

New Hampshire Medicaid Fee-for-Service Program Zurzuvae™ (zuranolone) Criteria

Approval Date: June 10, 2024

Medications

Brand Names	Generic Names	Indication
Zurzuvae™	zuranolone	Treatment of postpartum depression in adults

Criteria for Approval

1. Patient is 18 years of age or older; **AND**
2. Prescriber is a psychiatrist or an obstetrician-gynecologist or one has been consulted; **AND**
3. Patient has a diagnosis of severe postpartum depression (PPD) determined by a standardized, screening tool for depression (such as, but not limited to, Edinburgh Postnatal Depression Scale [EPDS], Hamilton Rating Scale for Depression [HAM-D], Patient Health Questionnaire-9 [PHQ-9], Beck Depression Inventory [BDI]); **AND**
4. The time of the onset of PPD symptoms is provided, and onset of symptoms occurred during the third trimester of pregnancy (week 27 of the pregnancy) up to 1 year after delivery; **AND**
5. Patient is 12 months or less postpartum on the date of the request (date of delivery will be provided) and the patient has received counseling concerning potential risk of fetal harm; **AND**
6. Patient 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; **AND**
7. Prescriber attests to counseling the patient to refrain from engaging in potentially hazardous activities requiring mental alertness, including driving, for 12 hours or more after each zuranolone dose; **AND**
8. Prescriber attests to counseling the patient to take the medication with 400–1,000 calories of food containing 25–50% fat; **AND**
9. If the patient is taking another oral antidepressant medication, the dose has been stable for at least 30 days; **AND**
10. Prescriber attests to assessing concomitant medications for potential drug interactions and adjusting zuranolone dosage according to labeling (e.g., CNS depressants, CYP3A4 inhibitors, CYP3A4 inducers); **AND**
11. Baseline renal and hepatic function have been assessed and dosing is appropriate according to label; **AND**
12. Patient has an estimated glomerular filtration rate (eGFR) of 15 mL/min/1.73m² or more and does not require dialysis.

Initial approval period: 14 days

Criteria for Denial

1. Failure to meet approval criteria.

Renewal Criteria

1. Zurzuvae™ treatment has not been evaluated for more than one course of treatment per pregnancy. Cannot be renewed for current postpartum depression (PPD) episode.

References

Available upon request.

Revision History

Reviewed by	Reason for Review	Date Approved
DUR Board	New	05/07/2024
Commissioner designee	Approval	06/10/2024