

ALASKA MEDICAID
Prior Authorization Criteria

**Zurzuvae™
(zuranolone)**

FDA INDICATIONS AND USAGE¹

Zurzuvae™ 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 age meets FDA labeled indication **AND**;
2. Prescribed by or in consultation with a psychiatrist **AND**;
3. Patient has the diagnosis of postpartum depression (PPD)
 - a. Diagnosis of major depressive episode that began no earlier than the third trimester of pregnancy and no later than four weeks following delivery
4. No more than 12 months have elapsed since delivery **AND**;
5. Patient has tried and failed for a minimum of six weeks at a recognized therapeutic dose an agent from one of the following classes, or has a contraindication to all:
 - a. Selective Serotonin Reuptake Inhibitor (SSRI)
 - b. Serotonin-Norepineprine Reuptake Inhibitor (SNRI)
 - c. Bupropion
 - d. Mirtazepine
 - e. Tricyclic Antidepressant (TCA) **AND**;
6. Patient has had current laboratory assessments, including renal and liver function tests within the last 60 days.

DENIAL CRITERIA¹

1. Failure to meet approval criteria **OR**;
2. Patient has an eGFR < 15mL/min/1.73m²
3. Patient has received prior treatment with Zulresso™ or Zurzuvae™ for the current pregnancy.

CAUTIONS¹

- Avoid concomitant use with CYP4A4 inducers.
- Known to cause CNS depression and impaired driving. Patient should not drive or engage in other potentially hazardous activities until at least 12 hours after administration.
- Zuranolone has abuse potential with associated risks of misuse, abuse, and substance abuse disorder including addiction.
- May cause fetal harm.

DURATION OF APPROVAL¹

- Initial Approval: 1 month. Duration of treatment limited to 14 days, extension of therapy will not be authorized.

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QUANTITY LIMIT

- #28 for 14 days (one course of treatment per pregnancy)

REFERENCES / FOOTNOTES:

1. Zurzuvae (zuranolone) [prescribing information]. Cambridge, MA: Biogen Inc; November 2023
2. American Psychiatric Association. Practice Guideline for the Treatment of Patients With Major Depressive Disorder, Third Edition. November 2010. Available at: <http://psychiatryonline.org/guidelines.aspx>
3. Deligiannidis KM, Meltzer-Brodsky S, Gunduz-Bruce H, et al. Effect of Zuranolone vs Placebo in Postpartum Depression: A Randomized Clinical Trial. *JAMA Psychiatry*. 2021;78(9):951-959. doi:10.1001/jamapsychiatry.2021.1559
4. Clayton AH, Lasser R, Nandy I, Sankoh AJ, Jonas J, Kaner SJ. Zuranolone in Major Depressive Disorder: Results From MOUNTAIN-A Phase 3, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial. *J Clin Psychiatry*. 2023 Feb 20;84(2):22m14445. doi: 10.4088/JCP.22m14445. PMID: 36811520.