



Pharmacy Drug Policy & Procedure

Policy Name:	Zurzuvae (zuranolone)	Policy#:	3254P
---------------------	-----------------------	-----------------	-------

Purpose of the Policy

The purpose of this policy is to define coverage criteria for Zurzuvae (zuranolone)

Statement of the Policy

Health Alliance Medical Plans will approve the use of Zurzuvae (zuranolone) under specialty pharmacy the benefit if the following criteria are met.

Criteria

1. Postpartum Depression (PPD)

- 1.1 Diagnosis of postpartum depression
- 1.2 Onset of symptoms (major depressive episodes) in the third trimester or within 4 weeks of delivery AND patient is ≤12 months postpartum
- 1.3 Age 18 years or older
- 1.4 Prescriber attests that the patient has been counseled and has agreed to adhere to the following:
 - Patient 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
- 1.5 Documented trial and failure of 3 months, contraindication, or intolerance to at least one SSRI or SNRI (e.g., escitalopram, sertraline) during current PPD episode or previous depressive episodes

2. Exclusion Criteria

- 2.1 Patient is currently pregnant
- 2.2 Attempted suicide or at significant risk of suicide associated with current episode of PPD
- 2.3 Medical history of seizures, bipolar disorder, schizophrenia or schizophrenic disorder
- 2.4 Zurzuvae is considered experimental for the treatment of major depressive disorder

3. Managed Dose Limit

- 3.1 20mg, 25mg capsules: #28 per 365 days
- 3.2 30mg capsules: #14 per 365 days
 - 30mg dosing recommended in patients with renal impairment (GFR < 60 ml/min) or taking a strong CYP3A4 inhibitor or severe hepatic impairment (Child Pugh C)

4. Approval Period

- 4.1 14 days over 12 months
- 4.2 Limited to one approval within 12 months

CPT Codes

--	--

HCPCS Codes

--	--

References

1. Zurzuva (zuranolone) [prescribing information]. Cambridge, MA: Biogen Inc; August 2023.
2. Deligiannidis KM, Meltzer-Brody S, Maximos B, et al. Zuranolone for the Treatment of Postpartum Depression (SKYLARK). *Am J Psychiatry*. 2023 Sep 1;180(9):668-675.
3. Deligiannidis KM, Meltzer-Brody S, Gunduz-Bruce H, et al. Effect of Zuranolone vs Placebo in Postpartum Depression: A Randomized Clinical Trial (ROBIN). *JAMA Psychiatry*. 2021 Sep 1;78(9):951-959.
4. 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.
5. American College of Obstetricians and Gynecologists (ACOG) Practice Advisory. Zuranolone for the treatment of postpartum depression. 2023. <https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/08/zuranolone-for-the-treatment-of-postpartum-depression>

Created Date: 08/07/24

Effective Date: 08/07/24

Posted to Website: 08/07/24

Revision Date:

DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.