Oscar Clinical Guideline: Zurzuvae (zuranolone) (PG182, Ver. 1)

Zurzuvae (zuranolone)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Postpartum depression (PPD) is a major depressive disorder that occurs during pregnancy or within 4 weeks after delivery, affecting approximately 14% of postpartum women. It is one of the most common complications of childbirth and a leading cause of maternal mortality.

First-line treatments for PPD include psychotherapy such as cognitive behavioral therapy (CBT) and antidepressant medications like selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs). However, response with standard antidepressants can be delayed by weeks. Prior to zuranolone, the only FDA-approved medication specifically for PPD was brexanolone, which requires a 60-hour continuous IV infusion and restricted distribution program.

Zurzuvae (zuranolone) is a neuroactive steroid gamma-aminobutyric acid (GABA)A receptor positive allosteric modulator indicated for the treatment of postpartum depression (PPD) in adults. It is the first FDA-approved oral antidepressant specifically for PPD. Zurzuvae (zuranolone) offers rapid improvement in depressive symptoms within 3 days and continued efficacy over the 2-week treatment course.

Definitions

"**Antidepressant**" refers to a medication used to treat depression and other mental health conditions. Common classes include SSRIs, SNRIs, and atypical antidepressants.

"**Edinburgh Postnatal Depression Scale (EPDS)**" is a 10-item self-rated depressive symptom severity scale specific to the perinatal period. Each item is rated on a 4-point scale from 0 to 3. The total score ranges from 0 to 30 points, calculated by summing the 10 individual item scores. Higher total scores indicate more severe depression.

"**Patient Health Questionnaire-9 (PHQ-9)**" is a 9-item self-rated depressive symptom severity scale used to monitor depression treatment over time. Each item is scored from 0 to 3 based on symptom frequency over the past 2 weeks. The total score ranges from 0 to 27 calculated by summing the 9 item scores. Higher scores indicate more severe depression.

"**Peripartum**" onset refers to the onset of mood symptoms during pregnancy or within 4 weeks postpartum.

"**Postpartum depression (PPD)**" refers to major depressive disorder with peripartum onset, defined as depression with onset during pregnancy or within 4 weeks after delivery.

"**Psychotherapy**" refers to treatment involving counseling and therapeutic techniques to address psychological, emotional, and behavioral issues. Common forms used for PPD include cognitive behavioral therapy (CBT) and interpersonal therapy.

"**Selective serotonin reuptake inhibitor (SSRI)**" refers to a class of antidepressants that work by blocking the reabsorption (reuptake) of serotonin in the brain, increasing levels of this neurotransmitter. Examples include fluoxetine, sertraline, and paroxetine.

"**Serotonin-norepinephrine reuptake inhibitor (SNRI)**" refers to a class of antidepressants that block the reuptake of both serotonin and norepinephrine. Examples include duloxetine and venlafaxine.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Zurzuvae (zuranolone)** medically necessary when **ALL** of the following criteria are met:

1. Prescribed by or in consultation with a psychiatrist or OB/GYN; ***AND***

2. Age ≥18 years old; ***AND***
3. Diagnosis of postpartum depression (PPD) with onset during pregnancy or within 4 weeks postpartum; ***AND***
4. Documentation of current depressive symptoms consistent with a diagnosis of major depressive disorder with peripartum onset; ***AND***
5. Baseline assessment using a validated depression rating scale indicates at least moderate severity depression (e.g. PHQ-9 score ≥10, EPDS score ≥14); ***AND***
6. Documentation provided confirms that the member:
    a. is not actively suicidal, homicidal, or an imminent danger to self or others based on clinical assessment; ***and***
    b. is not currently pregnant; ***and***
    c. does not have a history of seizures, bipolar disorder, schizophrenia, or schizoaffective disorder; ***and***
    d. agrees to use effective contraception during treatment and for at least 7 days after final dose; ***AND***
7. Dosage does not exceed 50 mg orally once daily for 14 days.

If the above prior authorization criteria are met, Zurzuvae (zuranolone) will be authorized for one 14-day course.

Medical Necessity Criteria for Reauthorization

Reauthorization for one additional 14-day course in a 12-month period will be granted if the member has recent (within the last 30 days) clinical chart documentation demonstrating **ALL** of the following criteria:

1. Prescribed by or in consultation with a psychiatrist or OB/GYN; ***AND***
2. The member has completed the initial 14-day treatment course of Zurzuvae (zuranolone); ***AND***
3. The initial 14-day treatment course did not adequately resolve patient's PPD symptoms as evidenced by validated rating scale (e.g. EPDS, PHQ-9); ***AND***
4. At least 8 weeks have elapsed since completion of the prior Zurzuvae (zuranolone) treatment course.

Experimental or Investigational / Not Medically Necessary

Zurzuvae (zuranolone) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Treatment of non-FDA approved indications (e.g. anxiety, bipolar depression, major depressive disorder).
- Members with a suicidal or homicidal risk factor or who are deemed unsafe to self or others.

References

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Clinical Guideline Revision / History Information

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