Prior Authorization Checklist

ZURZUVAE®
(zuranolone) capsules Ⓒ IV
20 mg • 25 mg • 30 mg

The prior authorization (PA) process requires healthcare providers (HCPs) to provide additional rationale or clinical information to a patient's health plan to determine if a specific medication will be covered.

This checklist is presented for informational purposes only and is not intended to be a substitute for information that an individual HCP deems appropriate to provide. It is not a statement, promise, or guarantee concerning coverage and/or levels of reimbursement.

PAs are very common for branded medications, such as ZURZUVAE, to help health plans decide whether certain drugs or services will be used appropriately.

*PAs initiated by the HCP**

- Once the ZURZUVAE prescription has been sent to a network specialty pharmacy, the PA should be created in an ePA system or using the health plan's specific PA form
- You can initiate, submit, and monitor the status of a PA through an online ePA platform such as CoverMyMeds® to help streamline the process
- Once the ZURZUVAE prescription has been sent to the specialty pharmacy, please respond to all communications from them and/or the patient's health plan accurately and as soon as possible to help minimize potential denials and delays in accessing therapy for your patients

PAs initiated by the specialty pharmacy

- Sage Therapeutics and Biogen have collaborated with a limited network of specialty pharmacies to provide support throughout the PA process
- The specialty pharmacy network for ZURZUVAE has the ability to initiate the PA process; however, this may delay patient access as your office will still need to collect the required information and submit the PA
- In most cases, the network specialty pharmacy will provide you with a key to an ePA system to review, complete, and submit the PA request
- The HCP will complete the PA request form and verify that all information included in the form is complete and accurate before submitting it to the health plan to minimize delays

*Preferred method for PA initiation.
CoverMyMeds® is a registered trademark of CoverMyMeds, LLC.
ePA=electronic prior authorization.

INDICATION

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

IMPORTANT SAFETY INFORMATION

WARNING: IMPAIRED ABILITY TO DRIVE OR ENGAGE IN OTHER POTENTIALLY HAZARDOUS ACTIVITIES

ZURZUVAE causes driving impairment due to central nervous system (CNS) depressant effects.

Advise patients not to drive or engage in other potentially hazardous activities until at least 12 hours after ZURZUVAE administration for the duration of the 14-day treatment course. Inform patients that they may not be able to assess their own driving competence, or the degree of driving impairment caused by ZURZUVAE.

Please see additional Important Safety Information throughout and full Prescribing Information, including **Boxed Warning**.

PA checklist

1 Send ZURZUVAE prescription to the network specialty pharmacy

☐ ***Include all necessary patient and provider information within the prescription and files sent to the network specialty pharmacy***

- ☐ Patient details
- ☐ Date of birth
- ☐ Date of service/prescription
- ☐ Patient's **pharmacy** benefit information such as RxBIN, RxPCN, RxGroup, and member ID number (separate information from medical benefit)
- ☐ Physician name, specialty, and tax ID number
- ☐ Facility name and tax ID number

☐ ***Ensure the ZURZUVAE prescription is sent to one of the network specialty pharmacies***

Verify specialty pharmacy options or requirements with your patient's insurance to prevent potential delays in the process

Network Specialty Pharmacy	Contact Information
[Accredo]	Phone: [800-272-3858]; Fax: [888-302-1028]
[Alto Pharmacy®]	Phone: [800-874-5881]; Fax: [415-484-7058]
[CVS Specialty®]	Phone: [866-993-4779]; Fax: [844-850-7915]
[Special Care Pharmacy Services]	Phone: [888-727-1727]; Fax: [787-783-2951]
[Walmart Specialty Pharmacy]	Phone: [877-453-4566]; Fax: [866-537-0877]

2 Complete and submit the PA request

☐ ***Identify***, review, and document any health plan–specific requirements for the PA request

☐ ***Create*** the PA within the ePA system or complete the health plan's specific PA form including any supplemental documentation that supports the treatment decision for ZURZUVAE, such as the patient diagnosis ICD-10 code: F53.0: Postpartum Depression[1]

☐ ***Submit*** the PA form via the ePA system or the preferred method of the patient's health plan (eg, phone, fax, email, health plan website)

3 Track the status of the request and follow up as needed

☐ ***Track*** the status of the PA request using the link and/or key provided by the network specialty pharmacy; once a PA decision is received, provide documentation to the specialty pharmacy as soon as possible to avoid delays in dispensing ZURZUVAE

☐ ***Follow up:***

- With the health plan on their PA decision and provide any requested information as soon as possible
- With the specialty pharmacy by phone to ensure ZURZUVAE dispensing is in progress following a PA approval

ICD-10=International Classification of Diseases, Tenth Revision; ID=identification; RxBIN=prescription bank identification number; RxGroup=prescription group number; RxPCN=prescription processor control number.

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PA considerations

Include a documented diagnosis supported by clinical records

If requested by the plan, include the postpartum depression–specific ICD-10 diagnosis code, as noted below. Using other ICD-10 codes related to depression will likely require resubmission with an appropriate ICD-10 code and may delay coverage decisions.

ICD-10 diagnosis code[1]
F53.0: Postpartum depression

This code is presented for informational purposes only. It is not a statement, promise, or guarantee concerning coverage and/or levels of reimbursement, payment, or charge and is not intended to increase or maximize reimbursement by any payer. It is the responsibility of the healthcare provider to determine the appropriate code(s) for service provided to his or her patient.

Some health plans may ask for additional supporting information; include the following as applicable:

- Some plans may require trial and failure of generic medications before approving ZURZUVAE. If so, ensure proper documentation of each medication trial is included, specifying dates of use and reason for discontinuation
- Results of your patient's depression screening assessment(s) (eg, EPDS or PHQ-9)
- A letter of medical necessity, especially if a lengthier rationale or additional context for the patient's medical history is needed
- A copy of the Prescribing Information

EPDS=Edinburgh Postnatal Depression Scale; PHQ-9=Patient Health Questionnaire, 9th module.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

Impaired Ability to Drive or Engage in Other Potentially Hazardous Activities

- ZURZUVAE causes driving impairment due to central nervous system (CNS) depressant effects
- Advise patients not to drive a motor vehicle or engage in other potentially hazardous activities requiring complete mental alertness, such as operating machinery, until at least 12 hours after ZURZUVAE administration for the duration of the 14-day treatment course. Inform patients that they may not be able to assess their own driving competence or the degree of driving impairment caused by ZURZUVAE

Central Nervous System Depressant Effects

- ZURZUVAE can cause CNS depressant effects such as somnolence and confusion
- Somnolence developed in 36% of patients who received ZURZUVAE (50 mg) and in 6% of patients who received placebo daily. Some ZURZUVAE-treated patients developed confusional state. One of these cases was severe, and was also associated with somnolence, dizziness, and gait disturbance

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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Central Nervous System Depressant Effects (continued)

- A higher percentage of ZURZUVAE-treated patients, compared to placebo-treated patients, experienced somnolence, dizziness, or confusion that required dosage reduction, interruption, or discontinuation
- Because ZURZUVAE can cause CNS depressant effects, patients may be at higher risk of falls
- Other CNS depressants such as alcohol, benzodiazepines, opioids, tricyclic antidepressants, or drugs that increase zuranolone concentration, may increase impairment of psychomotor performance or CNS depressant effects such as somnolence, cognitive impairment, and the risk of respiratory depression in ZURZUVAE-treated patients
- To reduce the risk of CNS depressant effects and/or mitigate CNS depressant effects that occurs with ZURZUVAE treatment:
  - If patients develop CNS depressant effects, consider dosage reduction or discontinuation of ZURZUVAE
  - If use with another CNS depressant is unavoidable, consider dosage reduction
  - Reduce the ZURZUVAE dosage in patients taking strong CYP3A4 inhibitors

Suicidal Thoughts and Behavior

- In pooled analyses of placebo-controlled trials of chronically administered antidepressant drugs (SSRIs and other antidepressant classes) that included approximately 77,000 adult patients and 4,500 pediatric patients, the incidence of suicidal thoughts and behaviors in antidepressant-treated patients age 24 years and younger was greater than in placebo-treated patients. There was considerable variation in risk of suicidal thoughts and behaviors among drugs, but there was an increased risk identified in young patients for most drugs studied. There were differences in absolute risk of suicidal thoughts and behaviors across the different indications, with the highest incidence in patients with major depressive disorder (MDD)
- ZURZUVAE does not directly affect monoaminergic systems. Consider changing the therapeutic regimen, including discontinuing ZURZUVAE, in patients whose depression becomes worse or who experience emergent suicidal thoughts and behaviors

Embryo-fetal Toxicity

- Based on findings from animal studies, ZURZUVAE may cause fetal harm when administered to a pregnant woman
- Advise a pregnant woman of the potential risk to an infant exposed to ZURZUVAE in utero. Advise females of reproductive potential to use effective contraception during treatment with ZURZUVAE and for one week after the final dose

ADVERSE REACTIONS

- The most common adverse reactions (≥5% and greater than placebo) in ZURZUVAE-treated patients were somnolence, dizziness, diarrhea, fatigue, nasopharyngitis, and urinary tract infection

DRUG INTERACTIONS

CNS Depressant Drugs and Alcohol

- Caution should be used when ZURZUVAE is administered in combination with other CNS drugs or alcohol. If use with another CNS depressant is unavoidable, consider dosage reduction

Strong CYP3A4 Inhibitors

- Reduce the ZURZUVAE dosage when used with a strong CYP3A4 inhibitor

CYP3A4 Inducers

- Avoid concomitant use of ZURZUVAE with CYP3A4 inducers

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IMPORTANT SAFETY INFORMATION (continued)

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USE IN SPECIFIC POPULATIONS

Pregnancy

- There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antidepressants, including ZURZUVAE, during pregnancy. Healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visiting online at https://womensmentalhealth.org/research/pregnancyregistry/antidepressants/
- Based on findings from animal studies, ZURZUVAE may cause fetal harm. Advise pregnant women of the potential risk to a fetus. Available data on ZURZUVAE use in pregnant women from the clinical development program are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes

Lactation

- Available data from a clinical lactation study in 14 women indicate that zuranolone is present in low levels in human milk. There are no data on the effects of zuranolone on a breastfed infant and limited data on the effects on milk production
- The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ZURZUVAE and any potential adverse effects on the breastfed child from ZURZUVAE or from the underlying maternal condition

Hepatic Impairment

- The recommended ZURZUVAE dosage in patients with severe hepatic impairment (Child-Pugh C) is lower than patients with normal hepatic function

Renal Impairment

- The recommended ZURZUVAE dosage in patients with moderate and severe renal impairment is lower than those with normal renal function

DRUG ABUSE AND DEPENDENCE

- ZURZUVAE contains zuranolone, a Schedule IV controlled substance
- Zuranolone has abuse potential with associated risks of misuse, abuse, and substance use disorder including addiction
- ZURZUVAE may produce physical dependence

Please see full Prescribing Information, including **Boxed Warning**.

Reference: 1. ICD code lists. Centers for Medicare & Medicaid Services. Updated October 29, 2024. https://www.cms.gov/medicare/coordination-benefits-recovery/overview/icd-code-lists. Accessed March 3, 2025.

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