



Brexanolone Treatment for Post-Partum Depression

Origination: 02/06/20	Revised: 7/24/20	Annual Review: 11/05/20
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Purpose:

To provide guidelines for drug testing during substance abuse treatment for Population Health and Provider Alliances associates for reference when making benefit determinations.

Coverage Guidelines:

Brexanolone injection can be considered medically necessary for the treatment of moderate to severe postpartum depression (PPD) in adult women (18 years of age or older) when **ALL** of the following criteria are met:

- Member has had a major depressive episode that began no earlier than the third trimester of pregnancy and no later than the first 4 weeks following delivery, *and*
- Diagnosis is verified by a psychiatrist, and treatment is recommended and ordered by a psychiatrist; *and*
- Member is 6 months postpartum or less; *and*
- Breast feeding will not be used during the infusion and up to 4 days following infusion completion; *and*
- Member does not have current substance or alcohol use disorder.

Exclusion Criterion:

- Approval is for only one brexanolone infusion per pregnancy/childbirth. More than one infusion is considered to be experimental and investigational because the safety and efficacy have not been established in the peer-reviewed published literature.
- Brexanolone is not covered, but not limited to, the following indications:
 - Mood disorders other than postpartum depression
 - Status epilepticus.



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References:

1. Sage Therapeutics, Inc. Zulresso (brexanolone) injection, for intravenous use, [controlled substance schedule pending]. Prescribing Information. Reference ID: 4405779. Cambridge, MA: Sage; revised March 2019.
2. Kaness, Colquhoun H, Gunduz-Bruce H, et al. Brexanolone (SAGE-547 injection) in postpartum depression: A randomised controlled trial. *Lancet*. 2017b;390(10093):480-489.
3. Kaness SJ, Colquhoun H, Doherty J, et al. Open-label, proof-of-concept study of brexanolone in the treatment of severe postpartum depression. *Hum Psychopharmacol*. 2017a;32(2): e2576.
4. Meltzer-Brody S, Colquhoun H, Riesenberg, et al. Brexanolone injection in postpartum depression: Two multicentre, double-blind, randomised, placebo-controlled, phase 3 trials. *Lancet*. 2018;392 (10152):1058-1070.
5. Rosenthal ES, Claassen J, Wainwright MS, et al. Brexanolone as adjunctive therapy in super-refractory status epilepticus. *Ann Neurol*. 2017;82(3):342-352.

Disclaimer Information:

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed's benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.