

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 20, 2020 October 14, 2022

ZULRESSO® (brexanolone)

LENGTH OF AUTHORIZATION: One treatment (60 hours) per postpartum depression

REVIEW CRITERIA:

- Patient is ≥ 15 years of age.
- Patient has the diagnosis of moderate to severe postpartum depression as defined by DSM-5 criteria and/or appropriate depression rating scale (e.g. Hamilton Rating Scale for Depression [HAM-D], Montgomery-Asberg Depression Rating Scale [MADRS], Patient Health Questionnaire [PHQ-9], Clinically Useful Depression Outcome Scale, Edinburgh Postnatal Depression Scale [EPDS], Quick Inventory of Depressive Symptomatology-Self Report 16 Item).
- The patient’s onset of depressive episode occurred during the third trimester or within 4 weeks postpartum;
- The patient has previous treatment, contraindication, or intolerance to at least one antidepressant from the following:
 - Selective Serotonin Reuptake Inhibitor;
 - Selective Norepinephrine Reuptake Inhibitor;
 - Bupropion;
 - Mirtazapine
- The patient is not pregnant and not more than 6 months postpartum at initiation of Zulresso (brexanolone) therapy:
 - The patient is not experiencing active psychosis and does not have a history of bipolar disorders, schizophrenia, and/or schizoaffective disorder
 - The patient has not attempted suicide in the current episode of postpartum depression
- A healthcare provider must be available on site to continuously monitor the patient and intervene as necessary for the duration of the infusion.

DOSING AND ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as a 100 mg/20 mL (5 mg/mL) single-dose vial
- Due to the risk of serious harm resulting from excessive sedation or sudden loss of consciousness, ZULRESSO is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ZULRESSO REMS. Further information, including a list of certified healthcare facilities, is available at www.zulressorems.com or 1-844-472-4379.