PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Zulresso (brexanolone)
BILLING CODE	J1632
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient
STATUS	Prior Authorization Required

Zulresso is a neuroactive steroid gamma-aminobutyric acid (GABAA) receptor positive modulator initially approved by the FDA in 2019. It is indicated for the treatment of postpartum depression (PPD) in adults. The mechanism of action of Zulresso in the treatment of postpartum depression is thought to be associated with its positive allosteric modulation of GABAA receptors. With approximately 1 in 8 moms experiencing symptoms of postpartum depression (PPD), it is one of the most common pregnancy-related medical conditions. In clinical studies, adults who took Zulresso experienced a greater improvement in depressive symptoms vs placebo in 2.5 days as measured by a standard depression scale.

Zulresso (brexanolone) will be considered for coverage when the following criteria are met:

Postpartum Depression (PPD)

For **initial** authorization:

1. Member is 18 years old or older and ≤ 6 months postpartum; AND
2. Medication must be prescribed by or in consultation with psychiatrist or an ob/gyn provider; AND
3. Member has diagnosis of moderate to severe PPD as defined by DSM-5 criteria or an appropriate depression rating scale (ie HAM-D, PHQ-9, etc); AND
4. Member has documented onset of symptoms in the third trimester or within 4 weeks of delivery; AND
5. Member must have ceased lactating before drug administration, or if still lactating or actively breastfeeding, agreed to temporarily cease giving breastmilk to their infant(s); AND
6. Member has previously tried and failed an antidepressant medication (ie SSRI); OR
7. Prescriber attests the severity of depression would place the health of the mother or infant at significant risk; AND
8. Member does **not** have ANY of the following:
   a) Active psychosis,
   b) Attempted suicide associated with index case of postpartum depression,
   c) Medical history of bipolar disorders, schizophrenia, and/or schizoaffective disorder.
9. **Dosage allowed:** Infusion over a total of 60 hours (2.5 days) 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.

If all the above requirements are met, the medication will be approved for 1 month.

For **reauthorization**:
1. Zulresso will not be authorized for continuous administration (it is a single time injection).

CareSource considers Zulresso (brexanolone) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/12/2019	New policy for Zulresso created.
05/26/2022	Transferred to new template. Updated references. Added site of service and J code. Expanded the type of baseline depression scale acceptable for diagnosis.

References:

1. Zulresso [prescribing information]. Cambridge, MA: Sage Therapeutics, Inc.; June 2019.
2. ClinicalTrials.gov Identifier: NCT02942004. A Study to Evaluate Efficacy and Safety of SAGE-547 in Participants With Severe Postpartum Depression (547-PPD-202B). Available at: https://clinicaltrials.gov/ct2/show/NCT02942004?term=NCT02942004&rank=1.
3. ClinicalTrials.gov Identifier: NCT02942017. A Study to Evaluate Safety and Efficacy of SAGE-547 in Participants With Moderate Postpartum Depression (547-PPD-202C). Available at: https://clinicaltrials.gov/ct2/show/NCT02942017?term=NCT02942017&rank=1.
4. Hamilton M. A rating scale for depression. Journal of Neurology, Neurosurgery and Psychiatry, 1960; 23:56-62. Available at: https://www.outcometracker.org/library/HAM-D.pdf.
5. Gelenberg AJ, Freeman MP, Markowitz JC, et al**.** American Psychiatric Association Practice Guideline for the Treatment of Patients With Major Depressive Disorder, Third Edition. Am J Psychiatry. 2010;167(sup- pl):1-152. 9 Available at: PG_Depression3e.book(PG_Depression_3e00Pre.fm) (psychiatryonline.org)
6. Langan, R. Identification and Management of Peripartum Depression. Am Fam Physician. 2016May 15;93(10):852-858. Available at: https://www.aafp.org/afp/2016/0515/p852.html

Effective date: 01/01/2023
Revised date: 05/26/2022