Zurzuvae Criteria

Revised: 06/26/2024

ZURZUVAE (ZURANOLONE)

Length of Authorization: One 14-day course of treatment (28 caps)/pregnancy

CHILDREN – CRITERIA TO APPROVE

N/A

ADULTS – CRITERIA TO APPROVE

All the following must be met:

- Individual is 18 years of age or older
- Diagnosis of postpartum depression (PPD) based on Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria for a major depressive episode (DSM-5)
- 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-Asberg Depression Rating Scale [MADRS])
- Individual is not currently pregnant and is using effective contraception; **AND**
- Individual has ceased lactating or has agreed to refrain from providing breast milk to the infant prior to receiving the first dose until 7 days after the last dose

ADULTS – RENEWAL CRITERIA

Zuranolone treatment has not been evaluated for more than 1 course of treatment per pregnancy; cannot be renewed for current postpartum depression (PPD) episode.

ADULTS – RECOMMENDED DOSAGE CRITERIA

- The recommended dosage of zuranolone is 50 mg (two 25 mg capsules) once daily in the evening for 14 days taken with 400 to 1,000 calories of food containing 25% to 50% fat. The dose may be reduced to 40 mg (two 20 mg capsules) once daily in the evening in patients who experience CNS depressant effects. When used concomitantly with a strong CYP3A4 inhibitor, in patients with moderate or severe renal impairment, or in patients with severe hepatic impairment, the recommended dosage is 30 mg once daily in the evening for 14 days. There is no data to support use beyond a single 14-day treatment course.
- Zuranolone may be used alone or in conjunction with oral antidepressant therapy.

REVISION HISTORY

Date	Issues/Updates
06/26/2024	• Initial draft creation