

Zulresso (brexanolone) Effective 12/01/2019 ☐ MassHealth UPPL Plan □ Prior Authorization □ Commercial/Exchange **Program Type** ☐ Quantity Limit ☐ Pharmacy Benefit **Benefit** ☐ Step Therapy Specialty N/A Limitations **Medical and Specialty Medications** Phone: 877-519-1908 All Plans Fax: 855-540-3693 Contact Information **Non-Specialty Medications All Plans** Phone: 800-711-4555 Fax: 844-403-1029 **Exceptions** N/A

Overview

Brexanolone is a neuroactive steroid gamma-aminobutyric acid (GABA)-A receptor positive allosteric modulator that is chemically identical to endogenous allopregnanolone. Zulresso is FDA indicated for the treatment of postpartum depression (PPD) in adults. Zulresso is given as a continual intravenous infusion over 60 hours.

Coverage Guidelines

Approval of Zulresso will be granted if the member meets all following criteria and documentation has been submitted:

- 1. The member is 18 years of age or older
- 2. The medication is being prescribed by or in consultation with a psychiatrist.
- 3. The member is ≤ 6 months postpartum
- 4. The member does not have active psychosis
- 5. The member is not actively breastfeeding at the time of treatment
- 6. The member must be enrolled in the Zulresso REMS Program prior to administration

Limitations

1. Approvals will be granted for one infusion per pregnancy

References

- 1. Zulresso (brexanolone) [prescribing information]. Cambridge, MA: Sage Therapeutics, Inc; June 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 [published correction appears in Lancet. 2018;392(10153):1116]. Lancet. 2018;392(10152):1058-1070. doi: 10.1016/S0140-6736(18)31551-4
- 3. Hoffmann, E Wald J, Colquhoun H. Evaluation of breast milk concentrations following brexanolone iv administration to healthy lactating women: 850. AJOG. 2019;220(S1):S554. doi 10.1016/j.ajog.2018.11.873
- 4. Stewart DE, Vigod SN. Postpartum Depression: Pathophysiology, Treatment, and Emerging Therapeutics. Annu Rev Med 2019; 70:183

5. Molyneaux E, Howard LM, McGeown HR, et al. Antidepressant treatment for postnatal depression. Cochrane Database Syst Rev 2014; :CD002018

Review History

09/18/2019 – Reviewed. Effective 12/1/2019. 05/19/2021- Reviewed for May P&T; no clinical changes.

