

Zulresso™ (brexanolone injection)

When requesting Zulresso™ (brexanolone injection), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

Zulresso is indicated for the treatment of postpartum depression (PPD) in adults.

Coverage Guidelines

For the treatment of postpartum depression

An individual must meet **all** of the following criteria for approval:

- Has been diagnosed with moderate to severe depression with symptom onset during the third trimester of pregnancy or up to 4 weeks post-delivery;
- Is ≤ 6 months postpartum;
- Is not currently pregnant;
- Is 18 years of age or older; AND
- Zulresso is prescribed by or in consultation with a psychiatrist or an obstetrician-gynecologist.

Approval duration: one time dose

Dosing Recommendations

Approve up to 90 mcg/kg/hour intravenously once per postpartum period as a one-time, 60-hour infusion.

References

1. Zulresso™ injection for intravenous use [prescribing information]. Cambridge, MA: Sage Therapeutics; June 2019.
2. Meltzer-Brody S, Colquhoun H, Riesenberger R, et al. Brexanolone injection in post-partum depression: two multicentre, double-blind, randomised, placebo-controlled, phase 3 trials. *Lancet*. 2018;392(10152):1058-1070.
3. FDA briefing document for Zulresso. Psychopharmacologic Drugs Advisory Committee (PDAC) and Drug Safety and Risk Management (DSaRM) Advisory Committee Meeting on November 2, 2018. Available at: <https://www.fda.gov/media/121345/download>. Accessed on May 14, 2021.
4. FDA News Release. FDA approves first treatment for post-partum depression. Published on March 19, 2019. Available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm633919.htm>. Accessed on May 14, 2021.
5. Food and Drug Administration. Zulresso Risk Evaluation and Mitigation Strategy (REMS). October 14, 2020. Available at: <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=IndvRemisDetails.page&REMS=387>. Accessed on May 14, 2021.