

<b>Effective date: 9/1/2019</b>
Review Date: 10/2020, 7/2021, 4/2022, 4/2023, 12/2023, 01/2024
Scope: Medicaid, Commercial, Medicare- Medicaid Plan (MMP)

## SPECIALTY GUIDELINE MANAGEMENT

### ZULRESSO (brexanolone)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indication

Treatment of postpartum depression (PPD) in patients 15 years of age and older

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. CRITERIA FOR INITIAL APPROVAL

Authorization of 1 (one) infusion may be granted for treatment of moderate to severe postpartum depression in members 15 years of age or older when all of the following criteria are met:

- A. Member has had a major depressive episode that began no earlier than the third trimester of pregnancy and no later than the first 4 weeks following delivery, documented by standardized rating scales that reliably measure depressive symptoms (e.g., Beck Depression Scale [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], etc.)
- B. Diagnosis is verified by a psychiatrist
- C. Member is 6 months postpartum or less
- D. Lactation has ceased or breastmilk produced will not be used for feedings during the infusion and up to 4 days following infusion completion
- E. Member does not have current substance or alcohol use disorder
- F. Member will not receive more than one infusion per pregnancy/childbirth
- G. Authorizations will only be granted if Zulresso is provided at a Neighborhood Health Plan of Rhode Island authorized and approved facility for Zulresso administration
- H. The provider and/or the provider's healthcare setting is certified in the Zulresso REMS program, with ability to support onsite continuous monitoring
- I. Dose does not exceed the following:
  - 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

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**Approval Duration:** Approve to 6 months post delivery date with a limit on the dosage (Approval is for a single 60 hour infusion)

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

**III. REFERENCES**

1. Zulresso [package insert]. Cambridge, MA: Sage Therapeutics, Inc.; June 2022.

The following HCPCS/CPT codes are:

<b>HCPCS/CPT Code</b>	<b>Description</b>
J1632	Injection, brexanolone, 1mg