MEDICAL MUTUAL®

Drug Policy

Policy:	Zurzuvae (zuranolone)	Annual Review Date: 01/16/2025 Last Revised Date: 01/16/2025

OVERVIEW

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

POLICY STATEMENT

This policy involves the use of Zurzuvae. Prior authorization is recommended for pharmacy benefit coverage of Zurzuvae. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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, initial approval requires Zurzuvae be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Postpartum Depression (PPD)**
   Criteria. *Patient must meet the following criteria*
   - **A.** The patient is 18 years of age or older; AND
   - **B.** The patient is not currently pregnant; AND
   - **C.** Zurzuvae is being prescribed by or in consultation with a psychiatrist or an obstetrician-gynecologist (OB-GYN); AND
   - **D.** Symptom onset began during the third trimester of pregnancy or up to 4 weeks post-delivery; AND
   - **E.** The patient meets the criteria for a major depressive episode found in the Diagnostic and Statical Manual of Mental Disorders (DSM-5); AND
   - **F.** The patient is 1 year or less postpartum.

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Initial Approval/ Extended Approval.
A) *Initial Approval:* 14 days per postpartum period
B) *Extended Approval:* not recommended

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Zurzuvae has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Zurzuvae™ capsules [prescribing information]. Cambridge, MA: Biogen; July 2024.
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.
5. Zuranolone. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 4 December 2024. Accessed 22 January 2025.

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