Effective date: 9/1/2019
Scope: Medicaid, Exchange, Integrity

SPECIALTY GUIDELINE MANAGEMENT

ZULRESSO (brexanolone)

POLICY (Policy number: TBD)

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 adults

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

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 1 infusion may be granted for treatment of moderate to severe postpartum depression in members 18 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. 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

Approval Duration: Approve to 6 months post delivery date with a limit on the dosage

III. REFERENCES

1. Zulresso [package insert]. Cambridge, MA: Sage Therapeutics, Inc.; March 2019.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
C9399	Unclassified drugs or biologicals