PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 11/15/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

- **Zurzuvae™ (zuranolone capsules – Sage Therapeutics/Biogen)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

- **Zurzuvae™ (zuranolone capsules – Sage Therapeutics/Biogen)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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

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