Original Effective Date: 03/07/2024
Current Effective Date: 03/27/2026
Last P&T Approval/Version: 01/28/2026
Next Review Due By: 01/2027
Policy Number: C27170-A

Brixadi (buprenorphine extended release inj)

PRODUCTS AFFECTED

Brixadi (buprenorphine extended release inj)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Moderate to severe opioid use disorder

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. OPIOID USE DISORDER:

1. Documented diagnosis of opioid use disorder or opioid dependence
   AND
2. (a) FOR STATES WITH PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs): Prescriber attestation that they utilized (and will continue to utilize) the applicable State PDMP prior to issuance of a prescription or continuation of therapy request
   OR
   (b) FOR STATES WITHOUT PDMPs: Prescriber attestation that they will review member's records on a periodic basis or as necessary to ensure no abuse or diversion
   AND
3. Prescriber attestation of counseling member regarding a comprehensive substance use disorder treatment plan that includes biopsychosocial support and resource referral, and random clinical drug testing per ASAM guidelines
   AND
4. FOR BRIXADI MONTHLY REQUESTS: Documentation that Member is currently being treated with a transmucosal buprenorphine-containing product
   NOTE: Brixadi Monthly is not intended for patients who are not currently receiving buprenorphine treatment.
   OR
   FOR BRIXADI WEEKLY REQUESTS: Documentation that Member has tolerated a single 4mg dose of a transmucosal buprenorphine-containing product without precipitating withdrawal OR Member is currently being treated with a transmucosal buprenorphine-containing product

CONTINUATION OF THERAPY:

A. OPIOID USE DISORDER:

1. Adherence to therapy as verified by the prescriber or member medication fill history
   AND
2. Prescriber attestation of monitoring that member has adhered to any recommendations regarding comprehensive rehabilitation program that includes psychosocial support provided by a program counselor qualified by education, training, or experience to assess the psychological and sociological background of individuals receiving treatment, and random clinical drug testing per ASAM guidelines
   AND
3. (a) FOR STATES WITH PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs): Prescriber attestation that they utilized (and will continue to utilize) the applicable State PDMP prior to issuance of a prescription or continuation of therapy request
   OR
   (b) FOR STATES WITHOUT PDMPs: Prescriber attestation that they will review member's records on a periodic basis or as necessary to ensure no abuse or diversion
   AND
4. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 6 months

PRESCRIBER REQUIREMENTS:

Prescribed by an opioid use disorder specialist

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:
See Appendix for labeled dosing details
Doses of Brixadi weekly cannot be combined to yield a monthly dose

Not currently receiving buprenorphine treatment:
32mg of Brixadi weekly

Switching from transmucosal buprenorphine containing product to Brixadi:

Daily dose of SL buprenorphine	Brixadi weekly	Brixadi monthly
≤ 6mg	8 mg	-
8 to 10 mg	16 mg	64 mg
12 to 16 mg	24 mg	96 mg
18 to 24 mg	32 mg	128 mg

SWITCHING BETWEEN WEEKLY AND MONTHLY INJECTIONS: May transition from weekly to monthly dosing (or vice versa) based on clinical judgement.
Suggested transitions: 16 mg/week = 64 mg/month; 24 mg/week= 96 mg/month; 32 mg/week = 128 mg/month

Maximum Quantity Limits – Brixadi weekly: 32 mg/week Brixadi monthly: 128 mg/month
Doses of Brixadi weekly cannot be combined to yield a monthly dose

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Opioid Partial Agonist

FDA-APPROVED USES:
Indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. Brixadi should be used as part of a complete treatment plan that includes counseling and psychosocial support**.**

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
FDA Label Dosing Details for Brixadi:
Patients Not Currently Receiving Buprenorphine Treatment

The recommended weekly dose in patients not currently receiving buprenorphine treatment is 24 mg of BRIXADI (weekly) titrated up over the first week of treatment as follows:

1. To avoid precipitating an opioid withdrawal syndrome, administer a test dose of transmucosal buprenorphine 4 mg when objective signs of mild to moderate withdrawal appear.
2. If the dose of transmucosal buprenorphine is tolerated without precipitated withdrawal, administer the first dose of BRIXADI (weekly), 16 mg.
3. Administer an additional dose of 8 mg BRIXADI (weekly) within 3 days of the first dose to achieve the recommended 24 mg BRIXADI (weekly) dose.

If needed, during this first week of treatment, administer an additional 8 mg dose of BRIXADI (weekly), waiting at least 24 hours after the previous injection, for a total weekly dose of 32 mg BRIXADI (weekly). Administer subsequent BRIXADI (weekly) injections based on the total weekly dose that was established during Week One. Dosage adjustments can be made at weekly appointments with the maximum BRIXADI (weekly) dose being 32 mg.

Patients Switching from Transmucosal Buprenorphine-containing Products to BRIXADI

Patients currently being treated with a transmucosal buprenorphine-containing product may be switched directly to either BRIXADI (weekly) or BRIXADI (monthly).

Patients Transitioning Between BRIXADI (weekly) and BRIXADI (monthly)

Patients may be transitioned from weekly to monthly or from monthly to weekly dosing of BRIXADI based on clinical judgment

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

BRIXADI Risk Evaluation and Mitigation Strategy (REMS)

Brixadi is available only through a restricted program called the Brixadi REMS because of the risk of serious harm or death that could result from intravenous self-administration. The goal of the REMS is to mitigate serious harm or death that could result from intravenous self-administration by ensuring that healthcare settings and pharmacies are certified and only dispense Brixadi directly to a healthcare provider for administration by a healthcare provider.

Notable requirements of the Brixadi REMS include the following:

• Healthcare Settings and Pharmacies that order and dispense Brixadi must be certified in the Brixadi REMS.

• Certified Healthcare Settings and Pharmacies must establish processes and procedures to verify Brixadi is provided directly to a healthcare provider for administration by a healthcare provider, and the drug is not dispensed to the patient.

• Certified Healthcare Settings and Pharmacies must not distribute, transfer, loan, or sell Brixadi. Further information is available at www.BRIXADIREMS.com or by calling 1-833-274-9234.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Brixadi (buprenorphine) are considered experimental/investigational and

therefore, will follow Molina's Off- Label policy. Contraindications to Brixadi (buprenorphine) include: hypersensitivity to buprenorphine or any other ingredients in Brixadi.

OTHER SPECIAL CONSIDERATIONS:

Brixadi (buprenorphine) has a BLACK BOX WARNING for risk of serious harm or death with intravenous administration and Brixadi risk evaluation and mitigation strategy. Serious harm or death could result if administered intravenously. Brixadi forms a liquid crystalline gel upon contact with body fluids and may cause occlusion, local tissue damage, and thrombo-embolic events, including life-threatening pulmonary emboli, if administered intravenously. Brixadi is only available through a restricted program called the Brixadi REMS. Healthcare settings and pharmacies that order and dispense BRIXADI must be certified in this program and comply with the REMS requirements.

Only healthcare providers should prepare and administer Brixadi.

Brixadi (weekly) should be administered in 7-day intervals. Brixadi (monthly) should be administered in 28-day intervals. To avoid missed doses, the weekly dose may be administered up to 2 days before or after the weekly time point, and the monthly dose may be administered up to 1 week before or after the monthly time point. If a dose is missed, the next dose should be administered as soon as practically possible.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
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

AVAILABLE DOSAGE FORMS:

Brixadi SOSY 64MG/0.18ML
Brixadi SOSY 96MG/0.27ML
Brixadi SOSY 128MG/0.36ML
Brixadi (Weekly) SOSY 8MG/0.16ML
Brixadi (Weekly) SOSY 16MG/0.32ML

REFERENCES

1. Brixadi (buprenorphine) extended-release injection for subcutaneous use [prescribing information]. Cockeysville, MD: Braeburn Inc; December 2025.
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4. Coffa, D., & Snyder, H. (2019). Opioid Use Disorder: Medical Treatment Options. American Academy of Family Physicians, 100(7), 416–425. Retrieved from https://www.aafp.org/pubs/afp/issues/2019/1001
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6. Levy, S., et.al. (2016). Medication-Assisted Treatment of Adolescents With Opioid Use Disorders. PEDIATRICS, 138(3), e20161893–e20161893. https://doi.org/10.1542/peds.2016-1893
7. American Medical Association. (2019). AMA Substance Use and Pain Care Task Force: Recommendations for Policymakers. Retrieved from AMA End the Epidemic website: https://end-overdose-epidemic.org/task-force-recommendations/opioid-task-force/

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy References	Q1 2026
REVISION- Notable revisions: Coding/Billing Information References	Q1 2025
NEW CRITERIA CREATION	Q1 2024