Effective Date: 9/2018
Revised: 12/2019 Reviewed: 9/2018, 12/2019, 4/2020, 1/2021, 1/2022, 2/2023, 11/2023, 01/2024, 4/2024 Pharmacy Scope: Medicaid Medical Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

BRIXADI (buprenorphine extended-release) INJECTION
SUBLOCADE (buprenorphine extended-release) INJECTION

POLICY

I. SUMMARY OF EVIDENCE

Clinical trials have demonstrated the efficacy and safety of injectable buprenorphine products in the treatment of opioid use disorder. Injectable formulations of buprenorphine provide sustained release of the medication, offering benefits such as improved medication adherence, reduced risk of diversion, and minimized withdrawal symptoms and cravings. Studies have shown that injectable buprenorphine products effectively maintain stable plasma concentrations of buprenorphine, providing consistent opioid receptor blockade and reducing the risk of relapse.

II. CRITERIA FOR INITIAL APPROVAL

Moderate to severe opioid use disorder

Authorization of 6 months may be granted for treatment of moderate to severe opioid use disorder in members 18 years of age or older when all of the following criteria are met:

A. Member is part of a complete treatment program that includes counseling and psychosocial support.
B. Member is not receiving other opioids during therapy with Sublocade OR Brixadi
C. Rationale is provided to support the member's inability to continue to use oral formulations of buprenorphine.
D. MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements
E. For Brixadi requests:
    a) Member has initiated therapy with transmucosal buprenorphine at a dose of at least 4mg or member is transitioning from another buprenorphine-containing treatment for opioid use disorder and is stable with controlled withdrawal symptoms
    a) The dose of Brixadi does not exceed 32mg weekly (1 syringe per week) or 128mg a month (1 syringe per month).
F. For Sublocade requests:
    b) Member has initiated therapy with transmucosal buprenorphine or other buprenorphine-containing product (delivering the equivalent of 8-24mg of buprenorphine daily) over a minimum of a 7-day period and is stable with controlled withdrawal symptoms
    c) The dose of Sublocade does not exceed 300mg a month.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for treatment of moderate to severe opioid use disorder in patients when all of the following criteria are met:

A. Member continues to meet the initial criteria in section I.
B. Member is tolerating treatment.
C. Member has documentation of a decrease in signs of opioid dependence relapse.

IV. DOSING/ ADMINISTRATION

<table>
<tr><th>Drug</th><th>Indication</th><th>Dose</th><th>Medical Benefit Maximum Dose (1 billable unit = 100mg for Sublocade 100mg inj, 300mg for Sublocade 300mg inj, 1mg for Brixadi)</th></tr>
<tr><td>Sublocade</td><td>Opiate use disorder</td><td>300 mg monthly for the first two months followed by a maintenance dose of 100 mg monthly.

Maximum dose is 300 mg per month.</td><td>1 unit for the first two months (Q9992), followed by a maintenance dose of 1 unit monthly (Q9991)</td></tr>
<tr><td>Brixadi</td><td>Opiate use disorder</td><td>The dose of Brixadi must be individualized based on patient tolerability and/or efficacy.

<u>Patients Switching from Transmucosal Buprenorphine-containing Products to Brixadi</u>
<table>
<tr><th>Daily dose of sublingual buprenorphine</th><th>Brixadi (weekly)</th><th>Brixadi (monthly)</th></tr>
<tr><td>≤6 mg</td><td>8mg</td><td>--</td></tr>
<tr><td>8-10mg</td><td>16mg</td><td>64mg</td></tr>
<tr><td>12-16mg</td><td>24mg</td><td>96mg</td></tr>
<tr><td>18-24mg</td><td>32mg</td><td>128mg</td></tr>
</table>
Brixadi (weekly) 8 mg, 16 mg, 24 mg, or 32 mg should be administered at 7-day intervals.</td><td>128 units per 28 days</td></tr>
</table>

		Brixadi (monthly) 64 mg, 96 mg, or 128 mg should be administered at 28-day intervals. Maximum dose is 32 mg per week or 128 mg per 28 days.	

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:
Brixadi and Sublocade was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Brixadi and Sublocade according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

The following HCPCS/CPT codes are:

HCPCS/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
J0577	Injection, buprenorphine extended-release (brixadi), less than or equal to 7 days of therapy
J0578	Injection, buprenorphine extended-release (brixadi), greater than 7 days and up to 28 days of therapy

References:

1. Sublocade [prescribing information]. Indivior Inc. North Chesterfield, VA; August, 2022.
2. Brixadi [prescribing information]. Braeburn Inc. Plymouth Meeting, PA; May, 2023.
3. 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.