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

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

POLICY

I. 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.

II. 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.

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III. 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.
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.</td><td>128 units per 28 days</td></tr>
</table>

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).

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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
C9154 (effective 10/1/2023 - 12/1/2023)	Injection, buprenorphine extended-release (brixadi), 1 mg
J0576 (effective 01/01/2024)	Injection, buprenorphine extended-release (brixadi), 1 mg

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.