Zurzuvae (zoranolone) Prior Authorization with Quantity Limit Criteria

FDA APPROVED INDICATIONS AND DOSAGE[1]

Agent	Indication	Dosage
Zurzuvae® (zoranolone) Capsule Strengths: 20 mg, 25 mg, and 30 mg	Treatment of adults with postpartum depression (PPD) Can be monotherapy or adjunct to oral antidepressant therapy	50 mg taken orally once daily in the evening with fat-containing food for 14 days Dosage may be reduced to 40 mg once daily if CNS depressant effects occur Severe Hepatic Impairment: 30 mg orally once daily in the evening for 14 days. Moderate or Severe Renal Impairment: 30 mg orally once daily in the evening for 14 days

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TARGET AGENT
Zurzuvae ® (zoranolone)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Initial Evaluation

Target Agent will be approved when ALL of the following are met:

1. The patient is 18 years and older
   AND
2. The patient is not currently pregnant
   AND
3. Patient meets ALL of the following:
   A. Symptom onset began during the third trimester of pregnancy or up to 4 weeks post-delivery
   AND
   B. Documented diagnosis of a major depressive episode, defined by DSM-5 criteria **AND**
   C. Patient has been diagnosed with depression determined by a standardized screening tool for depression [such as, but not limited to, Edinburgh Postnatal Depression Scale (EPDS), Patient Health Questionnaire (PHQ-9), Beck Depression Inventory (BDI), Hamilton Depression Rating Scale (HAM-D)]
   AND
4. Patient is not breast feeding or lactating **AND**
5. Patient is not pregnant and will use effective contraception during ZURZUVAE treatment and for one week after the final dose **AND**
6. Patient is less than 12 months postpartum
   AND
7. Patient meets **ONE** of the following:
   A. Patient has had a treatment failure with at least one preferred product **OR**

B. Patient has had an intolerable side effect to at least one preferred product (i.e. SSRIs, SNRIs, TCAs, bupropion, or mirtazapine) at a maximally tolerated therapeutic dose for a minimum duration of 2 months **OR**
C. Patient has documented contraindication(s) to ALL preferred products that are appropriate to use for the condition being treated **OR**
D. There is no preferred product that is appropriate to use for the condition being treated **AND**

8. Zurzuvae is being prescribed by a psychiatrist **OR** an obstetrician-gynecologist (OB-GYN)

Length of Approval: 14 days

Renewal Evaluation

1. The safety and effectiveness of Zurzuvae use beyond 14 days in a single treatment course have not been evaluated.
2. The use of Zurzuvae for any other indication has not been evaluated.