Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

Zurzuvae® (zuranolone) PA Criteria

Zurzuvae® (zuranolone) is indicated for the treatment of postpartum depression (PPD) in adults.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Approve if the patient meets the following:

Limitation: Initial approval period of 30 days. Duration of therapy limited to 14 days with quantity limit of #28 capsules

☐ Yes ☐ No Patient is ≥ 18 years of age;

AND

☐ Yes ☐ No Patient meets **ALL** of the following (i, ii, iii):

i. Patient has a documented diagnosis of a major depressive episode, defined by DSM-5 criteria; **AND**

ii. Patient has been diagnosed with severe depression, determined by (e.g. HAM-D, MADRS, PHQ-9); **AND**

iii. Symptom onset began during the third trimester of pregnancy or up to 4 weeks post-delivery; **AND**

☐ Yes ☐ No Patient is ≤ 12 months postpartum;

AND

☐ Yes ☐ No Patient is not currently pregnant;

AND

☐ Yes ☐ No Patient has tried and failed for a minimum of 4 weeks at up to maximally indicated dose but no less than the commonly recognized minimum therapeutic dose

(see Table 7 for reference), unless clinically significant adverse effects are experienced or all or contraindicated:

a. Selective Serotonin Reuptake Inhibitor (SSRI)
b. Serotonin-Norephineprine Reuptake Inhibitor (SNRI)
c. Buproprion
d. Mirtazepine
e. Tricyclic Antidepressant (TCA); **AND**

☐ Yes ☐ No Zurzuvae is being prescribed by or in consultation with a psychiatrist or an obstetrician-gynecologist;

AND

☐ Yes ☐ No Member has not received prior treatment with Zulresso™ or Zurzuvae for the current pregnancy;

AND

☐ Yes ☐ No Prescriber attests that the patient has been counseled and has agreed to adhere to the following:

i. Will follow instructions to not drive or operate machinery until at least 12 hours after taking each dose of Zurzuvae for the duration of the 14-day treatment course; **AND**

ii. Patient is informed that they may not be able to assess their own driving competence or the degree of driving impairment caused by Zurzuvae.

*** See Package Insert for specific details on Contraindications/Warnings/Precautions**

Dosage and Administration

Table 6. Dosing and Administration[1]

Adult Dose	Pediatric Dose	Availability
Monotherapy or adjunct to oral antidepressant therapy Capsule: 50 mg once daily in the evening with a fat-containing food for 14 days Reduce dose to 40 mg daily if CNS depressant effects occur Reduce dose to 30 mg daily for moderate/severe renal impairment or severe hepatic impairment.	Safety and efficacy in children have not been established.	20 mg Bottle of 14 capsules 25 mg Bottle of 14 capsules Blister-pack of 28 capsules 30 mg Bottle of 14 capsules

Clinical Alternatives

Table 7. Cost Comparison of Clinical Alternatives

Medication	Dosing Frequency
citalopram 10 mg citalopram 20 mg citalopram 40 mg	Major Depressive Disorder 10 mg to 40 mg once daily
bupropion 75 mg tablet bupropion 100 mg tablet	Major Depressive Disorder 100 mg twice daily to 100 mg three times daily (max 450 mg/day and max 150 mg/dose)
bupropion SR 100 mg tablet bupropion SR 150 mg tablet bupropion SR 200 mg tablet	Major Depressive Disorder 150 mg daily to 200 mg twice daily
bupropion XL 150 mg tablet bupropion XL 300 mg tablet bupropion XL 450 mg tablet	Major Depressive Disorder 150 mg to 40 mg once daily
duloxetine 20 mg capsule duloxetine 30 mg capsule duloxetine 60 mg capsule	Major Depressive Disorder 20 mg twice daily to 60 mg twice daily
escitalopram 5 mg tablet escitalopram 10 mg tablet escitalopram 20 mg tablet	Major Depressive Disorder 5 mg to 20 mg once daily
fluoxetine 10 mg capsule fluoxetine 20 mg capsule fluoxetine 40 mg capsule	Major Depressive Disorder 10 mg to 80 mg daily
mirtazapine 7.5 mg tablet mirtazapine 15 mg tablet mirtazapine 30 mg tablet mirtazapine 45 mg tablet	Major Depressive Disorder 15 mg to 45 mg once daily
sertraline 25 mg tablet sertraline 50 mg tablet sertraline 100 mg tablet	Major Depressive Disorder 25 to 200 mg once daily
venlafaxine 25 mg tablet venlafaxine 50 mg tablet	Major Depressive Disorder 25 mg three times daily to 125 mg three times daily

Medication	Dosing Frequency
venlafaxine 75 mg tablet venlafaxine 100 mg tablet	
venlafaxine 37.5 mg ER capsule venlafaxine 75 mg ER capsule venlafaxine 150 mg ER capsule venlafaxine 37.5 mg ER tablet venlafaxine 75 mg ER tablet venlafaxine 150 mg ER tablet venlafaxine 225 mg ER tablet	Major Depressive Disorder 37.5 mg to 375 mg once daily
Zulresso® (brexanolone)	Postpartum Depression One time infusion: hours 0 to 4: 30 mcg/kg/hour hours 4 to 24: 60 mcg/kg/hour hours 24 to 52: 90 mcg/kg/hour hours 52 to 56: 60 mcg/kg/hour hours 56 to 60: 30 mcg/kg/hour
Zurzuvae® 20 mg capsule Zurzuvae® 25 mg capsule Zurzuvae® 30 mg capsule	Postpartum Depression Initial dosing (normal hepatic/renal function): 50 mg once daily in the evening for 14 days. Dose may be reduced to 40 mg once daily if CNS depressant effects occur Severe Hepatic Impairment OR Moderate/Severe Renal Impairment: Recommended dosage is 30 mg once daily in the evening for 14 days