

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 has not received prior treatment with Zurzuvae 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.; November 2024.