CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Zulresso (brexanolone)
BILLING CODE	J3490
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	TBD
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see **Dosage allowed** below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Zulresso (brexanolone) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

POSTPARTUM DEPRESSION (PPD)

For **initial** authorization:

1. Member is 18 years old or older and ≤ 6 months postpartum; AND
2. Member has diagnosis of PPD and has documented onset of symptoms in the third trimester or within 4 weeks of delivery; AND
3. 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
4. Medication must be prescribed by or in consultation with psychiatrist, ob/gyn provider; AND
5. Member has documented total baseline score of Hamilton Rating Scale for Depression ≥ 20; AND
6. 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.
7. **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 member meets all the requirements listed above, the medication will be approved for 1 month.

For **reauthorization**:

1. Zulresso will not be authorized for continues administration (it is a single time injection).

CareSource considers Zulresso (brexanolone) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
08/12/2019	New policy for Zulresso created.
09/16/2021	Annual review, no changes

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.

Effective date: 01/01/2022
Revised date: 09/16/2021