



## Montana Healthcare Programs Physician Administered Drug Coverage Criteria

### Zulresso™ (brexanolone)

#### I. Medication Description

Zulresso™ is a neuroactive steroid gamma-aminobutyric acid (GABA), a receptor positive modulator indicated for:

- Treatment of postpartum depression (PPD) in adults.

#### 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:

- Member must be 18 years of age or older.
- Medication is being prescribed by a psychiatric specialist.
- Member is ≤6 months postpartum.
- Member meets Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria for major depressive disorder, **and** onset of symptoms began in the third trimester or within 4 weeks of delivery.
- Member must have moderate or severe postpartum depression consistent with a qualifying score using a standardized screening tool for depression (e.g., Hamilton Depression [HAM-D] Rating Scale, Montgomery-Asberg Depression Rating Scale [MADRS], Patient Health Questionnaire [PHQ-9]).
- Must meet at least one of the following criteria based on severity:
  - If moderate postpartum depression:
    - Must have had an inadequate response, intolerance to or contraindication to at least 2 oral antidepressants (each trialed for at least 6 weeks).
  - If severe postpartum depression:
    - Must have had an inadequate response, intolerance to or contraindication to at least 1 oral antidepressant (trialed for at least 6 weeks)
- OR**
  - Due to safety concerns for the member or the member's ability to care for the infant, the member's condition is too time sensitive to trial oral antidepressants or other treatments.
- Member has not previously received Zulresso™ for current postpartum depressive episode from the most recent pregnancy.

- Provider attests to the following:
  - The member and health care facility administering treatment are enrolled in the Zulresso™ Risk Evaluation and Mitigation Strategy (REMS) program.
  - A health care provider will be available on site to continuously monitor the member during the infusion.

**IV. Renewal Coverage Criteria**

Retreatment for current postpartum depression episode not indicated. One treatment per pregnancy.

**V. Quantity Limitations**

Continuous IV infusion over 60 hours in accordance with weight-based dosage regimen listed in the U.S. Food and Drug Administration (FDA)-approved labeling.

**VI. Coverage Duration**

Initial approval duration: one treatment per pregnancy

Renewal approval duration: N/A