HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Buprenorphine extended-release (Sublocade, Brixadi)
BENEFIT TYPE	Pharmacy/Medical
STATUS	Prior Authorization Required

Buprenorphine extended-release (Sublocade, Brixadi) is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor. It is indicated for the treatment of moderate to severe opioid use disorder. Buprenorphine extended-release should be used as part of a complete treatment program that includes counseling and psychosocial support.

Buprenorphine extended-release (Sublocade, Brixadi) will be considered for coverage when the following criteria are met:

Opioid Dependence

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Member must have a trial and failure of a preferred buprenorphine product; AND
3. Provider attests member will have a single dose of a transmucosal buprenorphine product prior to treatment (unless they are already being treated with buprenorphine).
4. **Dosage allowed/Quantity limit:**
   a) Sublocade: administer two monthly initial doses of 300 mg followed by 100 mg monthly maintenance doses subcutaneously. Quantity Limit: 300 mg per month.
   b) Brixadi: administer once weekly or once monthly subcutaneously per prescribing information. The maximum dose is 32 mg (1 injection) per week or 128 mg (1 injection) per month. Quantity limit: 128 mg per month.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must document positive response to therapy (i.e. urine samples negative for opioids, no signs of opioid dependence-relapse, etc.)

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Buprenorphine extended-release (Sublocade, Brixadi) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/23/2018	New policy for Sublocade created.
08/24/2022	Annual Review. Transferred to new template. Updated references. Updated initial approval duration to 6 months. Clarified reauthorization criteria.
07/20/2023	Policy name changed to Buprenorphine extended-release (Sublocade, Brixadi); Brixadi added to policy; removed DATA waiver prescriber requirement; added references; added an age limit, added trial of preferred buprenorphine product; added medical benefit option.
03/07/2025	Updated references; updated Sublocade initiation criteria to match Brixadi per label change and added provider attestation to transmucosal buprenorphine product; added quantity limit to Brixadi

References:

1. Sublocade [package insert]. North Chesterfield, VA: Indivior, Inc; 2025.
2. Brixadi [package insert]. Cockeysville, MD: Pharmaceutics International, Inc; 2023.
3. White L, et al. The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update. J Addict Med. 2020 Mar/Apr;14(2S Suppl 1):1-91.
4. Center for Substance Abuse Treatment. Clinical guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Treatment Improvement Protocol (TIP) series 40. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004.

Effective date: 10/01/2025
Revised date: 03/07/2025