

**Protocol for Zurzuvae® (zuranolone)
Approved January 2024**

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

Criteria for approval:

1. Patient has a diagnosis of postpartum depression with onset during pregnancy or within 4 weeks postpartum; **OR**
2. Patient has moderate to severe symptoms validated by a depression rating scale (e.g., EPDS score ≥ 12 , PHQ-9 score ≥ 10) at baseline; **AND**
3. Patient is ≤ 12 months postpartum; **AND**
4. Medication is prescribed by or in consultation with appropriate healthcare provider; **AND**
5. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Continuation of therapy:

1. Patient has previously completed a 14-day course of Zurzuvae
2. Medication is prescribed by or in consultation with appropriate healthcare provider or original prescriber
3. Prescriber attests that an additional course of Zurzuvae is needed – the initial treatment course did not adequately resolve patient's postpartum depression symptoms as evidenced by a validated recent rating scale (e.g., EPDS score, PHQ-9)
4. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Approval Duration: One Month

Quantity Level Limit: 28 capsules per 14 days

References:

1. Zurzuvaе [prescribing information]. Biogen Inc. Cambridge, MA. 02142 August 2023
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2020. Updated periodically
3. Viguera A. Postpartum unipolar major depression: Epidemiology, clinical features, assessment, and diagnosis. In: UpToDate April 2023. Payne J, Lockwood CJ (Eds). Wolters Kluwer. (Accessed on December 8, 2023)
4. Liu X, Wang S, Wang G. Prevalence and Risk Factors of Postpartum Depression in Women: A Systematic Review and Meta-analysis. *J Clin Nurs.* 2022 Oct;31(19-20):2665-2677