Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	July 2, 2024

Zurzuvae™ (zuranolone)

LENGTH OF AUTHORIZATION: 14-day treatment period

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age; **AND**
- Patient must have a diagnosis of postpartum depression (PPD); **AND**
- Baseline PPD severity has been assessed using a standardized, validated depression rating scale (e.g., Hamilton Rating Scale for Depression [HAM-D], Patient Health Questionnaire-9 [PHQ-9], Montgomery-Åsberg Depression Rating Scale [MADRS]); **AND**
- Symptom onset began during the third trimester of pregnancy or up to 4 weeks post-delivery; **AND**
- Patient is not currently pregnant and is using effective contraception; **AND**
- Prescriber attests to counseling the patient to refrain from engaging in potentially hazardous activities requiring mental alertness, including driving, for ≥ 12 hours after each zuranolone dose; **AND**
- If patient is taking another oral antidepressant medication, the dose has been stable for ≥ 30 days; **AND**
- Baseline renal and hepatic function have been assessed and dosing is appropriate according to labeling; **AND**
- Zurzuvae is being prescribed by or in consultation with a psychiatrist or an obstetrician-gynecologist (OB-GYN).

Note: Zuranolone treatment has not been evaluated for > 1 course of treatment per pregnancy. Cannot be renewed for current PPD episode.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 20 mg, 25 mg, and 30 mg capsules.