

ALASKA MEDICAID
Prior Authorization Criteria

**Zulresso™
(brexanolone)**

FDA INDICATIONS AND USAGE¹

Zulresso™ (brexanolone) is a neuroactive steroid Gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of postpartum depression (PPD) in adults.

APPROVAL CRITERIA^{1,2,3,4}

1. Patient is 18 years of age or older **AND**;
2. Patient has a diagnosis of major depressive episode defined by DSM-5 criteria **AND**;
3. Patient has a Hamilton Rating Scale for Depression (HAM-D) ≥ 20 **AND**;
4. Is being prescribed by or in consultation with a psychiatrist **AND**;
5. The patient must be ≤ 6 months postpartum **AND**;
6. Onset of the symptoms was in the third trimester or within 4 weeks of delivery **AND**;
7. Patient has tried and failed at least one oral antidepressant (I.E. SSRI, SNRI, TCA, etc.) at maximally indicated dose for at least 6-8 weeks or has a contraindication or intolerance to at least two antidepressants from two different classes **AND**;
8. The medication is being administered in a REMS certified healthcare setting **AND**;
9. The patient's weight is submitted.

DENIAL CRITERIA¹

1. Failure to meet approval criteria **OR**;
2. Patient has active psychosis **OR**;
3. Patient is lactating or actively breastfeeding upon initiation and during treatment, unless it is agreed to temporarily stop giving breastmilk to their infant.

CAUTIONS¹

- Monitor for excessive sedation and sudden loss of consciousness.
- Monitor for hypoxia using pulse oximetry.
- Use with caution in patients with end stage renal disease.
- Monitor for suicidal thoughts and behaviors.

DURATION OF APPROVAL

- Initial Approval: one 60 hour infusion

QUANTITY LIMIT

- Weight based dosing not to exceed a 60 hour infusion
- HCPCS – J1632

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REFERENCES / FOOTNOTES:

1. Zulresso™ [package insert]. Cambridge, MA: Sage Therapeutics; 2019.
2. Meltzer-Brody S, Colquhoun H, Riesenbergr R, Epperson CN, Deligiannidis KM, Rubinow DR, Li H, Sankoh AJ, Clemson C, Schacterle A, Jonas J, Kaner S. Brexanolone injection in post-partum depression: two multicenter, double-blind, randomized, placebo-controlled, phase 3 trials. *Lancet*. 2018 Sep 22;392(10152):1058-1070. doi: 10.1016/S0140-6736(18)31551-4. Epub 2018 Aug 31. Erratum in: *Lancet*. 2018 Sep 29;392(10153):1116.
3. Hamilton, M. A rating scale for depression; *Journal of Neurology, Neurosurgery, and Psychiatry*. 23:56-62, 1960.
4. American Psychiatric Association. DSM 5. Diagnostic and statistical manual of mental disorders. American Psychiatric Press Inc., (5th edition). 2013; Washington, DC: American Psychiatric Association.