Executive Summary

**Purpose:** Ensure appropriate utilization and control of Zulresso™ (brexanolone)

**Why Issue Selected:** On March 19, 2019, the FDA approved Zulresso™ (brexanolone) for the treatment of postpartum depression (PPD). Brexanolone is an analog of allopregnanolone, an endogenous steroid hormone metabolite that increases during pregnancy and then declines abruptly after birth; it is thought this decline may trigger depression and anxiety in some women. PPD is the most common postnatal psychiatric complication affecting an estimated 9-12% of postpartum women in the US (approximately 400,000 cases annually). It is well established that PPD can result in adverse short and long term effects on both the mother and the child; treatment focuses on cognitive-behavioral therapy and antidepressant medications. Zulresso, however, can improve symptoms of PPD in as little as 24 hours, while improvement with oral antidepressants may take weeks. Zulresso is a one-time treatment administered by continuous infusion over 60 hours; administration is complex as the product has limited stability (12 hours at room temperature) requiring a minimum of 5 infusion bag changes and recommended dosing requires several changes in infusion rates. There is also a risk of serious harm resulting from excessive sedation and loss of consciousness during the infusion, prompting the FDA to add a Black Box warning to the label and require a REMS program. Sage Therapeutics, the makers of Zulresso, are identifying “Centers of Excellence” that will be able to meet REMS requirements, have the capability to prepare and administer Zulresso, and can provide a positive patient experience.

**Program-Specific Information:**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Cost per vial</th>
<th>Cost per treatment</th>
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</thead>
<tbody>
<tr>
<td>Zulresso 100mg/20ml vial</td>
<td>$7,450 MAC</td>
<td>$37,250 MAC</td>
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**Type of Criteria:**
- ☑ Increased risk of ADE
- ☒ Preferred Drug List
- ☐ Appropriate Indications
- ☑ Clinical Edit
- ☐ Only Administrative Databases
- ☑ Databases + Prescriber-Supplied

**Setting & Population**

- Drug class for review: Zulresso™ (brexanolone)
- Age range: All appropriate MO HealthNet participants
Approval Criteria

- Documented diagnosis of moderate to severe postpartum depression:
  - Participant meets DSM-5 criteria for major depressive disorder (single or recurrent episode) AND
  - Participant has a clinical diagnosis, made by a psychiatrist or other specialist in the field of psychiatry, of moderate to severe postpartum depression AND
  - Diagnosis and severity of depression is supported by a validated rating scale AND
  - Onset of symptoms occurred in the third trimester of pregnancy or within 6 months of delivery AND
- Documentation of administration in a facility enrolled in the Zulresso REMS program AND
- Quantity limit of 5 vials per treatment – approval for a larger quantity requires documentation of appropriate dosing and participant weight above 90kg

Denial Criteria

- Previous history of Zulresso therapy in the past 9 months
- Documented history of end-stage renal disease
- Therapy will be denied if no approval criteria are met

Billing Information

- Utilize the following codes so that MO HealthNet will know the billing is for additional hours for the administration of Zulresso under the MO HealthNet FFS Program (You must ensure a Prior Authorization is on file for the medication prior to administering to the participant):
  - First 24 hours of observation
    - Revenue code 762 (Observation Room) AND
    - Procedure code G0378 (Hospital Observation per Hour)
  - Subsequent hours of observation
    - Revenue code 769 (Other Treatment/Observation) AND
    - Procedure code G0378 (Hospital Observation per Hour)
    - The above combination of billing codes has only been approved for the administration and monitoring of Zulresso.
- Managed Care Participants:
  - Prior to 7/1/2020 the Managed Care Organization is responsible for the payment of the medication and administration of Zulresso for Managed Care enrolled participants
  - Effective 7/1/2020 MO HealthNet FFS will be responsible for the payment of the medication. The participants Managed Care Organization is responsible for the payment of the administration and observation of Zulresso.
  - Please contact the participants managed care organization for instruction on how to bill properly for the administration of Zulresso.

Required Documentation

- Laboratory Results: 
- Progress Notes: X
- MedWatch Form: 
- Other: 

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

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Default Approval Period

1 month

References