VENTURA COUNTY
HEALTH CARE PLAN

# PRIOR AUTHORIZATION POLICY

**POLICY:** Psychiatry – Zurzuvae Prior Authorization Policy
- Zurzuvae™ (zuranolone capsules – Sage Therapeutics/Biogen)

**REVIEW DATE:** 11/15/2023

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## OVERVIEW

Zuranolone, a neuroactive steroid gamma-aminobutric acid (GABA) A receptor positive modulator, is indicated for the **treatment of postpartum depression in adults**.[1]

### Disease Overview

Postpartum (or peripartum) depression is a major depressive episode with onset during pregnancy or within 4 weeks of delivery that can have serious effects on the maternal-infant bond and later infant development.[3] Approximately 40% to 80% of cases of postpartum depression are considered moderate to severe.[2]

### Clinical Efficacy

The efficacy of Zurzuvae was established in two Phase III, randomized, double-blind, placebo-controlled, multicenter, pivotal studies in patients with severe postpartum depression initiating treatment within 6 or 12 months of delivery.[2,3] Eligible patients were diagnosed with a major depressive episode, which had an onset no earlier than the third trimester of pregnancy and no later than 4 weeks after delivery.

### Safety

Based on findings from animal studies, Zurzuvae may cause fetal harm.[1] Pregnant women should be advised of the potential risk to a fetus. Available data on Zurzuvae use in pregnant women from the clinical development program are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antidepressants, including Zurzuvae, during pregnancy.

Zurzuvae has a Boxed Warning regarding impairment in driving or engaging in other potentially hazardous activities due to central nervous system (CNS) depressant effects.[1] Warnings/Precautions for Zurzuvae also include suicidal thoughts and behaviors (which is similar to other antidepressants) and embryo-fetal toxicity.

## POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Zurzuvae. Because of the specialized skills required for evaluation and diagnosis of patients treated with Zurzuvae as well as the monitoring required for adverse events and long-term efficacy, approval requires Zurzuvae to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for the duration noted below.

**Automation**: None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Zurzuvae is recommended in those who meet the following criteria:

**FDA-Approved Indication**

1. **Postpartum Depression.** Approve for 14 days if the patient meets the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets BOTH of the following (i and ii):
     - **i.** Patient has been diagnosed with severe depression; AND
     - **ii.** Symptom onset began during the third trimester of pregnancy or up to 4 weeks post-delivery; AND
   - **C)** Patient is ≤ 12 months postpartum; AND
   - **D)** Patient is not currently pregnant; AND
   - **E)** Zurzuvae is being prescribed by or in consultation with a psychiatrist or an obstetrician-gynecologist.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Zurzuvae is not recommended in the following situations:

1. **Previous Treatment with Zurzuvae during the Current Episode of Postpartum Depression**.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Zurzuvae™ capsules [prescribing information]. Cambridge, MA: Biogen; August 2023.
2. Deligiannidis KM, Meltzer-Brody S, Maximos B, et al. Zuranolone for the treatment of postpartum depression. *Am J Psychiatry*. 2023 Jul 26. Epub ahead of print.
3. Deligiannidis KM, Meltzer-Brody 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.
4. FDA News Release. FDA approves first oral treatment for post-partum depression. Published on August 4, 2023. Available at: FDA Approves First Oral Treatment for Postpartum Depression | FDA. Accessed on August 7, 2023.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| New Policy | -- | 11/15/2023 |