

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

**Medical policy no. 65.20.00.E5-1**

**Effective Date: TBD**

Related medical policies:

- Transmucosal Buprenorphine 65.20.00.10

*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.*

## Background:

Substance use disorders (SUDs) impacts 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 ( <b>Sublocade</b> )	Sublocade may be considered medically necessary for: <ul style="list-style-type: none"> <li>• Maintenance treatment of moderate to severe opioid use disorder in accordance with the Sublocade REMs program.</li> </ul>

## Clinical policy:

Drug	Clinical Criteria
<b><u>Opioid dependence, maintenance treatment</u></b> Buprenorphine extended-release injection ( <b>Sublocade</b> )	Sublocade may be considered medically necessary when <b>ALL</b> of the following are met: <ol style="list-style-type: none"> <li>1. Diagnosis of moderate to severe opioid use disorder per DSM-5; AND</li> <li>2. Patient is 18 years of age or older; <b>AND</b></li> </ol>

	<ol style="list-style-type: none"> <li>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; <b>AND</b></li> <li>4. The Sublocade REMs program (sublocaderems.com) will be followed, including:             <ol style="list-style-type: none"> <li>a. Sublocade has been ordered by a healthcare facility <b>OR</b> pharmacy that has received Sublocade REMs certification. <b>NOTE:</b> A healthcare facility does not need to obtain certification if ordering Sublocade from a certified pharmacy; <b>AND</b></li> </ol> </li> <li>5. Sublocade will be administered by a healthcare professional; <b>AND</b></li> <li>6. Documentation of why continued use of a transmucosal buprenorphine-containing product is clinically inappropriate including:             <ol style="list-style-type: none"> <li>a. Previous failure on transmucosal buprenorphine, defined as:                 <ol style="list-style-type: none"> <li>i. Negative urine drug screen for buprenorphine</li> <li>ii. Positive urine drug screen for any other opioid</li> <li>iii. Hospitalization or emergency visit for opioid overdose</li> </ol> </li> <li>b. Concerns of non-adherence due to mental illness or homelessness</li> <li>c. History, or suspicion, of theft or diversion of transmucosal buprenorphine products</li> </ol> </li> <li>7. Patient does not have any of the following:             <ol style="list-style-type: none"> <li>a. Significant respiratory depression due to untreated pulmonary disease; <b>OR</b></li> <li>b. Known or suspected gastrointestinal obstruction, including paralytic ileus; <b>OR</b></li> <li>c. Pre-existing moderate to severe hepatic impairment</li> </ol> </li> <li>8. Patient is part of a treatment program which includes counseling and psychosocial support</li> </ol> <p>If all the above criteria are met, the request will be <b>approved for 6 months.</b></p>
	<b>Criteria (Reauthorization)</b>
	<p>Sublocade may be reauthorized when the following criteria are met:</p> <ol style="list-style-type: none"> <li>1. There is documentation of a positive clinical response</li> </ol> <p>If all the above criteria are met, the request will be <b>approved for 12 months</b></p>

## Dosage and quantity limits

Indication	Dose	Quantity Limits
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<b>Opioid dependence, maintenance treatment</b>	<b>Standard Dose:</b> 300 mg subcutaneously monthly for 2 doses followed by 100 mg monthly <b>Max Dose:</b> 300 mg monthly  There must be a minimum of 26 days in between injections.	<b>100 mg/0.5mL:</b> 1 syringe / 28 days <b>300 mg/1.5mL:</b> 1 syringe /28 days
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**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
<ul style="list-style-type: none"> <li>• Opioids are often taken in larger amounts or over a longer duration than intended.</li> <li>• Persistent desire or unsuccessful efforts to cut down or control opioid use</li> <li>• A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects</li> <li>• Craving or a strong desire to use opioids</li> <li>• Recurrent opioid use resulting in failure to fulfill major role obligations at work, school, or home</li> <li>• Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids</li> <li>• Important social, occupational, or recreational activities are given up or reduced because of opioid use</li> <li>• Recurrent opioid use in situations in which it is physically hazardous</li> <li>• 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</li> <li>• Tolerance, as defined by either of the following:                         <ul style="list-style-type: none"> <li>○ Need for markedly increased amounts of opioids to achieve intoxication or desired effect</li> <li>○ Markedly diminished effect with continued use of the same amount of opioid</li> </ul> </li> <li>• Withdrawal, as manifested by either of the following:                         <ul style="list-style-type: none"> <li>○ Characteristic opioid withdrawal syndrome</li> <li>○ Same, or similar, substance is taken to relieve or avoid withdrawal symptoms</li> </ul> </li> </ul>

**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
9/29/20	New Policy

DRAFT

**Buprenorphine extended-release injection (Sublocade™)**

Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength		Directions for use	Qty/Days supply

- Is this request for a continuation of existing therapy?  Yes  No  
If yes, is there documentation of a positive clinical response?  Yes  No
- Indicate patient's diagnosis:  
 Moderate to severe opioid use disorder  
 Other: Specify:
- Has the patient been stabilized on at least 8mg/day of transmucosal buprenorphine with initiation at least 7 days prior to first Sublocade injection?  Yes  No
- Is use of a transmucosal buprenorphine product clinically inappropriate : (check all that apply)  
 History or suspicion of theft or diversion of buprenorphine  
 Concern of non-adherence due to mental illness or homelessness  
 Negative urine drug screen for buprenorphine  
 Positive drug screen for any other opioid  
 Other. Explain:
- Does the patient have any of the following (check all that apply):  
 Significant respiratory depression due to untreated pulmonary disease  
 Known or suspected gastrointestinal obstruction, including paralytic ileus  
 Pre-existing moderate to severe hepatic impairment  
 None of the above
- Is the site to prepare and administer Sublocade a REMS certified site?  Yes  No
- Is the patient part of a treatment program which includes counseling and psychosocial support?  Yes  No

**CHART NOTES ARE REQUIRED WITH THIS REQUEST**

Prescriber signature	Prescriber specialty	Date
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**Notice Prohibiting Redisclosure of Alcohol or Drug Treatment Information**

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medial or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.