

<b>Policy Title:</b>	Sublocade (buprenorphine extended release) Injection (subcutaneous)		
		<b>Department:</b>	PHA
<b>Effective Date:</b>	01/01/2020		
<b>Review Date:</b>	09/12/2018, 12/13/2019, 1/22/20, 4/15/2020		
<b>Revision Date:</b>	09/12/2018, 12/13/2019, 1/22/20		

**Purpose:** To support appropriate use of Sublocade (buprenorphine extended release) in the treatment of opioid dependence.

**Scope:** Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

**Policy Statement:**

Sublocade (buprenorphine extended release) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

**Procedure:**

Coverage of Sublocade (buprenorphine extended release) will be reviewed prospectively via the prior authorization process based on criteria below.

***Initial Criteria :***

- Diagnosis of moderate to severe opioid use disorder; AND
- Member is 18 years of age or older; AND
- Member has initiated therapy with transmucosal buprenorphine containing product (delivering the equivalent of 8-24mg of buprenorphine daily) over a minimum of 7 day period and is stable with clinically controlled cravings and withdrawal symptoms; AND
- Member is part of a complete treatment program that includes counseling and psychosocial support; AND
- Member is not receiving other opioids during therapy with Sublocade; AND
- Rationale to support the member's inability to continue to use oral formulations of buprenorphine; AND
- Dose does not exceed 300mg a month;
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

***Continuation of therapy criteria :***

- Meet all initial approval criteria AND is tolerating Sublocade; AND
- Member has shown a decrease in signs of opioid dependence-relapse

**Coverage durations:**

- Initial coverage: 6 months
- Continued coverage: 12 months

\*\*\* Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.\*\*\*

**Dosage/Administration:**

Indication	Dose	Maximum dose (1 billable unit = 100 mg)
Opiate use disorder	300 mg monthly for the first two months followed by a maintenance dose of 100 mg monthly.	3 units for the first two months, followed by a maintenance dose of 1 unit monthly

**Investigational use:** All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

**Applicable Codes:**

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCP/CS/CPT 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

References:

1. Sublocade [prescribing information]. Indivior Inc. North Chesterfield, VA; November, 2017.
2. Comer S, Cunningham C, Fishman M, et al. ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. American Society of Addiction Medicine, Copyright 2015. Available at: <https://www.asam.org/resources/guidelines-and-consensus-documents/npg>. Accessed on 1/24/2018.
1. ClinicalTrials.gov. U.S. National Institutes of Health. Available at: <https://clinicaltrials.gov/>. Accessed on 1/24/2018.
2. U.S. Food and Drug Administration. U.S. Department of Health and Human Services. Available at: <http://www.fda.gov/>. Accessed on 1/24/2018.
3. AMCP eDossier System. Dymaxium Healthcare Innovations, Ltd. Available at: <https://amcp.edossiers.com/>. Accessed on 1/24/2018.