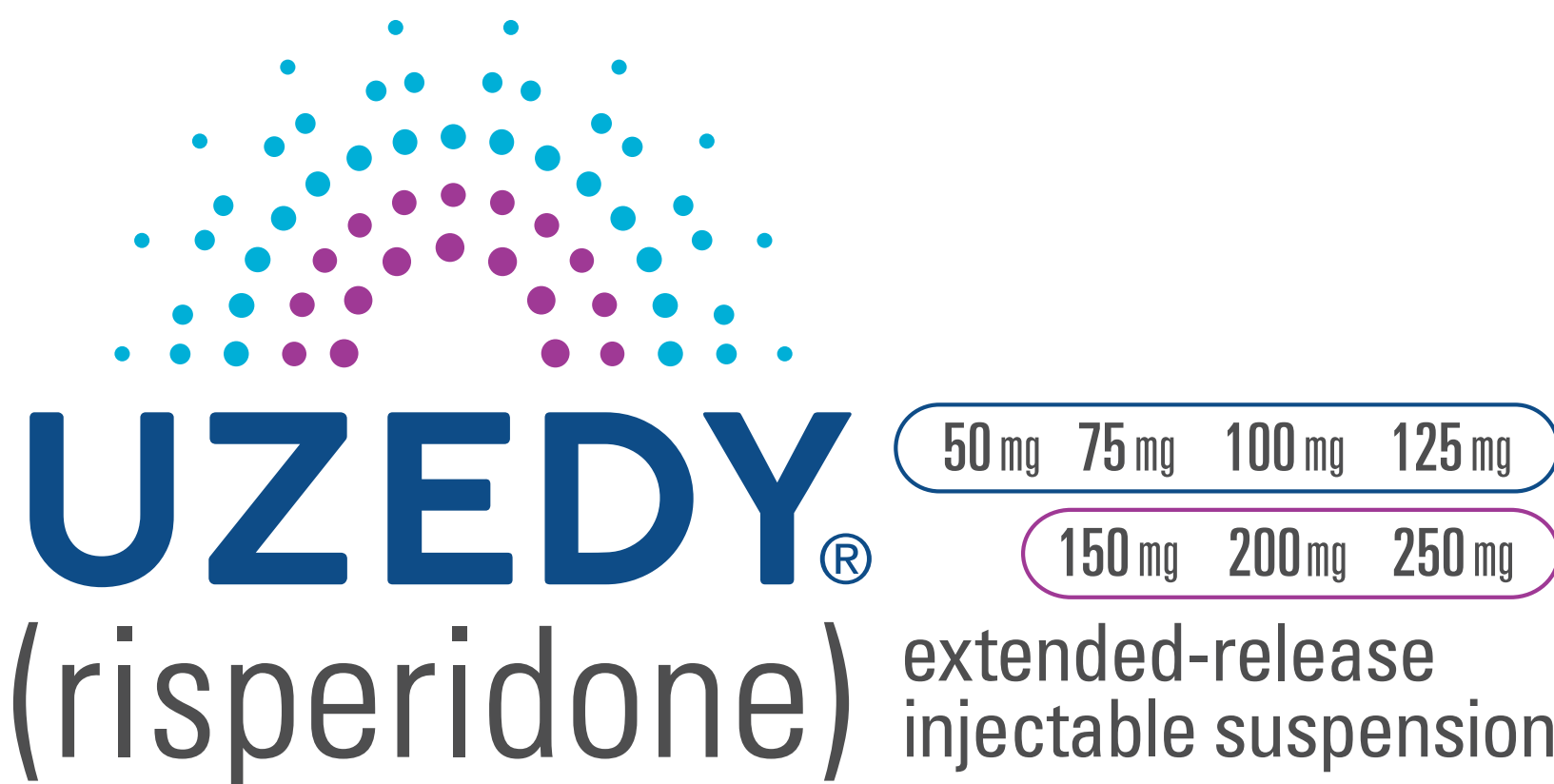




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# ACCESS GUIDE



## Practical guide for providers prescribing UZEDY: Authorizations, exceptions, and appeals

This is a resource to help providers understand how to work with government and private payers to secure coverage for medically necessary prescription drugs.

It covers the 3 primary categories or types of requests for additional information payers may ask a provider to complete regarding a prescribed medication.

These are:

- Prior authorization (PA)
- Exceptions (a type of coverage determination)
- Appeals

### Processes and procedures vary by plan and payer type.

Even if payer does not include a certain medication on their formulary or on a preferred tier, there are still ways to get patients the medications they have been prescribed.

This guide focuses on **practical tips** and **best practices** for a prescriber to provide a payer with the **necessary information** to help alleviate any barriers to patients’ access to medications.

- 1 PRIOR AUTHORIZATION (PA)
  - 1.1 Overview >  
Documentation with PA Requests >
  - 1.2 Checklist >

- 2 EXCEPTIONS
  - 2.1 Overview >  
Timelines >
  - 2.2 Checklist >

- 3 APPEALS
  - 3.1 Overview >
  - 3.2 Medicare Part D Appeals & Timelines >
  - 3.3 Medicaid Appeals >
  - 3.4 Checklist >

- 4 SAMPLE FORMS & LETTERS >

- 5 MEDICAID & MEDICARE RESOURCES >

- 6 ACCESSING UZEDY >

- 7 REFERENCES >

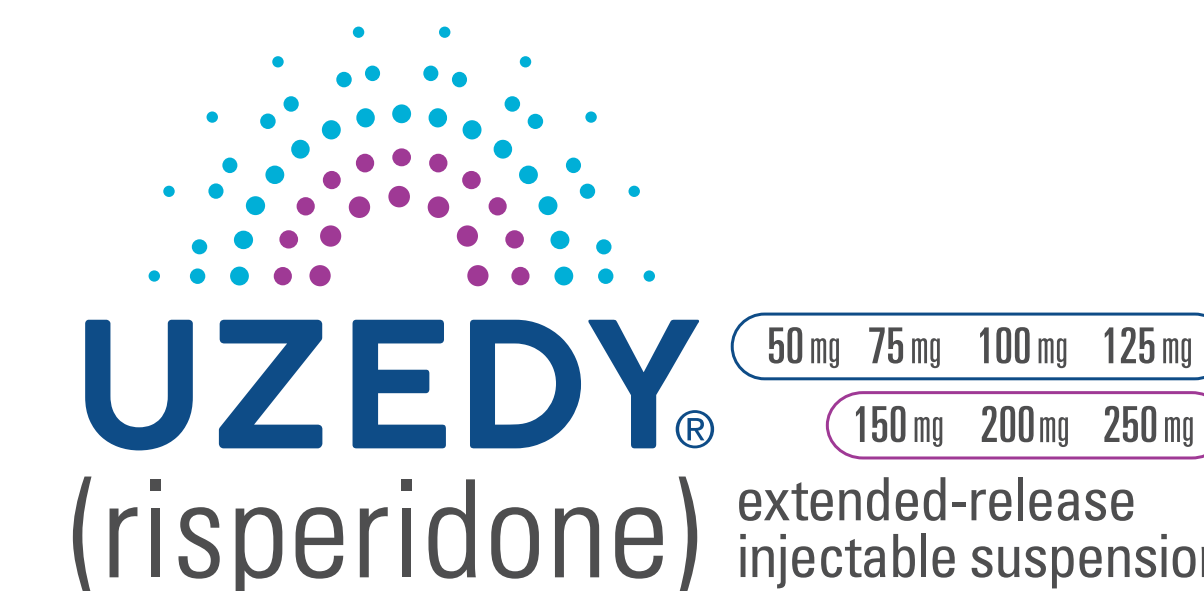
Please see the full [Prescribing Information](#) for UZEDY, including Boxed WARNING.

Prior Authorization	Exceptions	Appeals	Sample Forms & Letters	Medicaid & Medicare Resources	Accessing UZEDY	References
✓ Checklist	✓ Checklist	✓ Checklist				





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# 1.1 PRIOR AUTHORIZATION

## OVERVIEW

PA is a common requirement of government and commercial payers, including pharmacy benefit managers (PBMs). PA describes the processes payers use to **ensure appropriate use** of certain drugs and services.<sup>1</sup> Also called pre-authorization (or pre-auth), a PA process generally requires providers to submit payer-specific **documentation of medical necessity** for a requested therapy or service to be approved for coverage.<sup>2,3</sup>

- The PA process requires the provider to **contact a patient's payer** and receive approval before a certain drug or service will be covered
- The provider must demonstrate why the certain therapy or service is **medically necessary for the patient**



### Tips for success with PAs

- ✓ Many payers have moved PA processes online to streamline and automate review and authorization<sup>4</sup>
- ✓ Always **check the payer's provider portal** for the latest forms and information about how to submit
- ✓ PA support for UZEDY can also be obtained through the [CoverMyMeds](#) portal

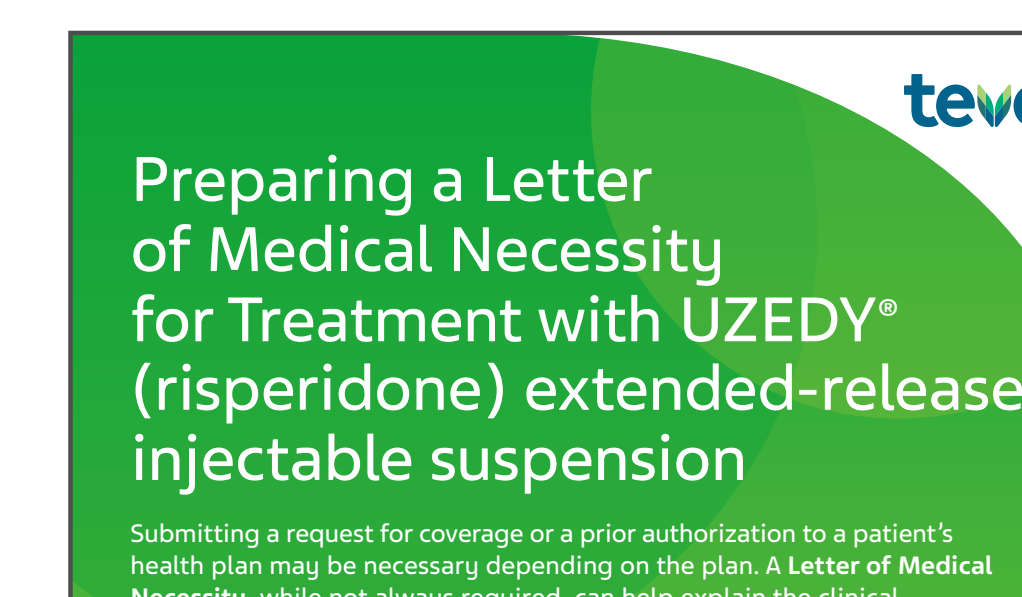
## DOCUMENTATION WITH PA REQUESTS

It's important to confirm each individual payer's **rules for submission** of PA requests.<sup>4</sup> For example:

- Does the payer require use of **plan- or product-specific PA forms**?
- Does the payer accept **verbal PA requests and information**?
- Is there a standard format for **statements of medical necessity**?

If the payer requires use of specific forms, it may be beneficial to submit additional information, such as a **letter of medical necessity**, to supplement the brief narratives allowed on the form. Some of the types of information that payers may specifically request, or that the provider may choose to provide to support medical necessity for UZEDY include<sup>3-5</sup>:

- Overview of the clinical course of schizophrenia and treatment challenges
- Severity of patient's condition, including functional status and limitations
- Previous treatments, including duration and response to treatment, and rationale for discontinuation
- Recent emergency treatment, hospitalization, and number of prior relapses and re-hospitalizations

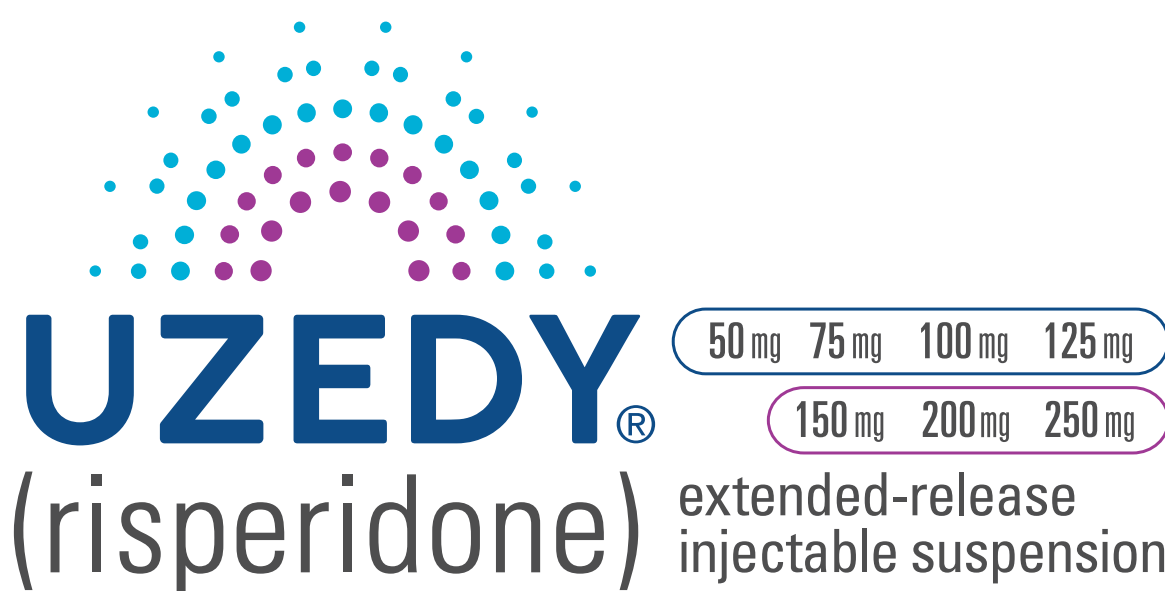


**Download a UZEDY sample letter of medical necessity** ➔

**IMPORTANT SAFETY INFORMATION**  
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 metabolites, paliperidone, or to any of its components. Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been reported in patients treated with risperidone or paliperidone.  
**WARNINGS AND PRECAUTIONS**  
**Cardiovascular Adverse Reactions:** In trials of elderly patients with dementia-related psychosis, there was a significantly higher incidence of cardiovascular adverse events (e.g., stroke, transient ischemic attacks), 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 hyperreflexia, muscle rigidity, altered mental status including delirium, and autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmias). Additional signs may include elevated creatine phosphokinase, myoglobinuria (myoglobinuria), and acute renal failure. If NMS is suspected, immediately discontinue UZEDY and provide symptomatic treatment and monitoring.  
Please see the full Prescribing Information for UZEDY, including Boxed WARNING.

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

<b>Prior Authorization</b>	Exceptions	Appeals	Sample Forms & Letters	Medicaid & Medicare Resources	Accessing UZEDY	References
✓ Checklist	✓ Checklist	✓ Checklist				



# 1.2 PRIOR AUTHORIZATION

## CHECKLIST

- 1

**Locate information** about the payer’s PA process in the patient or provider handbook or from customer service. Review the process and access any required forms.
- 2

**Develop** a brief, clear statement of the patient’s needs and rationale for the request and compile information to support the medical necessity and urgency of the authorization.
- 3

**Complete and submit** using payer-specific forms and submission methods.
- 4

**Gather details** on how and when the payer’s decision will be delivered to the provider and/or the patient. Confirm timing, based on standard or expedited timelines.

NEXT STEPS

**If coverage is not authorized**

Complete and correct PA requests are frequently authorized by payers. However, in the event a payer determines that a patient does not meet its PA criteria, the patient and/or provider may request a **coverage determination**.<sup>4,6</sup>

**teva** | Shared Solutions

**For additional support, contact Teva Shared Solutions.**

Call 1-800-887-8100 (9am to 8pm ET, M-F)

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

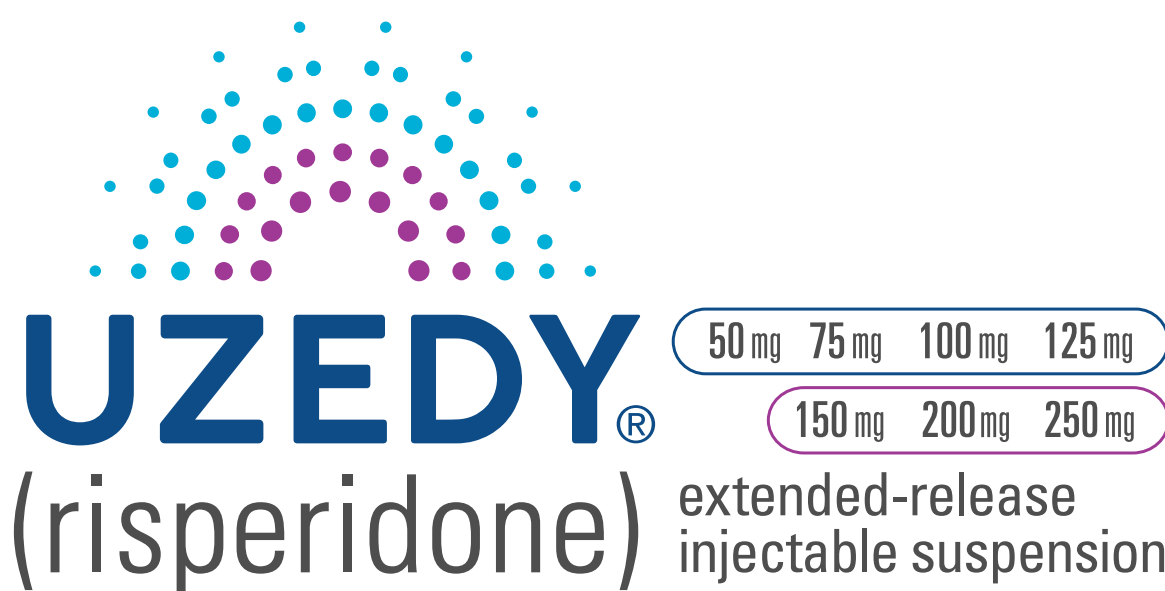
Prior Authorization	Exceptions	Appeals	Sample Forms & Letters	Medicaid & Medicare Resources	Accessing UZEDY	References
✓ Checklist	✓ Checklist	✓ Checklist				





## 4





# 2.2 EXCEPTIONS

## CHECKLIST

- 1

**Locate information** about the payer’s exception request process in the patient or provider handbook or from customer service. Review the process and access any required forms.
- 2

**Develop** a brief, clear statement of the patient’s needs and rationale for the request and compile information to support the medical necessity and urgency of the exception request.
- 3

**Complete and submit** using payer-specific forms and submission methods.
- 4

**Gather details** on how and when the payer’s decision will be delivered to the provider and/or the patient. Confirm timing, based on standard or expedited timelines.

NEXT STEPS

**If the exception request is denied**

If an exception request is denied, the payer will provide a written explanation of why and include information about how to appeal the decision.<sup>7</sup> A patient, their designated representative, or a provider can follow the progressive series of steps in the **appeals process**.<sup>7</sup>

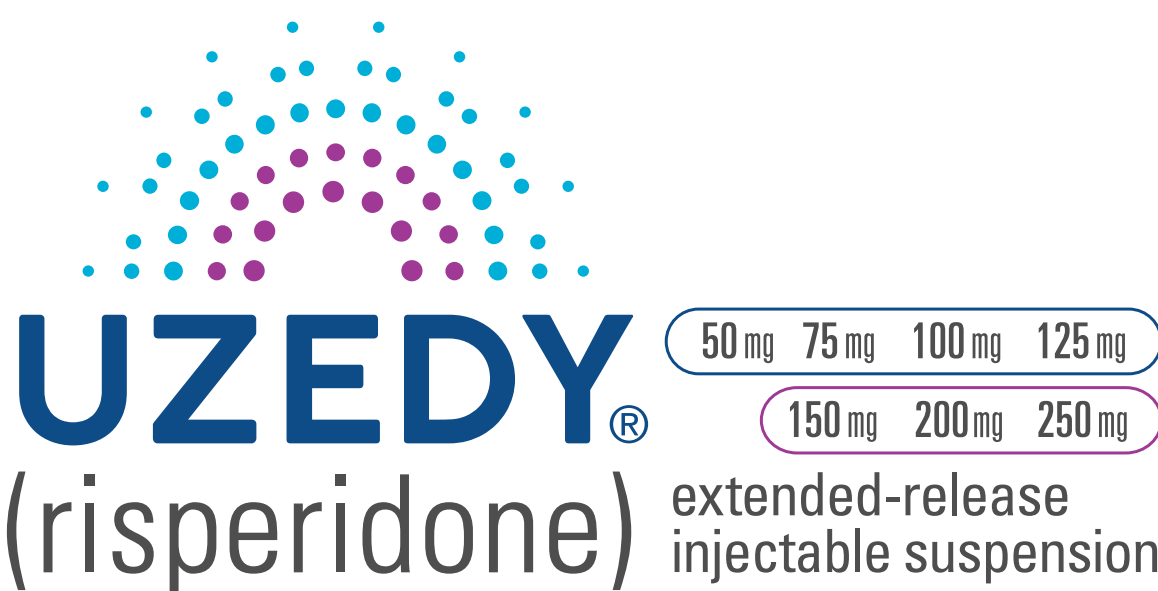
**teva** | Shared Solutions

**For additional support, contact Teva Shared Solutions.**

Call 1-800-887-8100 (9am to 8pm ET, M-F)

Please see the full [Prescribing Information](#) for UZEDY, including **Boxed WARNING**.

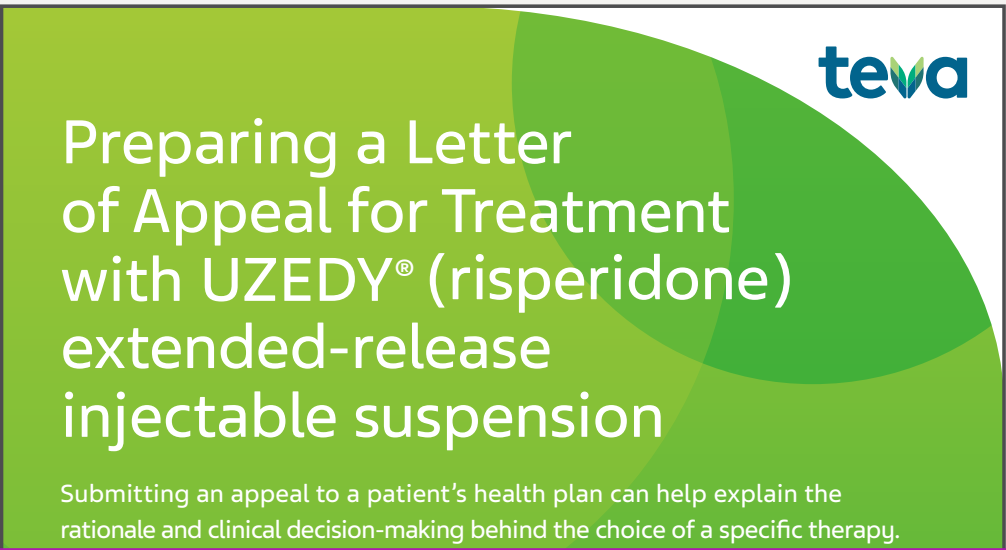
Prior Authorization	Exceptions	Appeals	Sample Forms & Letters	Medicaid & Medicare Resources	Accessing UZEDY	References
✓ Checklist	✓ Checklist	✓ Checklist				



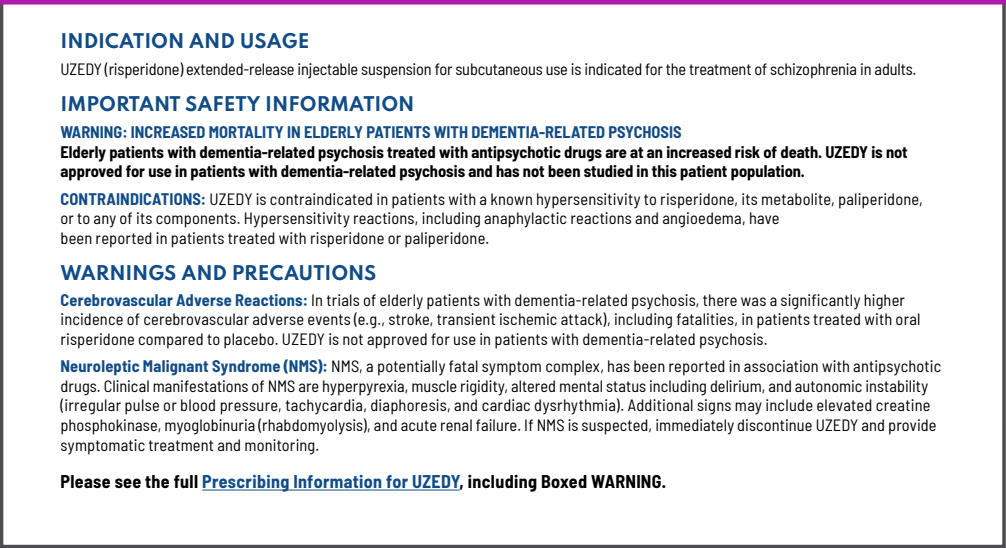
# 3.1 APPEALS

## OVERVIEW

The **next step after denial** of an exception request is to appeal. An appeal is a formal challenge of a payer’s adverse coverage determination regarding benefits that a provider believes a patient should receive.<sup>9</sup> All payers are **required to have formal appeals processes** and to provide a written explanation of the next possible level of appeal when a request is denied.<sup>10,11</sup>



Download a UZEDY sample letter of appeal ➤



## APPEALS

### Administrative denial

In many cases, the denial may be the result of an administrative error or omission such as<sup>12</sup>:

- Incorrect dates
- Improper coding
- Missing documentation



Providers can **amend and resubmit** the request, rather than launching a formal appeal.<sup>12</sup>

### Clinical denial

In the event of a clinical denial – for example, the payer has determined a patient has not met the PA criteria for the requested drug – an appeal may be appropriate<sup>3,11</sup>:

- Payer appeal processes generally have several levels
- Individual payers and PBMs may have unique appeals processes



Many payers follow the well-established **Medicare Part D appeals model**.<sup>10</sup>

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

Prior Authorization	Exceptions	Appeals	Sample Forms & Letters	Medicaid & Medicare Resources	Accessing UZEDY	References
✓ Checklist	✓ Checklist	✓ Checklist				





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## 3.2 APPEALS

### MEDICARE PART D APPEALS & TIMELINES

#### Appeals levels

Payers are required to respond to each level of appeal within a specified time frame and offer both standard and expedited processes.<sup>11</sup> The figure below illustrates the Medicare timelines for each level of appeal.<sup>10,13</sup> 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.

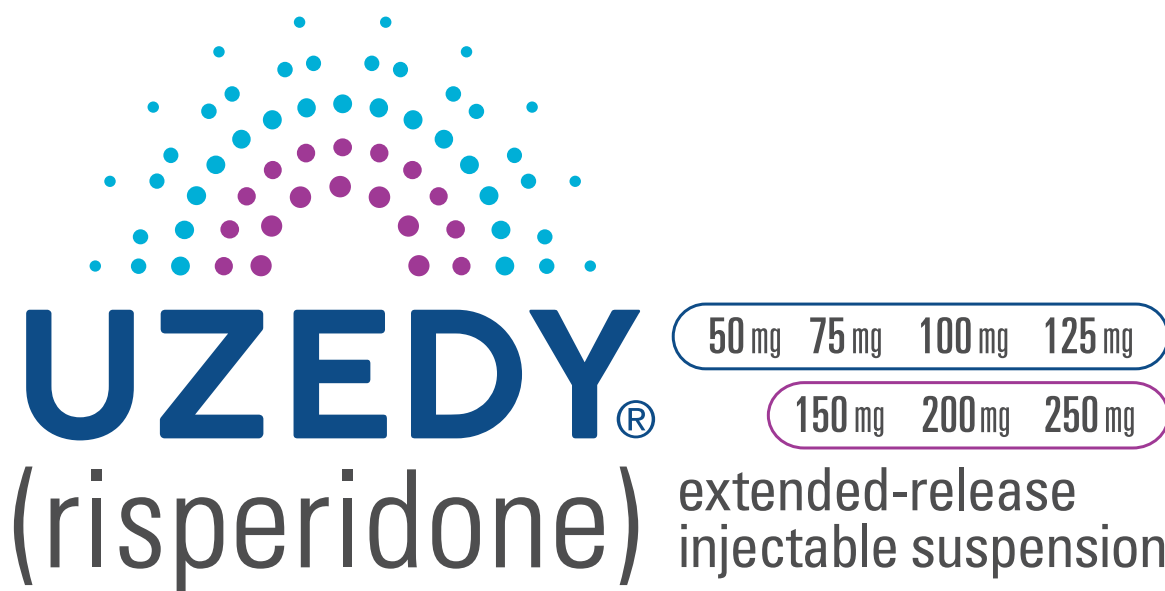


**Appeals must be filed by the deadline** that the Part D plan sponsor provides to the patient. However, appeals are possible if a good reason for missing the deadline can be shown.<sup>14</sup>

**For more information about Medicare Part D appeals**

[Learn more at CMS.gov](#) >

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



# 3.3 APPEALS

## MEDICAID APPEALS

### Federal requirements and state options

Federal law requires that state Medicaid programs have a process for beneficiaries to appeal adverse decisions. These rules apply to decisions about eligibility or coverage of services under fee-for-service Medicaid or by a Medicaid managed care plan.<sup>11</sup>

### Federal

Federal requirements for Medicaid plan appeals include<sup>15</sup>:

- Initiation of the process by **providing to the beneficiary a written notice** from the Medicaid program or health plan of an intended termination or suspension

### State

States can opt to offer the beneficiary a local hearing (at the local or county level) before a state-level appeal.

- If the state does not offer local hearings, a state-level hearing, if requested, must be provided within a reasonable time frame<sup>15</sup>
- In general, **states must take action within 90 days** after a request for a hearing has been received<sup>15</sup>
- States may not terminate or reduce services until a final decision is reached<sup>15</sup>



### Tips and more information about your state

Medicaid plan rules vary by state.<sup>16</sup> The official Medicaid website has compiled a state-by-state summary of Medicaid and Children’s Health Insurance Program (CHIP) plans.

[Learn more at Medicaid.gov](#) >

Please see the full [Prescribing Information](#) for UZEDY, including Boxed WARNING.

Prior Authorization	Exceptions	Appeals	Sample Forms & Letters	Medicaid & Medicare Resources	Accessing UZEDY	References
✓ Checklist	✓ Checklist	✓ Checklist				





## 3.4 APPEALS

### CHECKLIST

1

**Locate information** about the payer’s appeals process in the patient or provider handbook or from customer service. Review the process and access any required forms.

2

**Develop** a brief, clear statement of the patient’s needs and rationale for the appeal and compile information to support the medical necessity and urgency of the appeal.

3

**Complete and submit** using payer-specific forms and submission methods.

4

**Gather details** on how and when the payer’s decision will be delivered to the provider and/or the patient. Confirm timing, based the type or level of appeal.

### NEXT STEPS

#### If the appeals are unsuccessful

- An unfavorable decision by the payer at any level of appeal will include information about **requirements to file for the next level of appeal**<sup>10</sup>
- Once all internal appeal levels have been exhausted, the case may be eligible for **external review**<sup>13</sup>
- A provision of the Affordable Care Act (ACA) was to require all health insurers in all states to participate in an **external review process** that meets minimum consumer protection standards<sup>11</sup>
  - Note that the ACA external review process rules do not apply to **self-funded** plans. If your patient belongs to a self-funded plan, it may be appropriate to contact the employer’s human resources department for additional guidance<sup>11</sup>
- If the appeal reaches an external review, **the payer must accept the reviewer’s decision**<sup>11</sup>

**teva** | Shared Solutions

**For additional support, contact Teva Shared Solutions.**

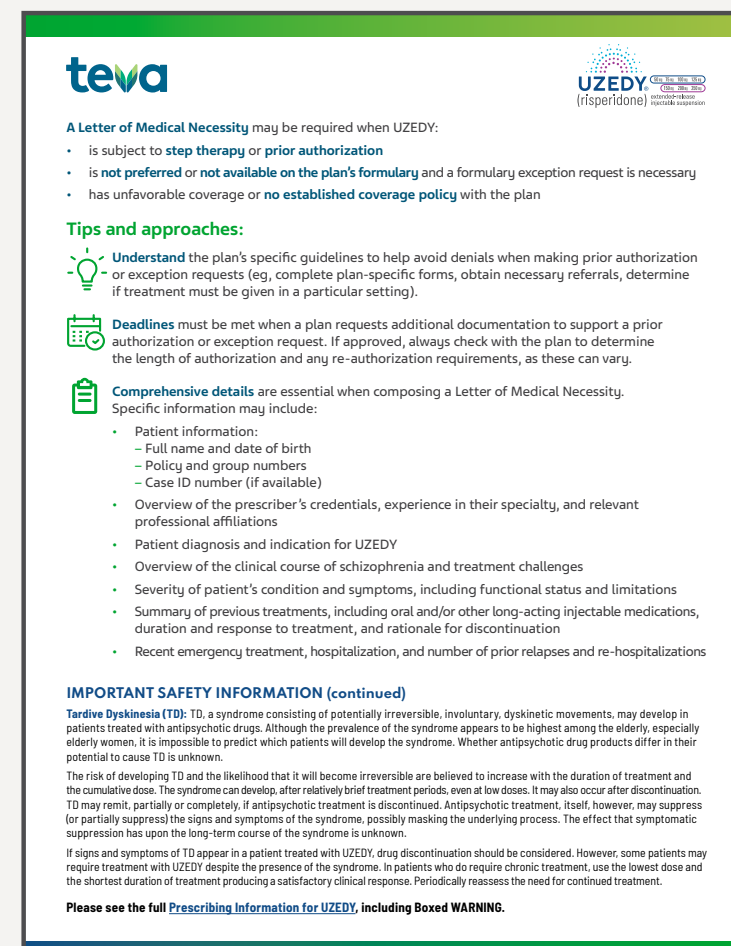
Call 1-800-887-8100 (9am to 8pm ET, M-F)

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





## UZEDY sample letter of medical necessity >



**Request for a Medicare Prescription Drug Coverage Determination Form** >

**REQUEST FOR MEDICARE DRUG COVERAGE DETERMINATION**

**Use this form to ask for plan for a coverage determination.** You can also ask for a coverage determination by phone at [insert plan telephone number] or through our website at [insert plan web address]. You, your doctor or prescriber, or your authorized representative can make this request.

**Plan Enrollee**

Name	Date of birth
Street address	City
State	ZIP
Phone	Member ID #

**If the person making this request isn't the plan enrollee or prescriber:**

Requester's name
Relationship to plan enrollee
Plan address (include City, State and ZIP)
Phone

☐ Submit authorization of this plan showing your authority to represent the enrollee (a completed Authorization of Representation Form CMS-1092 or equivalent). For more information on appointing a representative, contact our plan or call 1-800-MEDICARE (1-800-438-4272). TTY users can call 1-877-486-2048.

**Name of drug this request is about** (include dosage and quantity information if available)

**Type of Request**

☐ My drug plan charged me a higher copayment for a drug than it should have

☐ I want to be reimbursed for a covered drug I already paid for out of pocket

☐ I'm asking for prior authorization for a prescribed drug (this request may require supporting information)

**For the types of requests listed below, your prescriber must also provide a statement supporting the request. Your prescriber can complete pages 3 and 4 of this form. Supporting information for an Exception Request (see "Prescription Authority")**

☐ I need a drug that's not on the plan's list of covered drugs (family exception)

☐ I've been using a drug that was not on the plan's list of covered drugs before, but has been or will be removed during the plan year (family exception)

☐ I need a drug in exception to the requirement that I try another drug before I get a prescribed drug (family exception)

☐ I'm asking for an exception to the plan's limit on the number of pills (quantity limit) I can get so that I can get the number of pills prescribed to me (family exception)

☐ I'm asking for an exception to the plan's prior authorization rules that must be met before I get a prescribed drug (family exception)

☐ My drug plan conditionally requires a prescription drug for a prescribed drug but (things for another drug that meet my condition, and I want to pay the lower copayment (steering exception)

☐ I've been using a drug that was on a lower copayment category before, but has or will be moved to a higher copayment tier (steering exception)

Additional information we should consider (submit any supporting documents with this form):

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Do you need a decision on exception request?**

☐ If you or your prescriber believe that waiting 7 hours for a decision on a decision request would seriously harm your health, or ability to obtain maximum function, you can ask for an expedited Tier 1 decision. If your prescriber indicates that waiting 7 hours would seriously harm your health, we will expedite your decision within 24 hours. If you don't get your prescriber's support for an expedited request, we'll decide if you need a request a faster decision. You can ask for an expedited decision if you're asking us to pay for a drug you already received.

☐ **YES, I need a decision within 24 hours.** If you have a supporting statement from your prescriber, attach it to this request.

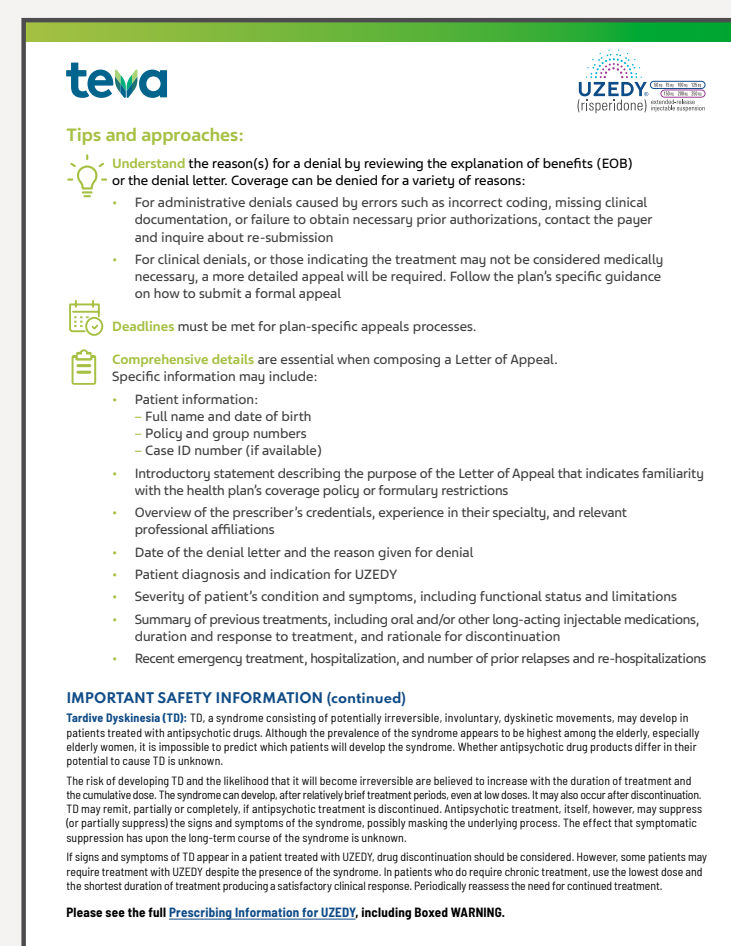
**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**How to submit this form**

Submit this form and any supporting information by mail or fax:

Address: \_\_\_\_\_ Fax Number: \_\_\_\_\_  
[insert plan address(es)] [insert plan fax number(s)]

## UZEDY sample letter of appeal >



<p align="center"><b>Supporting Information for an Exception Request or Prior Authorization To be completed by the prescriber</b></p>	
<p><input type="checkbox"/> <b>REQUEST FOR EXPEDITED REVIEW:</b> By checking this box and signing below, I certify that applying the 72-hour standard review timeframe may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.</p>	
<p><b>Prescriber Information</b></p>	
<p>Name _____</p>	
<p>Street Address (Include City, State and ZIP) _____</p>	
<p>Office phone _____</p>	
<p>Fax _____</p>	
<p>Signature _____</p>	<p>Date _____</p>
<p><b>Diagnosis and Medical Information</b></p>	
<p>Medication: _____</p>	<p>Strength and route of administration: _____</p>
<p>Frequency: _____</p>	<p>Date started: _____</p>
<p>Expected length of therapy: _____</p>	<p><input type="checkbox"/> <b>QUANTITY</b>      <b>Quantity per 30 days:</b> _____</p>
<p>Height/Weight: _____</p>	<p>Drug allergies: _____</p>
<p><b>DIAGNOSIS – Please list all diagnoses being treated with the requested medication.</b> _____</p>	
<p><small>(If the condition being treated with the requested drug is a symptom e.g. anorexia, weight loss, dizziness of breath, chest pain, nausea etc., provide the diagnosis causing the symptoms) (if any)</small></p>	
<p align="right"><b>ICD-10 Code(s)</b></p>	
<p><b>OTHER RELEVANT DIAGNOSES:</b> _____</p>	
<p align="right"><b>ICD-10 Code(s)</b></p>	
<p><b>DRUG HISTORY:</b> (for treatment of the condition(s) requiring the requested drug)</p>	
<p><b>DRUGS DURING</b> _____</p>	<p><b>DATES OF Drug Trial</b> _____</p>
<p><b>RESULTS of previous drug trials</b></p>	
<p><b>FAILING vs. TOLERANCE</b></p>	
<p><b>(explain)</b> _____</p>	
<p>_____</p>	
<p>_____</p>	

What is the enrollee's current drug regimen (per the condition(s) requiring the requested drug)?

**DRUG SAFETY**

**Are there CONTRAINDICATIONS to the requested drug?** ☐ YES ☐ NO

Any concern for a **DRUG INTERACTION** when adding the requested drug to the enrollee's current regimen? ☐ YES ☐ NO

If the enrollee is on any of the questions above in yes, please, explain issue, i.e., discuss the benefits vs potential risks perceived (note the noted concern, and) monitoring plan to ensure safety

**HIGH RISK PATIENTS WITH CONTRAINDICATIONS IN THE ELDERLY**

If the enrollee is over the age of 65, do you feel that the enrollee's condition(s) of treatment with the requested drug outweigh the potential risks in the elderly patient? ☐ YES ☐ NO

**OPPIOIDS – (insert the duration of time if the requested drug is in trial)**

Will you prescribe a maximum Morphine Equivalent Dose (MED)?

mg/day:

Are you aware of other opioid prescribers for this enrollee? ☐ YES ☐ NO

Are you concerned? ☐ YES ☐ NO

Is the stated total MED dose needed clinically necessary? ☐ YES ☐ NO

Would a lower total daily MED dose be sufficient to control the enrollee's pain? ☐ YES ☐ NO

**RATIONALE FOR REQUEST**

☐ Patient is stable on current drug(s), but with adverse outcome (e.g., toxicity, allergy, or therapeutic failure) [Not needed in the DRUG HISTORY section, specify below.] (1) Drug(s) had been prescribed for adverse outcome (e.g., toxicity, allergy, or therapeutic failure) for \_\_\_\_\_ days (2) Therapeutic failure, but maximum dose and length of therapy for drug(s) was \_\_\_\_\_

☐ [Alternative drug(s) contraindicated; would not be as effective or likely to cause adverse outcome (e.g., toxicity, allergy, or therapeutic failure) for \_\_\_\_\_ days (3) Therapeutic failure, but significant adverse clinical outcome and why this outcome would be expected is required. A contraindication, if significant adverse clinical outcome (e.g., toxicity, allergy, or therapeutic failure) for \_\_\_\_\_ days (4) Therapeutic failure, but maximum dose and length of therapy for drug(s) was \_\_\_\_\_

☐ Patient would suffer adverse effects if he or she were required to satisfy the prior authorization requirement. A specific explanation of why anticipated significant adverse clinical outcome and why this outcome would be expected is required

☐ Patient is stable on current drug(s); high risk of significant adverse clinical outcome with any other drug(s) would be expected is required; a risk of the enrollee has been affected to control the enrollee's pain (e.g., toxicity, allergy, or therapeutic failure) for \_\_\_\_\_ days (5) Therapeutic failure, but maximum dose and length of therapy for drug(s) was \_\_\_\_\_

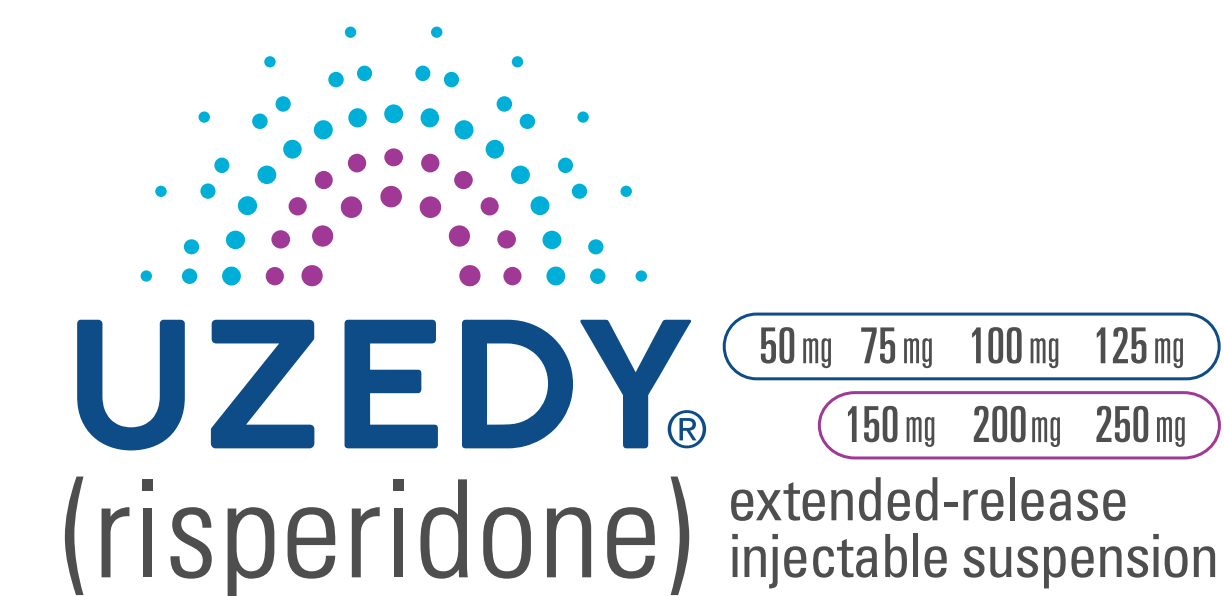
☐ Medical need for different dosage form and/or higher dosage level [Specify below: (1) Dosage form and/or (dosage(s)) tried and not outcome of drug(s). (2) Explain medical condition (3) Include why were frequent dosages with a higher strength not or not an option. (4) If a higher strength exists).

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



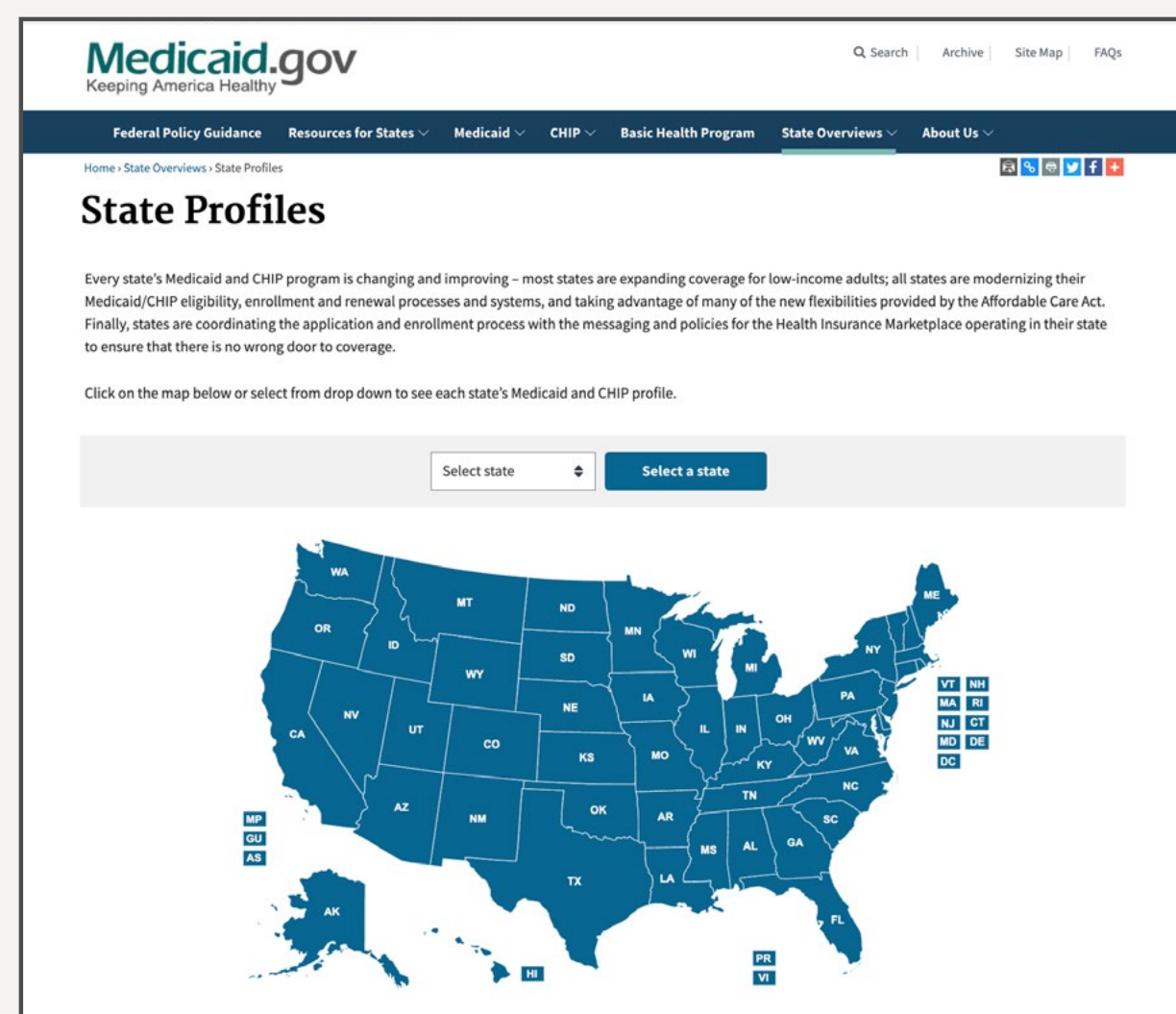


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# 5 MEDICAID & MEDICARE RESOURCES

## Medicaid



Use the interactive map to view information about Medicaid plans in your state

[View interactive map](#)

## Your Guide to Medicare Drug Coverage



Information about Medicare Part D plan drug coverage

[Go to Medicare.gov](#)

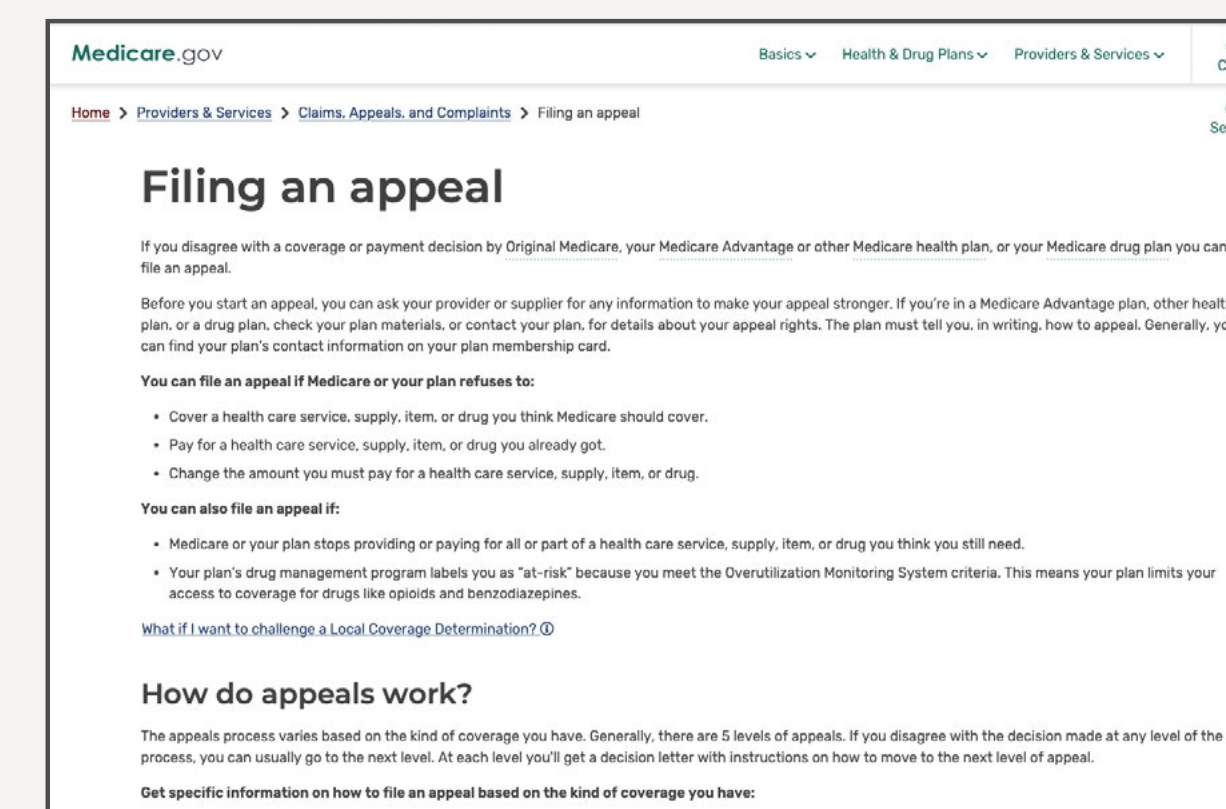
## State Health Insurance Assistance Program



Find your state-specific local contact for assistance navigating Medicare

[Go to Shiphelp.org](#)

## Medicare appeals



Guidance on how to file an appeal for Original Medicare, Medicare Advantage, and Part D plans

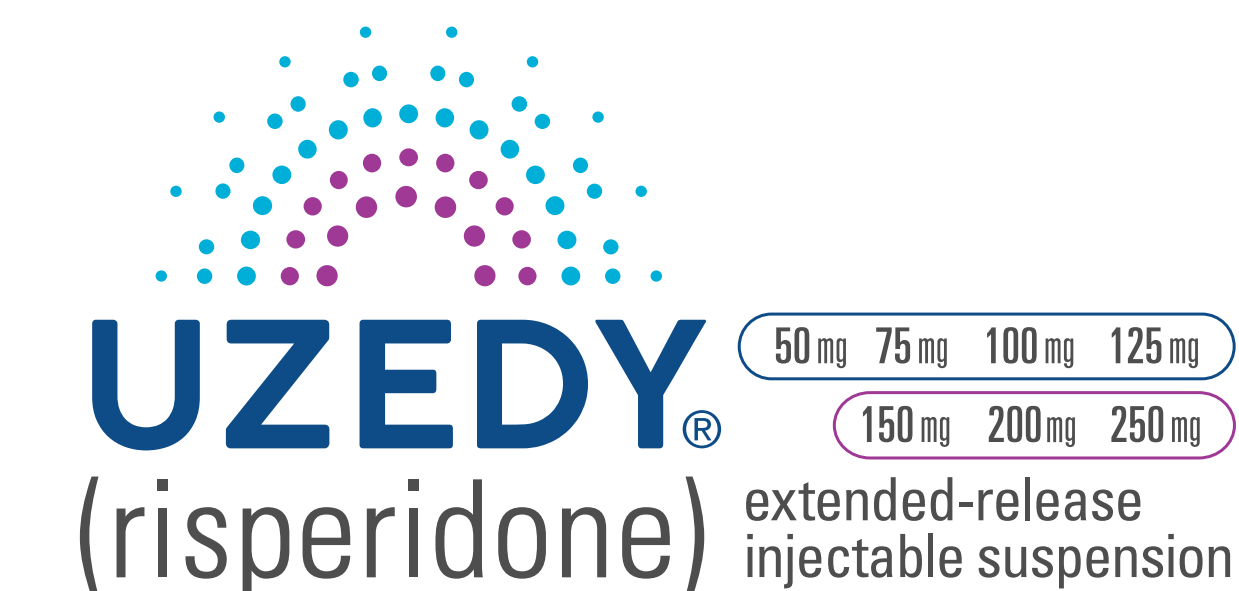
[Go to Medicare.gov](#)

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





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# 6 ACCESSING UZEDY

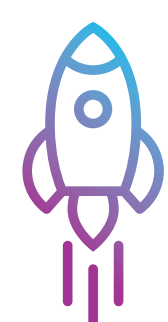


A dedicated team can support you through the steps of starting and staying on treatment.



## Benefits verification and support

Confirms prescription coverage and pharmacy options based on patient benefits from Medicare, Medicaid, or private insurance



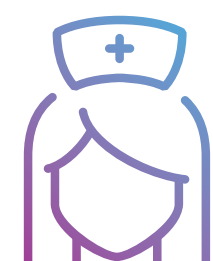
## Prior authorization/appeals support

Communicates the prior authorization requirements, and supports the appeals process if needed



## Coordination with the pharmacy

Coordinates care with the patient, prescriber, pharmacy, and site of care



## Nurse navigator guidance and support

Helps patients stay informed about their treatment journey with UZEDY and answer treatment-related questions



## Alternate site-of-care network

Provides a directory of available treatment locations



## Savings offer

Reduces costs for commercially insured patients (eligible patients may pay as little as \$0 for once-monthly or once-every-2-month dosing options of UZEDY)\*

\*Offer is available for patients with commercial insurance only. This offer is NOT available for patients eligible for Medicare, Medicaid, or any other form of government insurance coverage.

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.



## 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.health](https://covermymeds.health)

Resources: [covermymeds.com/main/support/](https://covermymeds.com/main/support/)



### UZEDY MEDICARE ACCESS GUIDE

Download the UZEDY Medicare Access Guide >



### TEVA SHARED SOLUTIONS BROCHURE

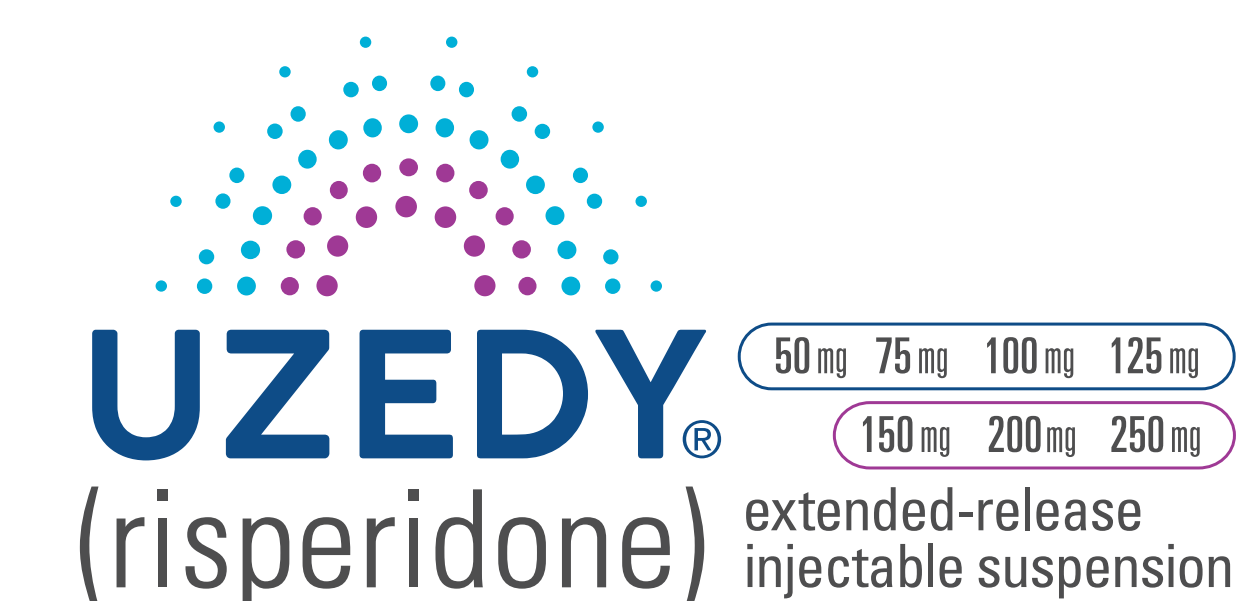
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