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### **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.

<b>Prior Authorization</b>	Exceptions	
Checklist	Checklist	

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

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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 services 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

## **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 include<sup>3-5</sup>:

- Concomitant therapies
- Previous medications and treatment outcomes
- Patient allergies or previous adverse reactions

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- Comorbidities
- Protected class status of the drug with no therapeutic equivalents

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### **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



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# 1.2 PRIOR AUTHORIZATION

## CHECKLIST





**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.



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



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.

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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>



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# NEXT STEPS

### If coverage is not authorized

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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.<sup>6</sup>

Most payers allow patients, designated representatives, or providers to request a coverage determination, such as an exception request, regarding prescription drug coverage.<sup>7</sup> 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<sup>6,7</sup>:

- 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

### 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<sup>7,8</sup>:

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### Medicare Part D exceptions

CMS recognizes **2 types of exception requests** for Medicare Part D patient<sup>7</sup>

• 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

### 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.<sup>7</sup>

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.<sup>7</sup>

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



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

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

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• **Tiering exception:** To obtain a non-preferred drug at equivalent cost sharing to drugs in the preferred tier

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

CHECK THIS BOX IF YOU BELIEVE YOU NEED A DECISION WITHIN 24 HOURS (if y e a supporting statement from your prescriber, attach it to this request

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# 2.2 EXCEPTIONS

## CHECKLIST





**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.



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



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.

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# 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>

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# 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>

## **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

### **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

<b>Prior Authorization</b>	Exceptions	
Checklist	🗸 Checklist	

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

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

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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>10,15</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.



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

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### If denied, 60 days allowed to file next-level appeal.



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For more information about Medicare Part D appeals

Learn more at CMS.gov

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# 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>13</sup>:

### State

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

- States may not terminate or reduce services until a final decision is reached<sup>13</sup>



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<b>Prior Authorization</b>	Exceptions	Appeals
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• 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

• If the state does not offer local hearings, a state-level hearing, if requested, must be provided within a reasonable time frame<sup>13</sup>

• In general, states must take action within 90 days after a request for a hearing has been received<sup>13</sup>

#### Tips and more information about your state

Medicaid plan rules vary by state.<sup>14</sup> The offical Medicaid website has compiled a state-by-state summary of Medicaid and Children's Health Insurance Program (CHIP) plans.

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# 3.4 APPEALS

## CHECKLIST





**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.



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



**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.

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

<b>Prior Authorization</b>	Exceptions	
Checklist	Checklist	

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# 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<sup>11</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>

• Once all internal appeal levels have been exhausted, the case may be eligible for **external review**<sup>15</sup>

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## TAP TO NAVIGATE TO EACH EXAMPLE

### **UZEDY** sample letter of media





#### **UZEDY** sample letter of





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# 5 MEDICAID & MEDICARE RESOURCES

### Medicaid



Use the interactive m information about Me plans in your state



### State health insurance assistance program



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

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Medicare.gov       Basics       Health & Drug Plans       Providers & S         Home > Providers & Services > Claims. Appeals. and Compliants > Filing an appeal       Filing an appeal       How every the a coverage or payment decision by Original Medicare, your Medicare Advantage or other Medicare health plan, or your Medicare Advantage or other Medicare health plan, or your Medicare Advantage or other Medicare health plan, or your Medicare Advantage or other Medicare health plan, or your Medicare Advantage or other Medicare health plan, or your Medicare Advantage or other Medicare health plan, or your Medicare Advantage or other Medicare health plan, or your Medicare Advantage or other Medicare health plan, or your Medicare Advantage or other Medicare health plan, or your Medicare Advantage or other Medicare health plan, or your Medicare Advantage or other Medicare health plan, or your Medicare Advantage or other Medicare health plan, or your Medicare Medic
Filing an appeal If you disagree with a coverage or payment decision by Original Medicare, your Medicare Advantage or other Medicare health plan, or your Medica
file an appeal. Before you start an appeal, you can ask your provider or supplier for any information to make your appeal stronger. If you're in a Medicare Advani plan, or a drug plan, check your plan materials, or contact your plan, for details about your appeal rights. The plan must tell you, in writing, how to can find your plan's contact information on your plan membership card. You can file an appeal if Medicare or your plan refuses to: • Cover a health care service, supply, item, or drug you think Medicare should cover. • Pay for a health care service, supply, item, or drug you already got. • Change the amount you must pay for a health care service, supply, item, or drug. You can also file an appeal if: • Medicare or your plan stops providing or paying for all or part of a health care service, supply, item, or drug you think you still need. • Your plan's drug management program labels you as "at-risk" because you meet the Overutilization Monitoring System criteria. This means y access to coverage for drugs like opioids and benzodiazepines. What if I want to challenge a Local Coverage Determination? @
What if I want to challenge a Local Coverage Determination? How do appeals work? The appeals process varies based on the kind of coverage you have. Generally, there are 5 levels of appeals. If you disagree with the decision made process, you can usually go to the next level. At each level you'll get a decision letter with instructions on how to move to the next level of appeal. Get specific information on how to file an appeal based on the kind of coverage you have:

Find your state-specific local contact for assistance navigating Medicare

### Go to Shiphelp.org

### Medicare drug plans fact sheet



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Health & Drug Plans ~ Providers & Services ~ Chat	
Medicare health plan, or your Medicare drug plan you can ronger. If you're in a Medicare Advantage plan, other health a plan must tell you, in writing, how to appeal. Generally, you	Guidance on how to file an appeal for Original Medicare, Medicare Advantage, and Part D plans
ug you think you still need. nitoring System criteria. This means your plan limits your	
If you disagree with the decision made at any level of the w to move to the next level of appeal.	Go to Medicare.gov >

Information about Medicare Part D plan formulary rules

Go to Medicare.gov

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# 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



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### **Financial Assistance** Help patients identify financial support options for UZEDY

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



# **Nurse Support**

**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



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

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Provides a directory of available treatment locations

Help patients stay informed about their treatment journey with UZEDY

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<b>Prior Authorization</b>	Exceptions	
Checklist	🗸 Checklist	V

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