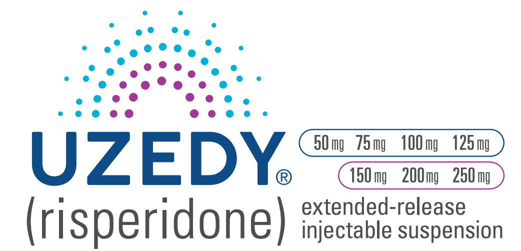
ACCESS GUIDE



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.

It often takes time for drugs that are new to market to be reviewed and added to payer formularies. During that time, patients or providers may be required to submit exception requests to access their prescribed medications.

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

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

1.1 PRIOR AUTHORIZATION

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

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.[1] 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 services to be approved for coverage.[2,3]

- 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[4]
- 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

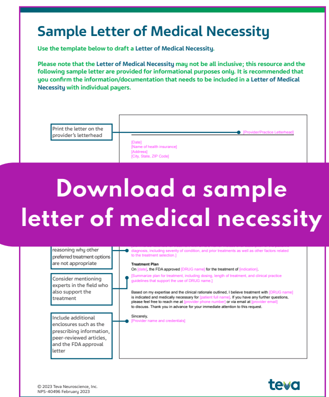
DOCUMENTATION WITH PA REQUESTS

It's important to confirm each individual payer's **rules for submission** of PA requests.[4] 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 include[3-5]:

- Concomitant therapies
- Previous medications and treatment outcomes
- Patient allergies or previous adverse reactions
- Comorbidities
- Protected class status of the drug with no therapeutic equivalents



Download a sample letter of medical necessity >

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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.**[4,6]

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2.1 EXCEPTIONS

OVERVIEW

A coverage determination is a request for a response to a formal inquiry about coverage. An **exception request** is a **type of coverage determination.**[6]

Most payers allow patients, designated representatives, or providers to request a coverage determination, such as an exception request, regarding prescription drug coverage.[7] Similar processes may apply to coverage determinations for pharmacy and medical benefit–covered drugs.

Types of exceptions

Requesting an exception to a payer's coverage policy may be appropriate if the provider's benefits investigation uncovers that[6,7]:

- A requested drug is **not on formulary**
- The payer has **denied access** to or payment for a requested drug
- An exception is needed regarding the **amount a patient must pay** for a drug (also called a tiering exception)
- There is a **quantity or dose limit** that is inappropriate for the patient, or the provider believes it is **medically necessary to not follow step therapy** rules
- There is a need to determine whether **PA or other requirements** have been met

Medicare Part D exceptions

CMS recognizes **2 types of exception requests** for Medicare Part D patient[7]

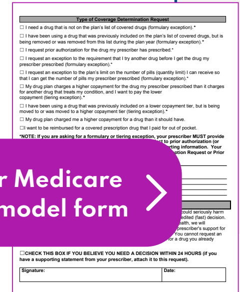
- **Formulary exception:** To obtain a prescription drug that is not on a Part D plan sponsor's formulary or to waive step therapy or quantity/dosing limits
- **Tiering exception:** To obtain a non-preferred drug at equivalent cost sharing to drugs in the preferred tier

How to submit an exception request

The patient, their representative, or the provider must submit a supporting statement to the plan sponsor that documents the medical necessity of the requested exception.[7]

A Medicare Part D plan sponsor may have their own request form, or a CMS **Request for Medicare Prescription Drug Coverage Determination** is available to download on the CMS website.[7]

Go to CMS.gov to download the Request for Medicare Prescription Drug Coverage Determination model form ›



Type of Coverage Determination Request

☐ I need a drug that is not on the plan's list of covered drugs (formulary exception).*

☐ I have been using a drug that was previously included on the plan's list of covered drugs, but is being removed or was removed from this list during the plan year (formulary exception).*

☐ I request prior authorization for the drug my prescriber has prescribed.*

☐ I request an exception to the requirement that I try another drug before I get the drug my prescriber prescribed (formulary exception).*

☐ I request an exception to the plan's limit on the number of pills (quantity limit) I can receive so that I can get the number of pills my prescriber prescribed (formulary exception).*

☐ My drug plan charges a higher copayment for the drug my prescriber prescribed than it charges for another drug that treats my condition, and I want to pay the lower copayment (tiering exception).*

☐ I have been using a drug that was previously included on a lower copayment tier, but is being moved to or was moved to a higher copayment tier (tiering exception).*

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

☐ I want to be reimbursed for a covered prescription drug that I paid for out of pocket.

***NOTE: If you are asking for a formulary or tiering exception, your prescriber MUST provide** ...

☐ **CHECK THIS BOX IF YOU BELIEVE YOU NEED A DECISION WITHIN 24 HOURS (if you have a supporting statement from your prescriber, attach it to this request).**

Signature:	Date:

TIMELINES

Payers **must respond to exception requests** within a specified amount of time, and both standard and expedited processes are available. The following response timelines are as defined by CMS for Part D plan sponsors and reflect general standards followed by many commercial payers[7,8]:

24 hours — **Expedited process:** Payers must respond within 24 hours; reserved for high-risk patients

72 hours — **Standard process:** Payers must respond within 72 hours

For either process, clock starts with receipt of provider supporting information

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2.2 EXCEPTIONS

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

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.[7] A patient, their designated representative, or a provider can follow the progressive series of steps in the **appeals process**.[7]

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3.1 APPEALS

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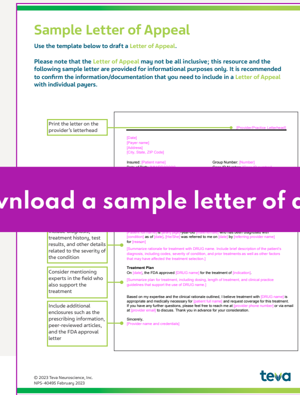
OVERVIEW

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.[9] 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.[10,11]



Download a sample letter of appeal

APPEALS

Administrative denial

In many cases, the denial may be the result of an administrative error or omission such as[12]:

- Incorrect dates
- Improper coding
- Missing documentation

Providers can **amend and resubmit** the request, rather than launching a formal appeal.[12]

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[3,11]:

- 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.[10]

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

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.[11] The figure below illustrates the Medicare timelines for each level of appeal.[10,15] 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 Medicare provides to the patient. However, appeals are possible if a good reason for missing the deadline can be shown.[16]

For more information about Medicare Part D appeals

Learn more at CMS.gov

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

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.[11]

Federal

Federal requirements for Medicaid plan appeals include[13]:

- Initiation of the process by **providing to the beneficiary a written notice** from the Medicaid program or heath 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[13]
- In general, **states must take action within 90 days** after a request for a hearing has been received[13]
- States may not terminate or reduce services until a final decision is reached[13]

Tips and more information about your state

Medicaid plan rules vary by state.[14] The offical 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, including Boxed WARNING for UZEDY.

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**[10]
- If the appeal reaches an external review, **the payer must accept the reviewer's decision**[11]
- 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[11]
  - 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[11]
- Once all internal appeal levels have been exhausted, the case may be eligible for **external review**[15]

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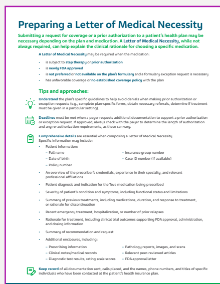
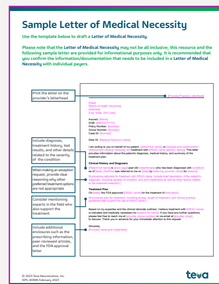
4 SAMPLE FORMS & LETTERS

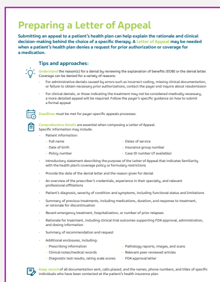
TAP TO NAVIGATE TO EACH EXAMPLE

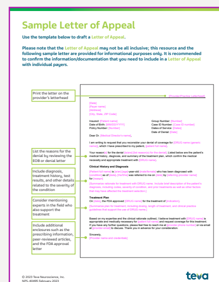
Sample letter of medical necessity resource ›





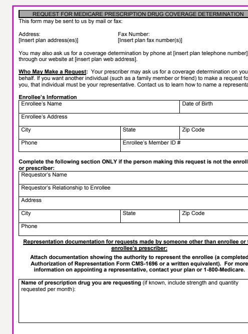
Sample letter of appeal resource ›

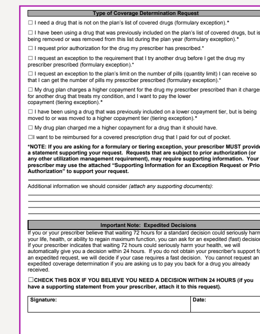


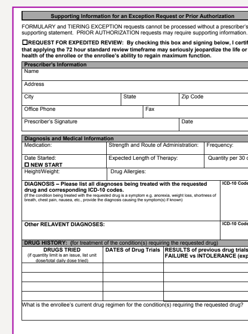


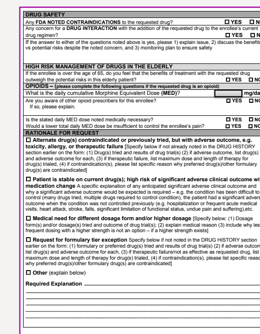
Request for a Medicare Prescription Drug Coverage Determination Form ›

(CMS Model Coverage Determination Form)


REQUEST FOR MEDICARE PRESCRIPTION DRUG COVERAGE DETERMINATION


Type of Coverage Determination Request


Supporting Information for an Exception Request or Prior Authorization


DRUG SAFETY

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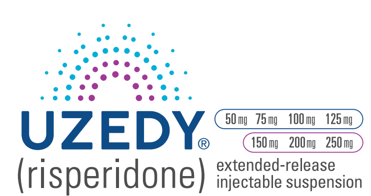
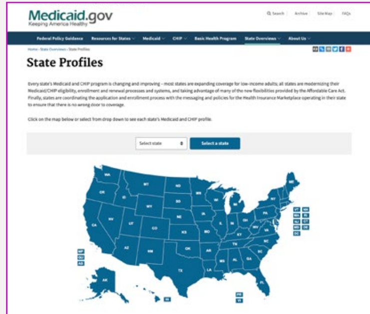
5 MEDICAID & MEDICARE RESOURCES



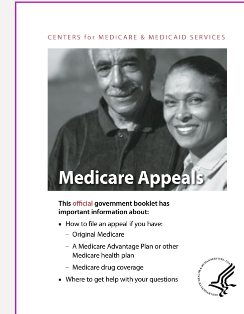
Medicaid



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

View interactive map

Medicare appeals


CENTERS for MEDICARE & MEDICAID SERVICES

Medicare Appeals

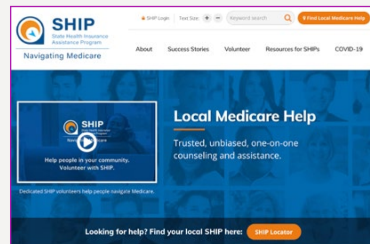
This official government booklet has important information about:

- How to file an appeal if you have:
  - Original Medicare
  - A Medicare Advantage Plan or other Medicare health plan
  - Medicare drug coverage
- Where to get help with your questions

Step-by-step information about how to file an appeal for original Medicare, Medicare Advantage, and Part D plans

Go to Medicare.gov

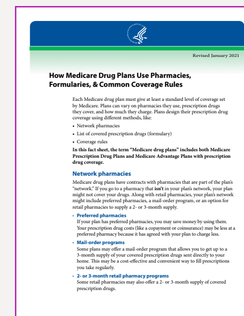
State health insurance assistance program



Find your state-specific local contact for assistance navigating Medicare

Go to Shiphelp.org

Medicare drug plans fact sheet

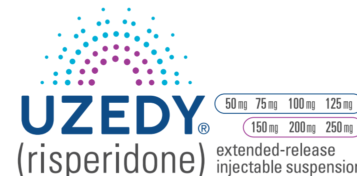

How Medicare Drug Plans Use Pharmacies, Formularies, & Common Coverage Rules

Information about Medicare Part D plan formulary rules

Go to Medicare.gov

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

6 TEVA SHARED SOLUTIONS®



Teva Shared Solutions is designed and committed to help patients gain affordable access to UZEDY. A dedicated team provides support through the following services and offerings to help patients get started and stay on treatment.

Patient Initiation and Coordination

Help patients get started with UZEDY

Benefits Verification

Confirms prescription coverage and pharmacy options based on specific eligibility and coverage

PA/Appeals Support

Communicates the prior authorization requirements, and supports the appeals process as requested

Medicare and Medicaid Benefits Navigation Support

Reviews Medicare and Medicaid coverage options

Coordination With a Dispensing Pharmacy

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

TEVA SHARED SOLUTIONS BROCHURE

Download the Teva Shared Solutions Brochure

Financial Assistance

Help patients identify financial support options for UZEDY

Patient Assistance Program (PAP)

Provides free product to eligible patients

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.

Alternate Site-of-Care Network

Help patients find convenient site-of-care locations

Directory

Provides a directory of available treatment locations

Nurse Support

Help patients stay informed about their treatment journey with UZEDY

Over-the-Phone Support and Education

Provides an introductory program welcome call and nurse support to patients and caregivers to answer questions and help with treatment adherence

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