Generic Name: zuranolone

Applicable Drugs: Zurzuvae (zuranolone)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/20/2024

Date Last Reviewed / Revised: 5/20/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to XIII are met)

I. Diagnosis of severe postpartum depression and the following criteria A and B are met:
   A. Documented diagnosis of major depressive episode without psychosis using the current Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnostic criteria.
   B. Documentation that the current depressive episode is severe based on a standardized, validated screening tool (eg, Hamilton Rating Scale for Depression [HAM-D], Patient Health Questionnaire [PHQ-9], Edinburgh Postnatal Depression Scale [EPDS], Montgomery-Asberg Depression Rating Scale [MADRS]).

II. Symptom onset of the current depressive episode began during the third trimester of pregnancy or within 4 weeks postpartum.

III. Minimum age requirement: 18 years old.

IV. Member is ≤ 12 months postpartum.

V. Documentation of a negative serum pregnancy test.

VI. Member does not have a diagnosis of bipolar disorder, schizophrenia, schizoaffective disorder, or active psychosis.

VII. Documentation of A or B:
   A. Treatment failure, intolerance, or contraindication to ≥ 2 antidepressants from the following classes at maximally tolerated therapeutic dose for a minimum of 4 weeks:
      i. Selective serotonin reuptake inhibitor (SSRI)
      ii. Serotonin-norepinephrine reuptake inhibitor (SNRI)
      iii. Bupropion
      iv. Mirtazapine
      v. Tricyclic Antidepressant (TCA)
   B. Prescriber submitted clinical justification to support the use of the requested agent over other guideline-recommended antidepressants.

VIII. Lactation has ceased, or breastmilk produced will not be used for feedings one day before starting Zurzuvae until 7 days after the last dose.

IX. Attestation that the member agrees to use contraception while on Zurzuvae and continue to for 7 days following the completion of the 14-day treatment course.

X. Attestation that the member has been counseled and has agreed to not drive or operate machinery at least 12 hours after taking each dose of Zurzuvae for the 14-day treatment course.

XI. Treatment is prescribed by or in consultation with a specialist in the management of patients with post-partum depression (eg, psychiatrist, obstetrician-gynecologist).

XII. The request is for a medication with the appropriate FDA labeling or current clinical practice guidelines supporting its use.

XIII. Documentation that the member has not received prior treatment with Zulresso (brexanolone) or Zurzuvae (zuranolone) for the current pregnancy.

Exclusion Criteria

- Pregnancy
- Renal impairment: eGFR <15 mL/minute/1.73 m2
- Prior treatment with Zurzuvae or Zulresso (brexanolone) for the current pregnancy.

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Zurzuvae 50 mg daily dose: Use 25 mg capsules; 28 per 14-day supply.
- Zurzuvae 40 mg daily dose: Use 20 mg capsules; 28 per 14-day supply.
- Zurzuvae 30 mg daily dose: Use 30 mg capsules; 28 per 14-day supply.

Approval Length

- **Authorization:** One 14-day treatment course per pregnancy.
- **Re-Authorization:** N/A: The safety and effectiveness of Zurzuvae use beyond 14 days in a single treatment course have not been evaluated.

Appendix

N/A

References

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2. American Psychiatric Association (APA). Depressive Disorders. In: Diagnostic and statistical manual of mental disorders: 5th edition text revision DSM-5-TR. 2022. Accessed January 9, 2024. https://dsm.psychiatryonline.org/doi/full/10.1176/appi.books.9780890425787.x04_Depressive_Disorders
3. Deligiannidis KM, Meltzer-Brody S, Gunduz-Bruce H, et al. Effect of Zuranolone vs Placebo in Postpartum Depression: A Randomized Clinical Trial [published correction appears in JAMA Psychiatry. 2022 Jul 1;79(7):740] [published correction appears in JAMA Psychiatry. 2023 Feb 1;80(2):191]. JAMA Psychiatry. 2021;78(9):951-959. doi:10.1001/jamapsychiatry.2021.1559
4. Deligiannidis KM, Meltzer-Brody S, Gunduz-Bruce H, et al. Effect of Zuranolone vs Placebo in Postpartum Depression: A Randomized Clinical Trial [published correction appears in JAMA Psychiatry. 2022 Jul 1;79(7):740] [published correction appears in JAMA Psychiatry. 2023 Feb 1;80(2):191]. JAMA Psychiatry. 2021;78(9) (suppl 1):951-959. doi:10.1001/jamapsychiatry.2021.1559
5. Deligiannidis KM, Meltzer-Brody S, Maximos B, et al. Zuranolone for the Treatment of Postpartum Depression. Am J Psychiatry. 2023;180(9):668-675. doi:10.1176/appi.ajp.20220785
6. Deligiannidis KM, Meltzer-Brody S, Maximos B, et al. Zuranolone for the Treatment of Postpartum Depression. *Am J Psychiatry*. 2023;180(9) (suppl 1): 668-675. doi:10.1176/appi.ajp.20220785
7. Zuranolone for the treatment of postpartum depression: ACOG Practice Advisory. 2023 August. Accessed March 15, 2024. https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/08/zuranolone-for-the-treatment-of-postpartum-depression
8. Treatment and management of mental health conditions during pregnancy and postpartum: ACOG Clinical Practice Guideline No. 5. Obstet Gynecol. 2023 Jun 1;141(6):1262-1288.
9. Screening and diagnosis of mental health conditions during pregnancy and postpartum: ACOG Clinical Practice Guideline No. 4. Obstet Gynecol. 2023 Jun 1;141(6):1232-1261.