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
- Is ≤ 6 months postpartum
- Is not currently pregnant
- Is 18 years of age or older
- Zulresso is prescribed by or in consultation with psychiatrist or an obstetrician-gynecologist

Approval duration: one time dose

Dosing Recommendations

Zulresso is administered as a continuous intravenous infusion over 60 hours as follows:

- 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 (may consider a dosage of 60 mcg/kg/hour for those who do not tolerate e90 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

References

1. Zulresso™ injection for intravenous use [prescribing information]. Cambridge, MA: Sage Therapeutics; March 2019.
2. Meltzer-Brody S, Colquhoun H, Riesenberg 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/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/ucm624642.htm. Accessed on April 14, 2019.
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 April 11, 2019.

© 2020 eviCore healthcare. All rights reserved.

5. Food and Drug Administration. Zulresso Risk Evaluation and Mitigation Strategy (REMS). March 19, 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/rems/Zulresso_2019_03_19_REMS_Full.pdf. Accessed on: March 26, 2019.

© 2020 eviCore healthcare. All rights reserved.