

**January 21, 2020**

## **Physician Administered Drug Prior Authorization Criteria for Zulresso™**

**Version 1, 1-21-20**

**Zulresso™ brexanolone**

Zulresso™ is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator

### **Indications:**

Zulresso™ is indicated for the treatment of postpartum depression (PPD) in adults.

### **Criteria for Approval:**

1. Member is 18 years of age or older; **AND**
2. Member is 6 months postpartum or less; **AND**
3. Medication is being prescribed by, or in consultation with, a psychiatrist; **AND**
4. Member meets Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria for major depressive episode **and** onset of symptoms was between the third trimester and within 4 weeks of delivery; **AND**
5. Member does not have a current or prior DSM-5 diagnosis of a concomitant psychotic disorder, major depressive disorder with psychosis, bipolar disorder, schizophrenia, schizoaffective disorder, or moderate to severe substance or alcohol use disorder; **AND**
6. The provider attests that the member has severe postpartum depression based on standardized assessment tools and that, 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 other treatments such as oral antidepressants or electroconvulsive therapy; **AND**
7. Member has not received brexanolone for current postpartum depressive episode from the most recent pregnancy; **AND**
8. The member and provider/facility are enrolled in the Zulresso™ Risk Evaluation and Mitigation Strategies (REMS) program; **AND**

9. A healthcare provider will be available on site to continuously monitor the member during the infusion.

**Dose:**

Administered as a continuous intravenous infusion over 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.

**Quantity Limit:**

- One treatment per pregnancy.

**Criteria for Renewal Authorization Approval:**

- Retreatment for current postpartum depression episode not indicated.

**References:**

1. Zulresso™ [package insert] Cambridge, MA; Sage Therapeutics, Inc.; 6/2019, Accessed January 19, 2020.
2. Viguera, Adele. Severe postpartum unipolar major depression: Choosing treatment. Solomon, David, ed. UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com> (Accessed on January 19, 2020)
3. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; January 19, 2020
4. [Sage Therapeutics. A Study to Evaluate Safety and Efficacy of SAGE-547 in Participants with Moderate Postpartum Depression \(547-PPD-202C\).](https://clinicaltrials.gov/ct2/show/NCT02942017) <https://clinicaltrials.gov/ct2/show/NCT02942017> (Accessed on January 19, 2020)
5. [Sage Therapeutics. A Study to Evaluate Efficacy and Safety of SAGE-547 in Participants with Severe Postpartum Depression \(547-PPD-202B\).](https://clinicaltrials.gov/ct2/show/NCT02942004) <https://clinicaltrials.gov/ct2/show/NCT02942004> (Accessed on January 19, 2020)