



Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 20, 2020

### **ZULRESSO™ (brexanolone)**

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

**REVIEW CRITERIA:**

- Patient is 18 years of age or older.
- 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:**

A continuous intravenous infusion over a total of 60 hours as follows:

- 0 to 4 hours: Initiate with a dosage of 30 mcg/kg/hour
- 4 to 24 hours: Increase dosage to 60 mcg/kg/hour
- 24 to 52 hours: Increase dosage to 90 mcg/kg/hour (a reduction in dosage to 60 mcg/kg/hour may be considered during this time period for patients who do not tolerate 90 mcg/kg/hour)
- 52 to 56 hours: Decrease dosage to 60 mcg/kg/hour
- 56 to 60 hours: Decrease dosage to 30 mcg/kg/hour