PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Sublocade (buprenorphine extended-release) injection, for subcutaneous use
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Sublocade is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor, initially approved by the FDA in 2002. It is indicated for the treatment of moderate to severe opioid use disorder in patients who have had indication and dose adjustment with a transmucosal buprenorphine-containing product for a minimum of 7 days. Sublocade should be used as part of a complete treatment program that includes counseling and psychosocial support.

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

Opioid Dependence

For **initial** authorization:

1. 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; AND
2. Medication must be prescribed and administered by addiction specialist (i.e., DATA 2000 certified) solely for the treatment of opioid dependence.
3. **Dosage allowed/Quantity limit:** Initially, two monthly doses of 300 mg after treatment has been inducted and adjusted with 8 to 24 mg of a transmucosal buprenorphine-containing product for a minimum of 7 days, followed by 100 mg monthly for maintenance. Increasing the maintenance dose to 300 mg monthly may be considered with submission of detailed chart notes documenting lack of satisfactory clinical response to Sublocade 100 mg, recent clinical opioid withdrawal scale and specific clinical reasons outlined by provider. Quantity Limit: 300mg 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 Sublocade (buprenorphine extended-release) 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.

References:

1. Sublocade [package insert]. North Chesterfield, VA: Indivior, Inc; August 2022.
2. 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.
3. 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: 01/01/2023
Revised date: 08/24/2022