MVP Health Care Medical Policy

Medicare Part B: Zulresso ™ (brexanolone)

Type of Policy: Medical Therapy
Prior Approval Date: 11/01/2023
Approval Date: 11/01/2024
Effective Date: 01/01/2025
Related Policies: NA

Please refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance

Codes Requiring Prior Authorization (covered under the medical benefit)

J1632 Zulresso ™ (brexanolone)

Overview/Summary of Evidence

Peripartum Depression (formerly Postpartum depression (PPD))is a mood disorder that can occur during pregnancy or after childbirth which is accompanied by persistent, intense feelings of anxiety, despair or sadness and changes in energy, sleep, and appetite. The symptoms can interfere with a mother's daily tasks and taking care of their child(ren). PPD is different from "baby blues", which is a common occurrence that subsides within a few days to 1-2 weeks without treatment. An estimated one in seven women experience peripartum depression. Current treatment includes psychotherapy (counseling or "talk therapy"), antidepressants or both. Zulresso ™ (brexanolone) is the first available medication specifically indicated for the treatment of postpartum depression (PPD) in adults. It is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator that is administered as a one-time continuous intravenous infusion given over 60 hours (2.5 days). Zulresso must be administered in an inpatient setting as it requires continuous monitoring by a healthcare provider for hypoxia, loss of consciousness and excessive sedation. Zulresso is only available through a REMS program.

Indications/Criteria

Zulresso will be considered for coverage when all the following are met:

- Must be 15 years old or older
- Must be biologically female
- Member is ≤ 12 months postpartum
- Must have a confirmed diagnosis of PPD
    - Member is assessed at baseline using an appropriate diagnostic instrument such as Hamilton Depression Rating Scale (HAM-D) score, PHQ-9 Patient

Depression Questionnaire or Montogomery Asberg Depression Rating Scale (MADRS).
    - Chart notes documenting a diagnosis of PPD
    - Symptom onset within third trimester of pregnancy or within 4 weeks of delivery
- Documentation of a failure, contraindication, or intolerance to at least a 4-week trial of first line antidepressant therapy (i.e. SSRI (sertraline, escitalopram), mirtazapine, venlafaxine, duloxetine) at the maximally tolerated FDA-approved dose **OR**
- If a 4-week trial with an oral antidepressant is inappropriate, clinical rationale must be documented in the medical record and will be considered on a case by case basis (such as cases of severe PPD)
- Limit one treatment course per postpartum period- one continuous 60-hour intravenous infusion with a healthcare provider available on site to continuously monitor the patient at a healthcare setting that is certified in the REMS program.

Approval will be for one infusion per postpartum period

Exclusions

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- End stage renal disease (ESRD)
- Home infusion
- Biologically male
- Concurrent active psychosis, bipolar disorder and schizoaffective disorder
- Multiple infusions in the same postpartum period

    - Symptom onset within third trimester of pregnancy or within 4 weeks of delivery
- Documentation of a failure, contraindication, or intolerance to at least a 4-week trial of first line antidepressant therapy (i.e. SSRI (sertraline, escitalopram), mirtazapine, venlafaxine, duloxetine) at the maximally tolerated FDA-approved dose **OR**
- If a 4-week trial with an oral antidepressant is inappropriate, clinical rationale must be documented in the medical record and will be considered on a case by case basis (such as cases of severe PPD) Limit one treatment course per postpartum period- one continuous 60-hour intravenous infusion with a healthcare provider available on site to continuously monitor the patient at a healthcare setting that is certified in the REMS program.

Approval will be for one infusion per postpartum period

Exclusions

- End stage renal disease (ESRD)
- Home infusion
- Male
- Concurrent active psychosis, bipolar disorder and schizoaffective disorder
- Multiple infusions in the same postpartum period
- Pregnant

References

1. Zulresso TM (brexanolone) injection, for intravenous use. Prescribing Information. Cambridge, MA. Sage Therapeutics. June 2022.
2. American College of Obstetricians and Gynecologists. Frequently Asked Question Labor, Delivery, and Postpartum Care. December 2013. Available at: https://www.acog.org/Patients/FAQs/Postpartum-Depression
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4. Melzer-Brody S, Colquhoun H, Reisenberg R, et al. Brenaxolone injection in post-partum depression: two multicenter, double-blind, randomized, placebo-controlled, phase 3 trials. *Lancet*. 2018; 392(10152):1058-1070.
5. Frieder A, Fersh M, Hainline R, et al. Pharmacotherapy of Postpartum Depression: Current Approaches and Novel Drug Development. *CNS Drugs*. 2019 Feb; 33(1): 265-282.

6. Williams J, Ryan D, Thomas-Peter K, et al. Best Practice Guidelines for Mental Health Disorders in the Perinatal Period. BC Reproductive Mental Health Program & Perinatal Services. 2014 Mar; 13-89
7. Yonkers KA, Wisner KL, Stewart DE, et al. The management of depression during pregnancy: a report from the American Psychiatry Association and the American College of Obstetricians and Gynecologists. *Gen Hosp Psychiatry* 2009;31:403-13

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