UZEDY®
(risperidone)
50 mg 75 mg 100 mg 125 mg
150 mg 200 mg 250 mg
extended-release injectable suspension

MEDICARE ACCESS AND COVERAGE

A provider's guide to Medicare—authorizations, exceptions, and appeals—for adult patients prescribed UZEDY® (risperidone)

INDICATION AND USAGE

UZEDY (risperidone) extended-release injectable suspension for subcutaneous use is indicated for the treatment of schizophrenia in adults.

IMPORTANT SAFETY INFORMATION

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. UZEDY is not approved for use in patients with dementia-related psychosis and has not been studied in this patient population.

CONTRAINDICATIONS: UZEDY is contraindicated in patients with a known hypersensitivity to risperidone, its metabolite, paliperidone, or to any of its components. Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been reported in patients treated with risperidone or paliperidone.

Please see the Important Safety Information on pages 6 to 8 and the full Prescribing Information for UZEDY, including Boxed WARNING.

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FORMULARY EXCEPTIONS

Say NO to access barriers—help your patient get UZEDY

When UZEDY is prescribed for a patient with Medicare insurance, there may be different coverage pathways based on their health plan's formulary and step requirements. Prior authorizations (PAs) are a common requirement payers implement to ensure appropriate use of certain drugs and services.[1] However, if UZEDY is not included on a plan sponsor's formulary, you may need to request a medical exception—specifically, a formulary exception. A formulary exception request is a type of PA used when a drug is non-formulary.[2] Completing the formulary exception process can help your patient access UZEDY.

ACCESS STEPS

STEP 1

Complete a letter of medical necessity

Prepare a letter of medical necessity to include with the formulary exception request for your patient, making sure to fill out all of the required information. A sample letter and additional instructions can be found on the next page.

STEP 2

Complete a Medicare prescription drug coverage determination form

Go to CoverMyMeds.com and look up your patient's prescription plan to find the appropriate Medicare prescription drug coverage determination form (sometimes called the Medicare non-formulary drug coverage form). Be sure to complete all of the information in the form carefully, including choosing the correct type of coverage determination, listing any medications the patient has previously tried, and providing all requested information.

CoverMyMeds® is a no-cost solution to help support providers through a UZEDY PA request.

STEP 3

Initiate the formulary exception request

Submit the Medicare prescription drug coverage determination form through CoverMyMeds or directly on the plan's website. Make sure to include the letter of medical necessity along with any other specific documentation that is required for the plan.

UZEDY Access and Reimbursement Managers (ARMs) are available with expertise at every step. Ask your sales representative how to contact your ARM today.

Medicare prescription drug coverage determination and redetermination

Learn more at CMS.gov >

A Medicare Part D plan sponsor may have their own request form, which should be completed when available as this may ensure appropriate and required information is provided. Additionally, completion and submission of a CMS coverage determination form may be required. A formulary exception request letter would accompany the CMS coverage determination form when it is submitted.

CMS, Centers for Medicare & Medicaid Services.

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LETTER OF MEDICAL NECESSITY

Be comprehensive—the details matter

A medical exception usually requires specific documentation, including a **letter of medical necessity**, and additional information about the patient's medical history. **A letter of medical necessity is often required when asking a health plan for a formulary exception.**

Be sure to include comprehensive details in the letter of medical necessity, such as:

- Patient diagnosis and indication for UZEDY
- Overview of the course of schizophrenia and treatment challenges
- Severity of the patient's condition and symptoms, including functional status and limitations
- Summary of previous treatments and rationale for discontinuation
- Recent emergency treatment, hospitalization, and number of prior relapses
- Clinical rationale for treatment with UZEDY specific to the patient's history and current functioning

Clinical rationale may include:

- Clinical trial outcomes supporting approval (e.g., reduction in risk of relapse)
- No need for a loading dose or oral supplementation
- 1- or 2-month dosing intervals and 8 dosing options
- Therapeutic plasma levels reached in 24 hours
- Modest needle size (5/8 inch, 21 gauge) with subcutaneous injection sites in the abdomen or upper arm
- Additional enclosures to support the request
  - UZEDY prescribing information
  - Clinical notes/medical records including scores on symptom rating scales (e.g., PANSS)

Sample letter of medical necessity

Rejections can occur if the formulary exception request form or the letter of medical necessity is missing information. Ensure all details are complete and keep a record of all documentation and communications to support your patient's access for UZEDY.

PANSS, Positive and Negative Syndrome Scale.

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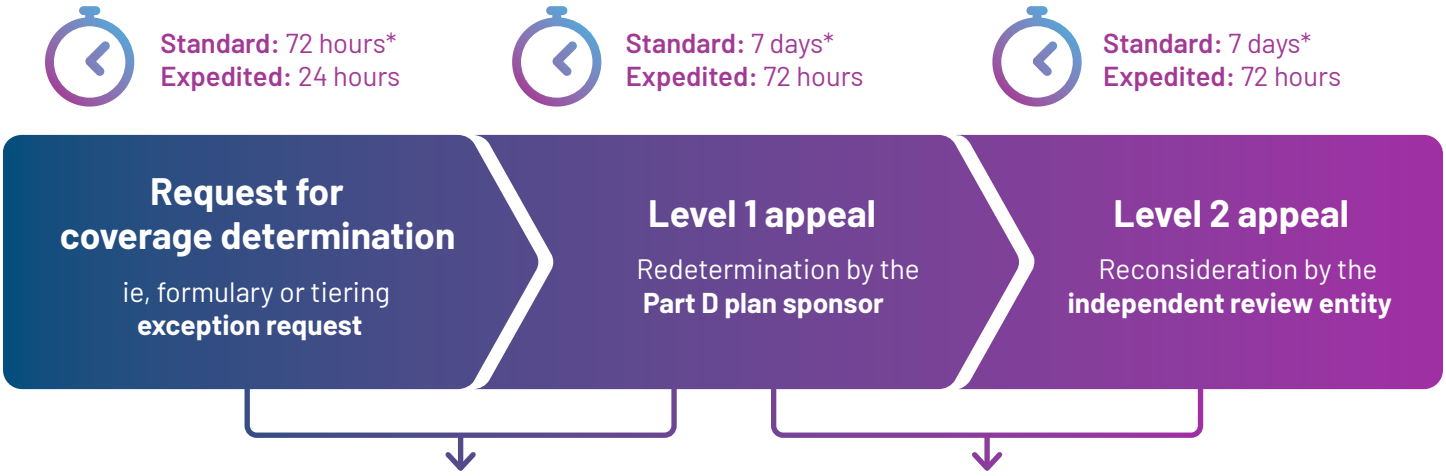
NAVIGATING THE APPEALS PROCESS

Denied coverage request? You and your patient have the right to submit an appeal to the health plan

There are multiple levels of appeals. The payer is required to respond to each level of appeal within a specified period and offer both standard and expedited processes.[3] The figure below illustrates the Medicare timelines for each level of appeal.[4,5]

An appeal must be filed by the deadline that Medicare provides to the patient. However, filing a late appeal and receiving a decision is possible if a good reason for missing the deadline can be shown.[6]

MEDICARE REVIEW TIMELINE[5]



As a reminder, non-Medicare payers may have different timelines.

*Time limits shown are for benefit-related appeals. Plans are allowed up to 14 days to respond to payment-related appeals.

Getting help with a UZEDY letter of appeal

To get started with the appeals process, access a sample letter of appeal and follow the instructions.

Sample letter of appeal >

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HELP YOUR PATIENT ACCESS UZEDY

teva | Shared Solutions®

Easy-to-use digital enrollment

Patient initiation and coordination

- Benefits verification
- PA/appeals support
- Medicare and Medicaid benefits navigation support
- Coordination with a dispensing pharmacy

Financial assistance options

- Patient assistance program
- Savings offer

Alternate-site-of-care network

- Directory of convenient locations

Nurse support

- Over-the-phone support and education for patients about their treatment journey

If you have any questions or need support, please call 1-800-887-8100, 9 AM to 8 PM ET, Monday through Friday.

Your UZEDY ARM team can also contact Teva Shared Solutions to assist you.

covermymeds®

PA support for UZEDY

By automating part of the process providers and pharmacists use for PA requests, CoverMyMeds helps patients access their medications faster.*

CoverMyMeds offers a streamlined process for submitting PA requests.

- Available at no cost to providers and their staff
- Receive faster PA determinations, often in real time*
- Submit requests for any medication and all plans

*Compared with phone and fax.

Questions?

CoverMyMeds can help.

Live support available: 1-866-452-5017
or chat at covermymeds.com
Resources: go.covermymeds.com/help

Interested in learning more?

Our UZEDY Access Guide provides information for navigating coverage and access barriers for both government and private payers to help secure coverage for UZEDY.

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IMPORTANT SAFETY INFORMATION

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WARNINGS AND PRECAUTIONS

Cerebrovascular Adverse Reactions: In trials of elderly patients with dementia-related psychosis, there was a significantly higher incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, in patients treated with oral risperidone compared to placebo. UZEDY is not approved for use in patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): NMS, a potentially fatal symptom complex, has been reported in association with antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status including delirium, and autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. If NMS is suspected, immediately discontinue UZEDY and provide symptomatic treatment and monitoring.

Tardive Dyskinesia (TD): TD, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements, may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to predict which patients will develop the syndrome. Whether antipsychotic drug products differ in their potential to cause TD is unknown.

The risk of developing TD and the likelihood that it will become irreversible are believed to increase with the duration of treatment and the cumulative dose. The syndrome can develop, after relatively brief treatment periods, even at low doses. It may also occur after discontinuation. TD may remit, partially or completely, if antipsychotic treatment is discontinued. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome, possibly masking the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.

If signs and symptoms of TD appear in a patient treated with UZEDY, drug discontinuation should be considered. However, some patients may require treatment with UZEDY despite the presence of the syndrome. In patients who do require chronic treatment, use the lowest dose and the shortest duration of treatment producing a satisfactory clinical response. Periodically reassess the need for continued treatment.

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and body weight gain. While all of the drugs in the class have been shown to produce some metabolic changes, each drug has its own specific risk profile.

Hyperglycemia and diabetes mellitus (DM), in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, have been reported in patients treated with atypical antipsychotics, including risperidone. Patients with an established diagnosis of DM who are started on atypical antipsychotics, including UZEDY, should be monitored regularly for worsening of glucose control. Patients with risk factors for DM (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics, including UZEDY, should undergo fasting blood glucose (FBG) testing at the beginning of treatment and

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periodically during treatment. Any patient treated with atypical antipsychotics, including UZEDY, should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics, including UZEDY, should undergo FBG testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic, including risperidone, was discontinued; however, some patients required continuation of antidiabetic treatment despite discontinuation of risperidone.

Dyslipidemia has been observed in patients treated with atypical antipsychotics.

Weight gain has been observed with atypical antipsychotic use. Monitoring weight is recommended.

Hyperprolactinemia: As with other drugs that antagonize dopamine D_2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents.

Orthostatic Hypotension and Syncope: UZEDY may induce orthostatic hypotension associated with dizziness, tachycardia, and in some patients, syncope. UZEDY should be used with particular caution in patients with known cardiovascular disease, cerebrovascular disease, and conditions which would predispose patients to hypotension and in the elderly and patients with renal or hepatic impairment. Monitoring of orthostatic vital signs should be considered in all such patients, and a dose reduction should be considered if hypotension occurs. Clinically significant hypotension has been observed with concomitant use of oral risperidone and antihypertensive medication.

Falls: Antipsychotics, including UZEDY, may cause somnolence, postural hypotension, motor and sensory instability, which may lead to falls and, consequently, fractures or other fall-related injuries. Somnolence, postural hypotension, motor and sensory instability have been reported with the use of risperidone. For patients, particularly the elderly, with diseases, conditions, or medications that could exacerbate these effects, assess the risk of falls when initiating antipsychotic treatment and recurrently for patients on long-term antipsychotic therapy.

Leukopenia, Neutropenia, and Agranulocytosis have been reported with antipsychotic agents, including risperidone. In patients with a pre-existing history of a clinically significant low white blood cell count (WBC) or absolute neutrophil count (ANC) or a history of drug-induced leukopenia or neutropenia, perform a complete blood count (CBC) frequently during the first few months of therapy. In such patients, consider discontinuation of UZEDY at the first sign of a clinically significant decline in WBC in the absence of other causative factors. Monitor patients with clinically significant neutropenia for fever or other symptoms or signs of infection and treat promptly if such symptoms or signs occur. Discontinue UZEDY in patients with ANC < 1000/mm^3) and follow their WBC until recovery.

Potential for Cognitive and Motor Impairment: UZEDY, like other antipsychotics, may cause somnolence and has the potential to impair judgement, thinking, and motor skills. Somnolence was a commonly reported adverse reaction associated with oral risperidone treatment. Caution patients about operating hazardous machinery, including motor vehicles, until they are reasonably certain that treatment with UZEDY does not affect them adversely.

Seizures During premarketing studies of oral risperidone in adult patients with schizophrenia, seizures occurred in 0.3% of patients (9 out of 2,607 patients), two in association with hyponatremia. Use UZEDY cautiously in patients with a history of seizures or other conditions that potentially lower the seizure threshold.

Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Antipsychotic drugs, including UZEDY, should be used cautiously in patients at risk for aspiration.

Priapism has been reported during postmarketing surveillance for other risperidone products. A case of priapism was reported in premarket studies of UZEDY. Severe priapism may require surgical intervention.

Body temperature regulation. Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Both hyperthermia and hypothermia have been reported in association with oral risperidone use. Strenuous exercise, exposure to extreme heat, dehydration, and anticholinergic medications may contribute to an elevation in core body temperature; use UZEDY with caution in patients who experience these conditions.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

ADVERSE REACTIONS

The most common adverse reactions with risperidone (≥5% and greater than placebo) were parkinsonism, akathisia, dystonia, tremor, sedation, dizziness, anxiety, blurred vision, nausea, vomiting, upper abdominal pain, stomach discomfort, dyspepsia, diarrhea, salivary hypersecretion, constipation, dry mouth, increased appetite, increased weight, fatigue, rash, nasal congestion, upper respiratory tract infection, nasopharyngitis, and pharyngolaryngeal pain.

The most common injection site reactions with UZEDY (≥5% and greater than placebo) were pruritus and nodule.

DRUG INTERACTIONS

- Carbamazepine and other strong CYP3A4 inducers decrease plasma concentrations of risperidone.
- Fluoxetine, paroxetine, and other strong CYP2D6 inhibitors increase risperidone plasma concentration.
- Due to additive pharmacologic effects, the concomitant use of centrally-acting drugs, including alcohol, may increase nervous system disorders.
- UZEDY may enhance the hypotensive effects of other therapeutic agents with this potential.
- UZEDY may antagonize the pharmacologic effects of dopamine agonists.
- Concomitant use with methylphenidate, when there is change in dosage of either medication, may increase the risk of extrapyramidal symptoms (EPS)

USE IN SPECIFIC POPULATIONS

Pregnancy: May cause EPS and/or withdrawal symptoms in neonates with third trimester exposure. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to atypical antipsychotics, including UZEDY, during pregnancy. Healthcare providers are encouraged to register patients by contacting the National Pregnancy Registry for Atypical Antipsychotics at 1-866-961-2388 or online at https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/.

Lactation: Infants exposed to risperidone through breastmilk should be monitored for excess sedation, failure to thrive, jitteriness, and EPS.

Fertility: UZEDY may cause a reversible reduction in fertility in females.

Pediatric Use: Safety and effectiveness of UZEDY have not been established in pediatric patients.

Renal or Hepatic Impairment: Carefully titrate on oral risperidone up to at least 2 mg daily before initiating treatment with UZEDY.

Patients with Parkinson's disease or dementia with Lewy bodies can experience increased sensitivity to UZEDY. Manifestations and features are consistent with NMS.

Please see the full Prescribing Information for UZEDY, including Boxed WARNING.

References: 1. Managed care glossary. Academy of Managed Care Pharmacy. Accessed June 17, 2024. https://www.amcp.org/about/managed-care-pharmacy-101/managed-care-glossary **2.** Curtiss FR. What are prior authorization and the formulary exception process? *J Manag Care Pharm.* 2005;11(4):359-361. doi:10.18553/jmcp.2005.11.4.359 **3.** *A Patient's Guide to Navigating the Insurance Appeals Process.* Patient Advocate Foundation. Accessed June 16, 2024. https://www.patientadvocate.org/wp-content/uploads/Navigating-the-insurance-appeals-guide-pages.pdf **4.** Appeals overview. Centers for Medicare & Medicaid Services. Updated September 6, 2023. Accessed June 16, 2024. https://www.cms.gov/medicare/appeals-grievances/prescription-drug/appeals-overview **5.** Medicare prescription drug coverage appeals. Medicare.gov. Accessed June 16, 2024. https://www.medicare.gov/medicare-prescription-drug-coverage-appeals **6.** *Medicare & You 2024*. Centers for Medicare & Medicaid Services. January 2024. Accessed June 17, 2024. https://www.medicare.gov/Pubs/pdf/10050-medicare-and-you.pdf