems. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request 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: Diagnosis]
6.	Deny	[PA Approved for 3 months. Approve 21 tablets per 75 days]. Approve, 3	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 (21 tablets per 90 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

		Months	documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial]