Effective Date: 05/01/2024
Reviewed: 02/2024
Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

ZURZUVAE (zuranolone)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Zurzuvae is indicated for the treatment of postpartum depression (PPD) in adults.

All other indications are considered experimental/investigational and not medically necessary.

II. PRESCRIBER SPECIALTIES

The requested medication must be prescribed by or in consultation with a psychiatrist.

III. CRITERIA FOR INITIAL APPROVAL

Postpartum depression (PPD)
Authorization of 1 month may be granted for treatment of postpartum depression in adults when all of the following criteria are met:

A. Member is 18 years of age or older.
B. Member has severe postpartum depression with documentation of diagnosis provided.
C. Member has had a major depressive episode with onset of symptoms that began no earlier than the third trimester of pregnancy and no later than the first 4 weeks following delivery, documented by standardized rating scales that reliably measure depressive symptoms (e.g., Beck Depression Inventory [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], etc.).
D. Member is 6 months postpartum or less.
E. Member is not currently pregnant.
F. Lactation has ceased or breastmilk produced will not be used for feedings from just prior to receiving treatment on day 1 until 7 days after the last dose.
G. Member will not receive more than one 14-day treatment course per pregnancy/childbirth.
H. Member will not use in combination with Zulresso and has not received prior treatment with Zurzuvae or Zulresso after the most recent pregnancy.
I. Member is not currently pregnant.
J. Member has experienced an inadequate treatment response from a 4-week trial of a formulary oral selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI)] for PPD, if appropriate, with documentation provided.
K. Zurzuvae will be used in combination with, or a recommendation will be given for psychotherapy, if appropriate.
L. Member does not have a past medical history of any of the following:
    a. Seizures
    b. Bipolar Disorder
    c. Schizophrenia
    d. Schizoaffective Disorder

IV. QUANTITY LIMIT

- Zurzuvae 25 mg capsules: 2 capsules/day, 28 capsules per pregnancy/childbirth*
- Zurzuvae 30 mg capsules: 1 capsule/day, 14 capsules per pregnancy/childbirth

**Note: For members who require a dose reduction to 40 mg daily (using 20 mg capsules) due to CNS depressant effects, the limited network of specialty pharmacies that dispense Zurzuvae will also administer a dose reduction program at no cost to payers and patients per Biogen.*

V. REFERENCES

1. Zurzuvae [package insert]. Cambridge, MA: Sage Therapeutics, Inc.; August 2023.