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Montana Healthcare Programs
Physicians Administered Drugs (PAD) Criteria
Interim Criteria
Brixadi® (buprenorphine extended-release injection)

I. Medication Description

Brixadi® contains buprenorphine, a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor. It is 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® is available in a weekly extended-release formulation and a monthly extended-release formulation. The **weekly and monthly products are not interchangeable**.

II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. Initial Coverage Criteria

Member must meet all the following criteria:

- Be 18 years of age or older.
- Assessment/screening supports a diagnosis of opioid use disorder (DSM-V).

Prescriber requirements:

- Must be a Montana Healthcare Programs enrolled provider.
- Must provide clinical rationale documenting necessity to switch to injectable product.
- Must perform an overdose risk assessment and recommend naloxone if appropriate.
- Attests to the following:
  - For injection of Brixadi® weekly:
    - Members **NOT currently receiving** buprenorphine treatment:
      - Have tolerated at least one sublingual 4mg dose of buprenorphine prior to injection AND
      - Will NOT receive injection in the **upper arm** until steady state has been achieved (4 consecutive doses). Buttock, thigh or abdomen are the appropriate sites of injection for those not previously maintained on buprenorphine until steady state.
    - Member **currently receiving** buprenorphine treatment:
      - Will be transitioned from another buprenorphine product according to labeling.
  - For injection of Brixadi® monthly:
    - Member is currently being treated with a transmucosal buprenorphine-containing product of at least 8mg per day OR

- Member is currently transitioning from Brixadi® weekly of at least a dose of 16mg per week.

Limitations:

Dosed subcutaneously by a health care provider and titrated per package labeling.

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.

IV. Renewal Coverage Criteria

Member must meet all of the following criteria:

- Has documentation of positive clinical response to therapy.

Prescriber requirements:

- Must be a Montana Healthcare Programs enrolled provider.

V. Quantity Limits

Maximum dose:

- Brixadi® weekly: 32mg every 7 days.
- Brixadi® monthly: 128mg every 28 days.

VI. Coverage Duration

Initial approval: Weekly and Monthly Brixadi® will be approved each month for 3 total months, then approval for an additional 3 months. Dose changes will require a new PA.

Renewal approval duration: Approvals after 6 months at the same dose will be approved for 12 months.

References:

https://www.brixadihcp.com/pdfs/brixadi-prescribing-information.pdf