



Prior Authorization Criteria

SUBLOCADE™ (buprenorphine) Extended Release Injection PA Criteria:

- Sublocade is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.
- Sublocade should be used as part of a complete treatment plan that includes counseling and psychosocial support.
- Sublocade is available only through a restricted program, called the “Sublocade REMS Program,” because of the risk of serious harm or death that could result from intravenous self-administration. Healthcare settings and pharmacies that order and dispense Sublocade must be certified in this program and comply with the REMS requirements.
- Under the Drug Addiction Treatment Act (DATA) codified at 21 United States Code (U.S.C.) 823(g), use of Sublocade in the treatment of opioid dependence is limited to healthcare providers who meet certain qualifying requirements, and who have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe or dispense this product for the treatment of opioid dependence and have been assigned a unique identification number that must be included on every prescription. Thus the prescriber must meet DATA 2000 requirements** and has been assigned a unique identification number specific to the prescription of medication assisted therapy (X-DEA).
- All buprenorphine prescribers must have a current X-DEA number.

***Substance Abuse and Mental Health Services Administration (SAMHSA) Verification of DATA-Certified Physicians*

The SAMHSA Buprenorphine Physician Locator website lists the physicians in each State who have DATA 2000 waivers. A physician listed on the site can be considered to have a valid DATA 2000 waiver. Note, however, that the site does not list every physician with a valid waiver, only those who have agreed to be listed on the site. Physicians with valid waivers may choose not to be listed on the site.

Buprenorphine Treatment Physician Locator

- <http://www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator>
- *A person desiring to verify that a physician who is not listed on the site has a valid DATA 2000 waiver can contact SAMHSA by phone at 1-866-BUP-CSAT (1-866-287-2728) or by e-mail at infobuprenorphine@samhsa.hhs.gov. The verifying person should convey their DEA registration number with these requests.*

- To verify a physician's data waiver, by searching his or her last name and DEA registration number, pharmacists can use the following website:
 - <https://www.samhsa.gov/bupe/lookup-form>
- Sublocade is not available in retail pharmacies and have limited specialty pharmacy distribution.

Initial authorization (must meet ALL) - Authorization will be for 6 months

- Age \geq 18 years **and**
- Diagnosis of Opioid Dependence **and**
- Must not be used in opioid naïve patients, **and**
- Must currently be on a maintenance dose of 8mg to 24 mg per day dose of an oral, sublingual, or transmucosal buprenorphine product equivalent for at least 7 days prior to initiation of extended-release buprenorphine injection **and**
- Will not receive supplemental, oral, sublingual, or transmucosal buprenorphine, **and**
- Has not had an opioid-positive urine drug screen within the previous 7 days prior to initial injection, **and**
- Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that the beneficiary has met all approval criteria upon request, **and**
- Sublocade dosing for is in accordance with the U. S. Food and Drug Administration approved labeling: 300mg subcutaneously monthly for the first 2 months, followed by a maintenance dose of 100 mg monthly. Dosing may be increased to 300mg monthly.

Continuation of Therapy (must meet all): Authorization will be for 6 months

- Beneficiary has experienced a treatment success to buprenorphine extended-release therapy, **and**
- One of the following is met (**a or b**):
 - a. Beneficiary has not received an opioid analgesic since last approval
 - b. Prescriber submits documentation acknowledging that the use of any opioid during the last approval period was due to diagnosis of acute pain:
- Beneficiary has not had an opioid-positive urine drug screen since starting Sublocade therapy, **and**
- Beneficiary has not, nor will receive supplemental oral, sublingual, or transmucosal buprenorphine; **and**
- Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria upon request,*** **and**
- If the request is for a dose increase, new dose does not exceed 300mg per month.

***Patients screening positive for opioid use outside of an opioid dependence treatment regimen is evidence that the patient has had illicit opioid use unless UNLESS the prescriber submits documentation acknowledging that the use of any opioid during the last approval period was due to diagnosis of acute pain.

Sublocade Risk Evaluation and Mitigation Strategy (REMS) Program

Notable requirements of the SUBLOCADE REMS Program include the following:

- Healthcare Settings and Pharmacies that order and dispense SUBLOCADE must be certified in the SUBLOCADE REMS Program.
- Certified Healthcare Settings and Pharmacies must establish processes and procedures to verify SUBLOCADE is provided directly to a healthcare provider for administration by a healthcare provider, and the drug is not dispensed to the patient.
- Certified Healthcare Settings and Pharmacies must not distribute, transfer, loan, or sell Sublocade.

Dosing:

- Administer Sublocade monthly with a minimum of 26 days between doses.
- The recommended dose of Sublocade following induction and dose adjustment with transmucosal buprenorphine is 300 mg monthly for the first two months followed by a maintenance dose of 100 mg monthly.
- The maintenance dose may be increased to 300 mg monthly for patients who tolerate the 100 mg dose, but do not demonstrate a satisfactory clinical response, as evidenced by self-reported illicit opioid use or urine drug screens positive for illicit opioid use.
- A patient who misses a dose should receive the next dose as soon as possible, with the following dose given no less than 26 days later. Occasional delays in dosing up to 2 weeks are not expected to have a clinically significant impact on treatment effect.

How Supplied:

Subcutaneous Injection: 100mg/0.5 ml and 300mg/1.5 ml provided in a prefilled syringe with a 19 gauge 5/8-inch needle.