

Clinical Policy Title:	zuranolone
Policy Number:	RxA.809
Drug(s) Applied:	Zurzuvae™
Original Policy Date:	5/29/2024
Last Review Date:	12/11/2025
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
Policy reviewed.	12/05/2024	N/A

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Policy reviewed.	12/11/2025	12/11/2025
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