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

### III. REFERENCES


The following HCPCS/CPT codes are:

<table>
<thead>
<tr>
<th>HCPCS/CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1632</td>
<td>Injection, brexanolone, 1mg</td>
</tr>
</tbody>
</table>