

# **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.

PRIOR AUTHORIZATION (PA) 11 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 TEVA SHARED SOLUTIONS® > 7 REFERENCES >

Please see the full <u>Prescribing Information</u>, including Boxed WARNING for UZEDY.



# 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. 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. Also called the process to be approved for coverage.

- 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

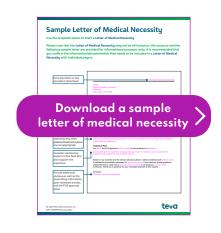
# **DOCUMENTATION WITH PA REQUESTS**

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

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



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# 1.2 PRIOR AUTHORIZATION



## **CHECKLIST**



**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.
- 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>



For additional support, contact Teva Shared Solutions.

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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. 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

## **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
- **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.<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>

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

Coston their Box if you distance you need a decision without producting in 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<sup>7,8</sup>:



#### **Expedited process:**

Payers must respond within 24 hours; reserved for high-risk patients

#### **Standard process:**

Payers must respond within 72 hours

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

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Prior Authorization Exceptions Appeals Sample Forms Medicaid & Medicare

Teva
Shared Solutions



# 2.2 **EXCEPTIONS**



# **CHECKLIST**



**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.
- 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>



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5

✓ Checklist

✓ Checklist

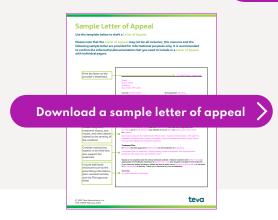


# 3.1 APPEALS



## **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. 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. Denial



## **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.<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**. 10

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6

Sample Forms & Letters Medicaid & Medicare
Resources



# 3.2 APPEALS



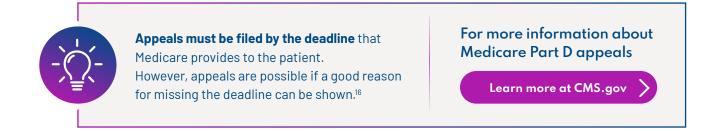
# **MEDICARE PART D APPEALS & TIMELINES**

#### **Appeals levels**

Payers are required to respond to each level of appeal within a specified time frame and offer both standard and expedited processes. The figure below illustrates the Medicare timelines for each level of appeal. Non-Medicare payers may have different timelines:



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



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<sup>\*</sup>Time limits shown are for benefit-related appeals. Plans are allowed up to 14 days to respond to payment-related appeals.



# 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>:

• 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<sup>13</sup>
- In general, states must take action within 90 days after a request for a hearing has been received13
- States may not terminate or reduce services until a final decision is reached<sup>13</sup>

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## 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.

Learn more at Medicaid.gov

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



# 3.4 APPEALS



## **CHECKLIST**



**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.
- 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>
- 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 eliqible for external review<sup>15</sup>

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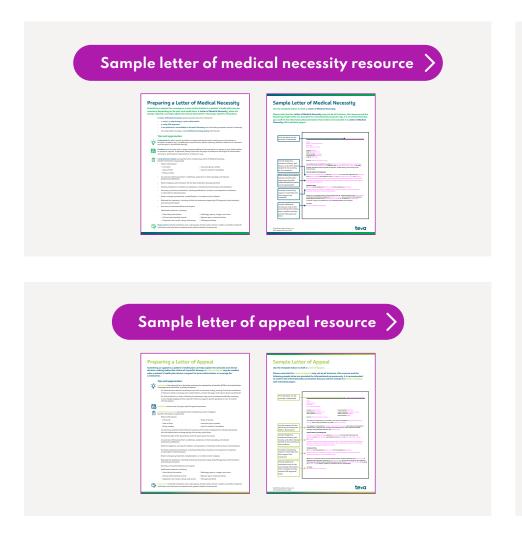
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# 4 SAMPLE FORMS & LETTERS



# TAP TO NAVIGATE TO EACH EXAMPLE



Peguest for a Medica	are Prescription Drug
Coverage Dete	rmination Form
MS Model Coverage	e Determination Form)
mo moder coverage	e Determination Form,
REQUEST FOR MEDICARE PRESCRIPTION DRUG COVERAGE DETERMINATION	Type of Coverage Determination Request
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You may also ask us for a coverage determination by phone at [insert plan telephone number] or through our website at [insert plan web address].	☐ I request prior authorization for the drug my prescriber has prescribed.* ☐ I request an exception to the requirement that I by another drug before I get the drug my prescriber prescribed (prescriber) exception.*
Who May Make a Request: Your prescriber may ask us for a coverage determination on your behalf. If you want another individual (such as a family member or friend) to make a request for you, that individual must be your representative. Contract us to learn how to name a representative.	☐ I request an exception to the plants limit on the number of pills (quantity limit) I can receive so that I can not the number of nills my resembled (formular) agreeting).*
Enrolles's information Errobes's Name Date of Brits	☐ My drug plan charges a higher copayment for the drug my prescriber prescribed than it changes for another drug that treats my condition, and I want to pay the lower copayment (filters) excepting.*
Erroller's Address City State (Zo Code	☐ I have been using a drug that was previously included on a lower copayment Ser, but it is being moved to or was moved to a higher copayment feer (fering exception).*  ☐ W drug plan channel me a higher coopwant for a drug than at about have.
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Requestor's Name Requestor's Relationship to Enrollee	Additional information we should consider (ettach any supporting documents):
Address  City State Zip Code	
Phone	Important Note: Expedited Decision Counting to the property of the property of the property of the sales of the property o
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Name of prescription drug you are requesting (if known, include strength and quantity requested per month):	have a supporting statement from your prescriber, attach it to this request).  Signature: Date:
Supporting Information for an Exception Request or Prior Authorization	ORUG SAFETY Any FOA MOTED CONTRAMACKATIONS to the requested drug?  DYES DING  ON THE PROPERTY OF THE PROPERTY
FORMULARY and TILRING EXCEPTION requests cannot be processed without a prescriber's supporting statement. FROCR AUTHORIZATION requests may require supporting information.  DESCRIPET FOR EXPEDITED REVIEW. By checking this box and signing below, I certify	Any concern for a DISIGN INTERACTION with the addition of the requested drug to the enrolles's current drug register?  If YS  If NO  If the advance to either of the questions noted above as yes, please of yeigher issue, 2 (addition the benefits as posterial risks despite the noted concern, and 3) monothing glass or enrolles and provided the despite of the provided provided the provided p
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	Required Explanation
What is the enrollee's current drug regimen for the condition(s) requiring the requested drug?	

Please see the full <u>Prescribing Information</u>, including Boxed WARNING for UZEDY.



# 5 MEDICAID & MEDICARE RESOURCES







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

View interactive map

## Medicare appeals



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



Information about Medicare Part D plan formulary rules

Go to Medicare.gov

Please see the full <u>Prescribing Information</u>, including Boxed WARNING for UZEDY.

 Prior Authorization
 Exceptions
 Appeals

 ✓ Checklist
 ✓ Checklist
 ✓ Checklist

Sample Forms & Letters Medicaid & Medicare Resources Teva Shared Solutions

References



# 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





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

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# 7 REFERENCES



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## Please see the full <u>Prescribing Information</u>, including Boxed WARNING for UZEDY.



✓ Checklist

13

**Prior Authorization** 

Appeals