Substance Use Disorders (SUDs)– Buprenorphine extended-release injection (Sublocade)

WA.PHAR.108 Substance Use Disorders (SUDs)– Buprenorphine extended-release injection (Sublocade)

Effective Date: May 1, 2021

Related medical policies:

- **Transmucosal Buprenorphine WA.PHAR.62**

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the current publication of the Coordinated Care of Washington, Inc. Preferred Drug List (PDL), please visit:
https://www.coordinatedcarehealth.com/content/dam/centene/centene-pharmacy/pdl/FORMULARY-CoordinatedCare_Washington.pdf

Background:

Substance use disorders (SUDs) impact the lives of millions of Americans in the general population, including individuals who are enrolled in the Medicaid program. The use of medications in combination with behavioral therapies to treat SUDs can help reestablish normal brain functioning, reduce cravings and prevent relapse. Multiple studies demonstrate that opioid agonists are the most effective treatment for opioid use disorders (OUD). The medications used can manage the symptoms of substance use withdrawal that often prompt relapse and allow individuals to utilize other treatments, such as behavior therapy.

Extended-release buprenorphine for subcutaneous injection (Sublocade) was approved by the Food and Drug Administration in 2018 as an alternative to oral buprenorphine-containing products. Primary advantages of Sublocade include once monthly administration, steady blood concentration levels, and its inability to be misused or diverted. As intravenous injection of Sublocade can be fatal, its use is restricted to a Risk Evaluation and Mitigation Strategy (REMS). This limits access to certified pharmacies or institutions and requires administration by a healthcare professional.

Medical necessity

Drug	Medical Necessity
Buprenorphine extended-release injection **(Sublocade)**	Sublocade may be considered medically necessary for: • Maintenance treatment of moderate to severe opioid use disorder in accordance with the Sublocade REMs program.

Clinical policy:

Drug	Clinical Criteria

<u>Opioid dependence, maintenance treatment</u> Buprenorphine extended-release injection **(Sublocade)**	Sublocade may be considered medically necessary when **ALL** of the following are met: 1. Diagnosis of moderate to severe opioid use disorder per DSM-5; **AND** 2. Patient is 18 years of age or older; **AND** 3. Patient is stabilized on at least 8mg daily of transmucosal buprenorphine or buprenorphine-naloxone, with initiation at least 7 days prior to first Sublocade injection; **AND** 4. The Sublocade REMs program (sublocaderems.com) will be followed, including: a. Sublocade has been ordered by a healthcare facility **OR** pharmacy that has received Sublocade REMs certification. **NOTE:** A healthcare facility does not need to obtain certification if ordering Sublocade from a certified pharmacy; **AND** 5. Sublocade will be administered by a healthcare professional; **AND** 6. Documentation of why continued use of a transmucosal buprenorphine-containing product is clinically inappropriate including: a. Previous failure on transmucosal buprenorphine, defined as: i. Negative urine drug screen for buprenorphine ii. Positive urine drug screen for any other opioid iii. Hospitalization or emergency visit for opioid overdose; **OR** b. Concerns of non-adherence due to mental illness or homelessness; **OR** c. History, or suspicion, of theft or diversion of transmucosal buprenorphine products; **AND** 7. Patient does not have any of the following: a. Significant respiratory depression due to untreated pulmonary disease; **OR** b. Known or suspected gastrointestinal obstruction, including paralytic ileus; **OR** c. Pre-existing moderate to severe hepatic impairment 8. Patient is part of a treatment program which includes counseling and psychosocial support If all the above criteria are met, the request will be **approved for 6 months**. If all criteria are not met, but there are documented medically necessary circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration.
	Criteria (Reauthorization)
	Sublocade may be reauthorized when the following criteria are met: 1. There is documentation of a positive clinical response

	If all the above criteria are met, the request will be **approved for 12 months** If all criteria are not met, but there are documented medically necessary circumstances based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the reauthorization duration.

Dosage and quantity limits

Indication	Dose	Quantity Limits
Opioid dependence, maintenance treatment	**Standard Dose**: 300 mg subcutaneously monthly for 2 doses followed by 100 mg monthly **Max Dose:** 300 mg monthly There must be a minimum of 26 days in between injections.	**100 mg/0.5mL:** 1 syringe / 28 days **300 mg/1.5mL:** 1 syringe /28 days

Coding:

HCPCS Code	Description
Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg
Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg

Evidence Review

A phase 3, double-blind, randomized-controlled trial evaluated the effect of extended-release buprenorphine subcutaneous injection on opioid abstinence in participants diagnosed with moderate to severe opioid use disorder. Participants (n=504) received either buprenorphine 300 mg injection (300mg/300mg) once monthly (n=201), buprenorphine 300 mg monthly for two doses followed by 100 mg monthly (300mg/100mg) (n=203), or volume-matched placebo (n=100). Each participant received a total of six doses. Percentage abstinence from illicit opioid use through week 24 was the primary outcome, identified via urine drug screen and self-report assessed weekly. Percent abstinence was similar between the buprenorphine 300 mg/300mg and 300mg/100mg groups (41.3% and 42.7%, respectively). Both active groups were significantly better than placebo, which recorded an abstinence rate of 5% ($p<0.0001$). Headache, constipation, nausea, and injection-site reactions occurred more frequently in the buprenorphine groups, however, no significant safety risks were observed.

Appendix

DSM-5 Criteria for Opioid Use Disorder
• Opioids are often taken in larger amounts or over a longer duration than intended. • Persistent desire or unsuccessful efforts to cut down or control opioid use • A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects • Craving or a strong desire to use opioids • Recurrent opioid use resulting in failure to fulfill major role obligations at work, school, or home

- Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids
- Important social, occupational, or recreational activities are given up or reduced because of opioid use
- Recurrent opioid use in situations in which it is physically hazardous
- Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids
- Tolerance, as defined by either of the following:
    - Need for markedly increased amounts of opioids to achieve intoxication or desired effect
    - Markedly diminished effect with continued use of the same amount of opioid
- Withdrawal, as manifested by either of the following:
    - Characteristic opioid withdrawal syndrome
    - Same, or similar, substance is taken to relieve or avoid withdrawal symptoms

Mild: 2-3 symptoms **Moderate:** 4-5 symptoms **Severe:** 6 or more symptoms

References

1. Haight BR, Learned SM, Laffont CM, et al. Efficacy and safety of a monthly buprenorphine depot injection for opioid use disorder: a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. Lancet. 2019;393(10173):778-790.
2. Sublocade Prescribing Information. North Chesterfield, VA: Indivior Inc.; February 2020
3. Crotty K, Freedman KI, Kampman KM. Executive Summary of the Focused Update of the ASAM National Practice Guideline for the Treatment of Opioid Use Disorder. J Addict Med. 2020;14(2):99-112.

History

Date	Action and Summary of Changes
10/21/2020	Approved by DUR Board
9/29/2020	New Policy Created