

Policy Title:	Sublocade (buprenorphine extended release) Injection		
Policy Number:	000585	Department:	PHA
Effective Date:	09/12/2018		
Review Date:	09/12/2018		
Revision Date:	09/12/2018		

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

Scope: Medicaid, Exchange, Integrity

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 Coverage:

- Diagnosis of moderate to severe opioid use disorder
- Member is 18 years of age or older
- 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
- Member is part of a complete treatment program that includes counseling and psychosocial support.
- Member is not receiving other opioids during therapy with Sublocade
- Rationale and medical documentation to support the member's inability to continue to use oral formulations of buprenorphine (such as failed treatment history with oral formulations, lack of adherence or patients at high risk of treatment failure due to other comorbidities)
- Dose does not exceed 300mg a month

Continuation of therapy:

- Meet all initial approval criteria AND is tolerating Sublocade
- Member has shown no signs of opioid dependence-relapse

Coverage durations:

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

Investigational use: Sublocade (buprenorphine extended release) is considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in one of the above listed resources. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Additional information:

Indications: Sublocade (buprenorphine extended release) is FDA approved for treatment of:

- Adult patients with moderate to severe opioid use disorder who have initiated treatment with a transmucosal buprenorphine containing product, followed by dose adjustment for a minimum of seven days and should be used as part of a complete treatment plan that includes counseling and psychosocial support

Limitation of Use: None

Dosing:

- The recommended dose of Sublocade following induction and dose adjustment with transmucosal buprenorphine is 300 mg via abdominal subcutaneous injection monthly for the first two months followed by a maintenance dose of 100 mg monthly, and may be increased to 300 mg monthly for patients who tolerate the 100 mg dose, but do not demonstrate a satisfactory clinical response.

Administration:

- Only healthcare providers should prepare and administer, with a minimum of 26 days between doses. Initiating treatment with Sublocade as the first buprenorphine product has not been studied.

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:

HCPCS/CPT Code	Description
96372	Therapeutic, prophylaxis, or diagnostic injection(specify substance or drug); subcutaneous or intramuscular
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.