

**Zulresso (brexanolone)**  
**Effective 12/01/2019**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	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, Riesenber 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.

