CareSource Rx Innovations

PHARMACY POLICY STATEMENT
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. If the request is for Sublocade, member must have had at least 7 days treatment with transmucosal buprenorphine-containing product (equivalent of 8 to 24 mg of buprenorphine daily) within the last 21 days; OR
4. If the request is for Brixadi, member must have had a single dose of a transmucosal buprenorphine product (unless they are already being treated with buprenorphine).
5. **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.

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).

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

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.

References:

1. Sublocade [package insert]. North Chesterfield, VA: Indivior, Inc; August 2022.
2. Brixadi [package insert]. Cockeysville, MD: Pharmaceutics International, Inc; May 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: 01/01/2024
Revised date: 07/20/2023