

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, 3/2025, 1/2026, 2/2026
Pharmacy Scope: Medicaid
Medical Scope: Medicaid, Commercial, Medicare

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. 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
 - b. The dose of Brixadi does not exceed 32mg weekly (1 syringe per week) or 128mg a month (1 syringe per month)
- E. For Sublocade requests:
 - a. Member has initiated treatment with a single dose of transmucosal buprenorphine (4mg) or who are already being treated with buprenorphine
 - b. The maintenance dose of Sublocade does not exceed 300mg a month

II. CONTINUATION OF THERAPY

Brixadi will continue to pay on the pharmacy benefit after the initial approval if there is at least one paid claim on the pharmacy benefit within the last 365 days for Brixadi.

Sublocade will continue to pay on the pharmacy benefit after the initial approval if there is at least one paid claim on the pharmacy benefit within the last 365 days for Sublocade.

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

- A. Member continues to meet the initial criteria in section II.
- B. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: adrenal insufficiency, severe injection site reactions, life-threatening respiratory and/or CNS depression, hepatitis, severe hypersensitivity reactions, QTc prolongation, severe orthostatic hypotension, etc

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C. Member has documentation of a decrease in signs of opioid dependence relapse.

III. DOSING/ ADMINISTRATION

Drug	Indication	Dose	Medical Benefit Maximum Dose (1 billable unit = 100mg for Sublocade 100mg inj, 300mg for Sublocade 300mg inj, 1mg for Brixadi)															
Sublocade	Opiate use disorder	<p>Loading dose: 300 mg for the first two doses; second injection may be administered as early as one week and up to one month after the first injection.</p> <p>Maintenance dose: 100 mg monthly.</p> <p>Maximum dose is 300 mg per month.</p>	1 unit for the first two doses (Q9992), followed by a maintenance dose of 1 unit monthly (Q9991)															
Brixadi	Opiate use disorder	<p>The dose of Brixadi must be individualized based on patient tolerability and/or efficacy.</p> <p><u>Patients Switching from Transmucosal Buprenorphine-containing Products to Brixadi</u></p> <table border="1"> <thead> <tr> <th>Daily dose of sublingual buprenorphine</th> <th>Brixadi (weekly)</th> <th>Brixadi (monthly)</th> </tr> </thead> <tbody> <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> </tbody> </table> <p>Brixadi (weekly) 8 mg, 16 mg, 24 mg, or 32 mg should be administered at 7-day intervals.</p> <p>Brixadi (monthly) 64 mg, 96 mg, or 128 mg should be administered at 28-day intervals.</p> <p>Maximum dose is 32 mg per week or 128 mg per 28 days.</p>	Daily dose of sublingual buprenorphine	Brixadi (weekly)	Brixadi (monthly)	≤6 mg	8mg	--	8-10mg	16mg	64mg	12-16mg	24mg	96mg	18-24mg	32mg	128mg	128 units per 28 days
Daily dose of sublingual buprenorphine	Brixadi (weekly)	Brixadi (monthly)																
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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
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; September 2025.
2. Brixadi [prescribing information]. Braeburn Inc. Plymouth Meeting, PA; December 2025.
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/ngp>. 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.