Zulresso

**Description**

Zulresso (brexanolone)

**Background**

Zulresso (brexanolone) is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator. The mechanism of action in the treatment of postpartum depression (PPD) in adults is thought to be related to its positive allosteric modulation of GABA_A receptors (1).

**Regulatory Status**

FDA approved indication: Zulresso is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression (PPD) in adults (1).

Clinical studies for Zulresso included the diagnosis of PPD with onset of symptoms in the third trimester or within 4 weeks of delivery. Patients had moderate to severe PPD with a baseline Hamilton Depression Rating Scale (HAM-D) score of 20 or greater (1).

Zulresso has a boxed warning regarding excessive sedation and sudden loss of consciousness. Patients must be monitored for excessive sedation and sudden loss of consciousness and have continuous pulse oximetry monitoring. Patients must be accompanied during interactions with their child(ren) (1).
Zulresso is only available through a restricted program under a REMS called the Zulresso REMS because excessive sedation or sudden loss of consciousness can result in serious harm (1).

A healthcare provider must be available on site to continuously monitor the patient, and intervene as necessary, for the duration of the Zulresso infusion. Patients should be monitored for hypoxia using continuous pulse oximetry equipped with an alarm. Patients should also be assessed for excessive sedation every 2 hours during planned, non-sleep periods (1).

The safety and effectiveness of Zulresso in pediatric patients have not been established (1).

**Related policies**

**Policy**

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Zulresso may be considered **medically necessary** in patients that are 18 years of age and older for the treatment of postpartum depression and if the conditions indicated below are met.

Zulresso may be considered **investigational** in patients under 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**

18 years of age or older

**Diagnosis**

Patient must have the following:

Postpartum depression (PPD)

AND ALL of the following:

1. Onset of depressive symptoms between the third trimester and 4 weeks postpartum
2. Severe PPD based on the Hamilton Rating Scale for Depression (HAM-D) or another valid scoring tool (https://www.psychcongress.com/hamilton-depression-rating-scale-ham-d)
3. A healthcare provider will be available on site for the duration of the infusion
4. Patient will be monitored for hypoxia using continuous pulse oximetry equipped with an alarm
5. Patient will be monitored for excessive sedation every 2 hours during planned, non-sleep periods
6. Healthcare facility, pharmacy, and patient are registered with the REMS program

Prior—Approval Renewal Requirements
None

Policy Guidelines

Pre—PA Allowance
None

Prior—Approval Limits

Duration 30 days
Each additional childbirth is initiation of therapy

Prior—Approval Renewal Limits
None

Rationale

Summary
Zulresso (bexanolone) is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator. The mechanism of action in the treatment of postpartum depression (PPD) in adults is thought to be related to its positive allosteric modulation of GABA\(_A\) receptors. The safety and effectiveness of Zulresso in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Zulresso while maintaining optimal therapeutic outcomes.
References

Policy History

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<tr>
<td>April 2019</td>
<td>Addition to PA</td>
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<tr>
<td>June 2019</td>
<td>Annual review. Revised requirement for moderate to severe PPD to just severe PPD per SME</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.