

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., HAM-D Rating Scale, MADRS, 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 healthcare facility administering treatment are enrolled in the Zulresso™ REMS program.
 - A healthcare 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 FDA approved labeling.

VI. Coverage Duration

Initial approval duration: one treatment per pregnancy

Renewal approval duration: N/A