Clinical Policy Title:	zuranolone
Policy Number:	RxA.809
Drug(s) Applied:	Zurzuvae™
Original Policy Date:	5/29/2024
Last Review Date:	6/6/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Postpartum Depression (PPD) (must meet all):

1. Diagnosis of mild, moderate, or severe postpartum depression (PPD)
2. For severe PPD, member meets one of the following (a or b):
   a) Ham-D score of ≥24
   b) Prescriber determines diagnosis of severe depression using the Edinburgh Postnatal Depression Scale and clinical evaluation
3. For diagnosis of mild to moderate PPD, member must have trial and failure of ≥6 weeks of at least 1 antidepressant from the following drug classes (a or b):
   a) Selective serotonin reuptake inhibitor (SSRI)
   b) Serotonin and norepinephrine reuptake inhibitor (SNRI)
4. Treatment duration does not exceed 14 days.
5. Prescriber attests that the member will follow up with a behavioral health professional for counselling and/or consultation.

Approval duration

All Lines of Business (except Medicare): 14 days per 365 days

II. Continued Therapy Approval

A. Postpartum Depression (PPD)

1. Therapy is limited to 14 days per 365-day period, additional therapy is subject to initial approval.

References

1. Zurzuvae. Package insert. Sage Therapeutics, Inc. 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217369s000lbl.pdf
2. Zimmerman M, Martinez JH, Young D, Chelminski I, Dalrymple K. Severity classification on the Hamilton Depression Rating Scale. *J Affect Disord*. 2013;150(2):384-388. doi:10.1016/j.jad.2013.04.028

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	6/6/2024	5/29/2024