



PHARMACEUTICAL COMPANIES  
OF *Johnson & Johnson*

# Supporting Appropriate Payer Coverage Decisions



Policy



Payer



Provider



Patient

# Table of Contents

---

**Introduction** . . . . . 3

---

**Prior Authorization.** . . . . . 4

Overview . . . . . 4

Step Therapy . . . . . 4

Quantity Limits . . . . . 4

The Prior Authorization Process . . . . . 4

Medical Necessity . . . . . 5

Documentation . . . . . 5

What if Coverage Is Not Authorized? . . . . . 5

---

**Exceptions** . . . . . 6

Overview . . . . . 6

The Exception Request Process . . . . . 6

Policy and Process . . . . . 7

Standard or Expedited Requests. . . . . 8

What if the Exception Request Is Denied? . . . . . 8

---

**Appeals.** . . . . . 9

Overview . . . . . 9

The Appeals Process . . . . . 9

Policy and Process . . . . . 10

Time Frames . . . . . 10

What if the Appeal Is Unsuccessful? . . . . . 11

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# Table of Contents

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<b>Additional Considerations</b> . . . . .	12
Pharmacy Benefit Managers . . . . .	12

---

<b>Appendix A</b> . . . . .	13
Payer Communication Checklist. . . . .	13

<b>Appendix B</b> . . . . .	14
Sample Format for Letter of Medical Necessity . . . . .	14

<b>Appendix C</b> . . . . .	15
Medicare Part D Coverage Determination (Exception) Request Form . . . . .	15

<b>Appendix D</b> . . . . .	20
Tools and Resources . . . . .	20

## Introduction

This brochure has been developed to help healthcare providers understand how to work with payers for coverage of medically necessary drug therapies. Circumstances under which a payer may require more information than the prescription alone may include:

- Patients need a product but cannot meet the prior authorization requirements
- Patients need a product that is not routinely available within a payer’s network or service area
- Initial requests for coverage are denied

There are three primary categories of requests:

- Prior authorizations
- Coverage determinations (including exception requests)
- Appeals

Although there is no standardized process that applies across all payers, the goal is the same: clinical justification of a patient’s need and appropriateness for the therapy.

## Prior Authorization

Payers employ a variety of routine processes to ensure that certain drugs or services are used correctly and only when medically necessary. Prior authorization (also called pre-authorization or “pre-auth”) is a common payer process that requires providers to submit medical necessity documentation in a specific way for a requested therapy or service before coverage is approved.

### Overview

Prior authorization (PA) requires healthcare providers to contact and receive approval from a patient’s payer before that payer will cover a certain prescription drug or authorize a service. In these situations the prescriber must substantiate why a particular therapy or service is medically necessary. Depending on the payer and the specific request, the PA decision may be managed by pharmacy staff, medical policy staff, or a designated prior authorization department. Covered drugs that require PA are commonly indicated in the plan’s formulary and may also be listed on the plan’s website.

### Step Therapy

Step therapy is a payer process in which patients must first try one therapy before another (usually because of cost or safety concerns) before they are permitted to move up a “step” to another drug. For example, the payer may require that prescribers first order a generic drug or a less expensive brand-name formulary drug, before it will cover a similar, more expensive brand-name prescription drug. Possible justifications for skipping a step include:

- Disease and treatment history, including failure with or lack of response to other regimens
- Allergies to components of preferred drugs
- Patient inability to take or use a preferred therapy (e.g., history of adverse reactions, physical inability to self-administer, etc.)
- History of positive response to the requested drug and potential consequences of switching

### Quantity Limits

Payers may limit the amount of prescription drugs they cover over a certain period of time. Quantity limits are generally based on the average patient’s usage, consistent with common medical practice. Drugs for which a plan may impose quantity limits can include pain medications, oral chemotherapy, steroids, and others. If a patient requires more than the allowed amount an authorization is needed. Examples of medically necessary reasons for exceeding quantity limits could include:

- Patient weight (larger patients may require greater than average dose)
- Variations in patient’s biochemistry or genetics, or other factors affecting how they absorb or metabolize a particular drug

### The Prior Authorization Process

Prior authorization requirements, and the list of drugs subject to PA, will vary among payers. It is not unusual for there to be different coverage rules for the same therapy among payers within the same geographic area. Additionally, payers may require that the drug and associated administration services (e.g. healthcare professional administered injection or infusion) be authorized separately.

## Medical Necessity

During the prior authorization process providers are required to submit evidence of medical necessity, often including a description of why the covered alternatives are clinically unacceptable. It is generally helpful for healthcare providers to explain, in clear and simple terms, the outcome that they are trying to accomplish – then describe the likely consequences of not providing the requested intervention.

For considerations on facilitating effective communication with a payer, providers may refer to the “Payer Communication Checklist” in Appendix A at the back of this brochure.

### Documentation

The payer may require use of general or drug-specific forms, or accept a statement of medical necessity. Appendix B of this guide presents a sample format for a letter of medical necessity. Some payers may accept prior authorization requests and information by phone, in which case it may be helpful to use the sample format as a guide for the conversation. Some states have passed “uniform prior authorization form” legislation to reduce the administrative burden of managing multiple payer forms. Rules vary by state. Regardless of the process, it is important that providers keep a record of all communication and correspondence, including the dates, times, and individuals contacted at the payer.

If the payer requires use of a specific form, it may be desirable to supplement the form’s checklist or brief narrative fields with documentation that further supports medical necessity. Some payers will specifically ask for such information, but if they do not, providers should be certain to provide enough detail to support the request. Depending upon the drug’s indication, those details may include:

- Concomitant therapies
- Previous medications/outcomes (e.g., failed drugs on the plan’s preferred list)
- Diagnosis that is specific for an indication
- Patient allergies or previous adverse reactions
- Comorbidities
- The drug is in a protected class<sup>1</sup> with no therapeutic equivalent

Payers will make determinations based on the information presented. A poorly documented prior authorization request may be denied and eventually even result in additional work for an exception request. The time frame for a prior authorization decision varies. Some plans will provide an immediate response during a phone communication while others may take several days to process a fax or e-mail request. If a healthcare provider feels that a delay in therapy could significantly jeopardize the patient’s health, the payer should be notified immediately and a request for “expedited review” made.

### What if Coverage Is Not Authorized?

Prior authorization is a routine payer process. It is not a request for the payer to deviate from usual procedures. A prior authorization request that is appropriately submitted and adequately supported will often result in a favorable coverage decision. However, if for some reason a patient cannot meet a payer’s prior authorization requirements for a drug they need, they have the right to request a coverage determination.

The following sections describe the progressive steps that are available to patients seeking coverage for medically necessary drugs that are outside of their prescription benefit design and discuss the healthcare provider’s role.

<sup>1</sup> Medicare Part D formularies must include substantially all drugs in the immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes, with few exceptions. [CMS. Medicare Prescription Drug Benefit Manual. Chapter 6, §30.2.5]

## Exceptions

A coverage determination is a payer’s response to a formal request about coverage. Under most prescription drug benefit programs, a beneficiary can request a coverage determination regarding their drug benefits, including:

- Access to or payment for a specific prescription drug
- A tiering or formulary exception request
- The amount that a payer requires a patient to pay for a prescription drug
- Quantity or dose limits
- Step therapy requirements
- A decision about whether prior authorization or other utilization management requirements have been satisfied

An exception request may also apply to coverage issues beyond prescription drugs under the pharmacy benefit. For example, drugs requiring administration by a healthcare professional may be covered under a patient’s medical benefit. The administration service and even the site of care can require separate authorization and an exception request may apply.

### Exception Types

An exception request is a specific type of coverage determination that asks a payer to reconsider an adverse tiering or formulary decision. It provides a payer the opportunity to move to an individualized, patient-centered decision-making process when the payer’s coverage policies do not meet a patient’s unique needs. There are two categories of exception requests:

- **Formulary exception:** used to obtain a prescription drug that is not included on a plan’s formulary or to change step therapy or quantity/dosage limits<sup>2</sup>
- **Tiering exception:** used to obtain a non-preferred drug at the cost-sharing terms applicable to drugs in the preferred tier<sup>3</sup>

### The Exception Request Process

An enrollee, their appointed representative, or the healthcare provider may request a formulary or tiering exception. Exception requests are granted when a plan determines that a requested drug is medically necessary for that patient. Therefore, no matter who initiates the exception request, the prescriber must submit a statement supporting medical necessity. This evidence may be submitted verbally or in writing, depending on the payer’s requirements. Medicare publishes requirements for Part D plans; however, most plans will seek similar information. The following table summarizes information that may be helpful for supporting a formulary or tiering exception request.

<sup>2</sup> For Medicare Part D plans, if a non-formulary drug is granted an exception, a tiering exception cannot also be requested for the same drug; if a utilization management exception is granted for a formulary drug, a tiering exception may also be requested. [CMS. Prescription Drug Benefit Manual. Chapter 18, §§30.2.1; 30.2.2.]

<sup>3</sup> Limitations may apply, depending upon a plan’s tier structure. For example, a tiering exception may not be used to obtain a brand name drug at the price of a generic and tiering exceptions may not be permitted for drugs on the specialty tier. [CMS. Prescription Drug Benefit Manual. Chapter 18, §30.2.1.4.]

### Exception Request Supporting Information<sup>4</sup>

Exception Type	Supporting Information
Formulary	<ul style="list-style-type: none"> <li>• Preferred drug would not be as effective as the requested drug for treating the condition, or/and</li> <li>• Preferred drug would have adverse effects</li> </ul>
Tiering	<ul style="list-style-type: none"> <li>• Non-formulary drug is necessary because all covered drugs on any tier would not be as effective or would have adverse effects</li> <li>• The number of doses under a dose restriction has been or is likely to be ineffective</li> <li>• The alternative listed on the formulary or required to be used in accordance with step therapy has been or is likely to be ineffective</li> </ul>

### Policy and Process

Most payers follow similar rules and processes for exception requests. The exceptions request policy may be found in the payer’s member or provider handbook, at the payer’s website, or by calling the payer. Exception discussions generally begin with the customer service department, accessed by calling the number located on the back of the patient’s insurance card. If at first the payer’s representative seems unfamiliar with the terms “exception” or “exception request,” providers may find it helpful to explain – in conversational terms – the patient’s situation and ask for direction. For example: “This patient [name] was unable to obtain [name drug] because it is not on your formulary. What can be done to help them acquire this medication that they need for their condition?” If the initial discussions prove unsuccessful, it may be necessary to advance the query to a customer relations supervisor or request that a clinical conversation be arranged between the prescriber and the payer’s Medical Director. In some circumstances, it may be helpful to ask that the request be reviewed by a physician practicing in the the same specialty (“like specialist”).

It is important to follow the plan’s rules, adhere to time lines, and track the process:

- Use any required forms
- Substantiate medical necessity
- Submit information via the required method (e.g., e-mail, fax, verbal, etc.)
- Retain copies of all correspondence and a log of all communication
- Clarify how and where the plan will communicate its decision

Medicare provides an optional model form that may be used to initiate the exceptions request with Part D payers and also for the prescriber to provide supporting information. If a payer does not require use of specific forms the Medicare Model Coverage Determination Request Form format may be helpful when structuring verbal or written communication about the request.

The “Medicare Model Coverage Determination Request Form” is available for download at: <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/CoverageDeterminationsandExceptions.html>

A copy of this form is included in Appendix C, at the back of this guide. Providers may also find the “Payer Communication Checklist” (Appendix A) helpful.

<sup>4</sup> CMS. Prescription Drug Benefit Manual Chapter 18. §§30.2.1.1; 30.2.2.1.

## Standard or Expedited Requests

Payers are required to respond to an exception request within specific time frames. Both standard and expedited processes are available. Medicare Part D payers must respond within 72 hours for a standard request and 24 hours for an expedited request. Although other coverage determination periods generally begin at the time of patient request, for most payers the time period for exception requests does not begin until they receive the prescriber's supporting information.

The expedited process is reserved for those circumstances in which a delay could cause imminent threat to the patient's life or health. If a prescriber believes that a patient requires the expedited process, the payer should be alerted and a specific request – with rationale – made.

Standard Process	Expedited Process
72 hours	24 hours
Starts with receipt of supporting information	Starts with receipt of supporting information
	Reserved for seriously at risk patients

## What if the Exception Request Is Denied?

An exception request that is appropriately submitted and adequately supported will often result in a favorable payer decision. If an exception request is not granted the payer will provide a written explanation as to why it was denied and include information about how to request an appeal.

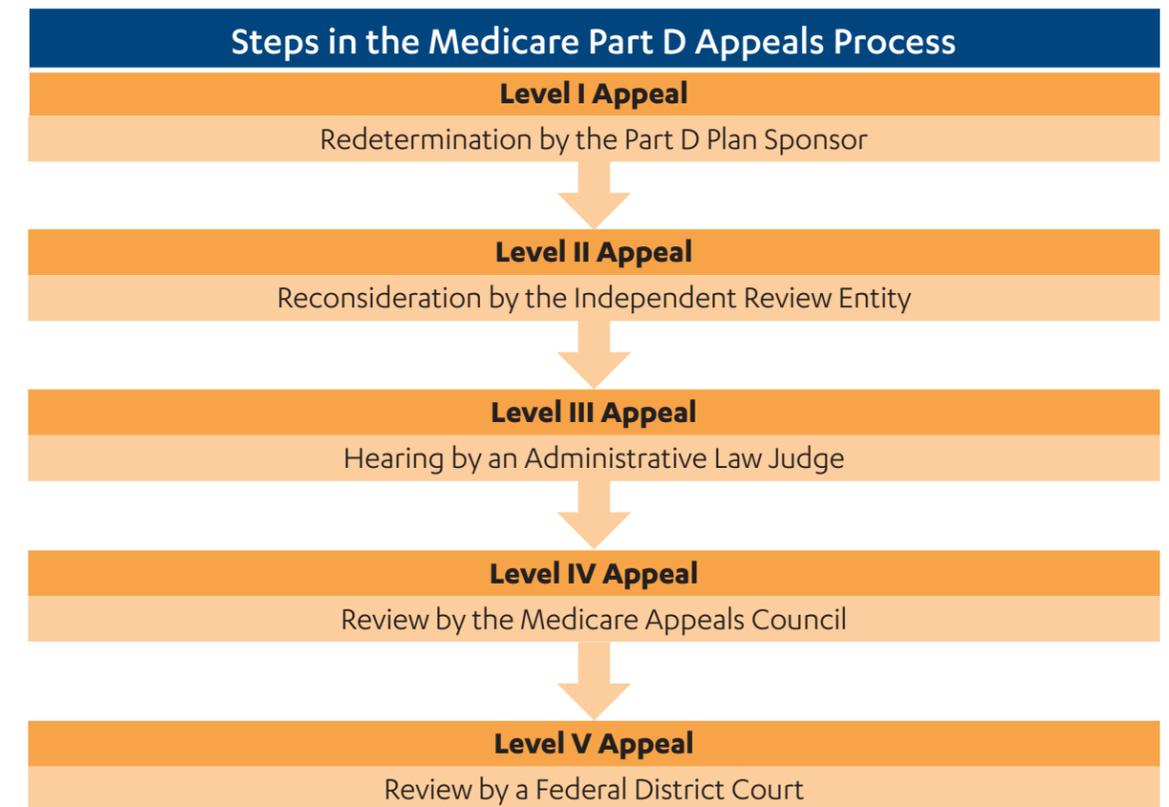
The next section will describe the progressive steps that are available to patients who choose to appeal following denial of an exception request and will discuss the healthcare provider's role.

## Appeals

An appeal refers to any of the procedures used to challenge a payer's adverse coverage determination regarding benefits that a beneficiary believes they are entitled to receive. If a payer does not grant an exception request, that decision may be appealed.

### Overview

When a payer issues an unfavorable coverage determination, the notice should contain the reason for the denial as well as information about filing an appeal. The appeals process is generally designed with a number of successive levels. If the patient disagrees with a payer's decision at any level, they can usually advance to the next. A non-Medicare payer may have an appeals process that is unique to that payer. The Medicare Part D appeals process has five levels, summarized in the exhibit below.



### The Appeals Process

The patient may file the appeal, appoint a representative to act on their behalf, or the prescribing provider may file it. Most payers have similar rules for filing:

- The request must commonly be made in writing
- A supporting statement, explaining the medical reason for the appeal, is required from the prescriber
- The steps of the appeals process must be followed in order
- The timelines assigned to each level must be met

## Policy and Process

A payer's appeals policy may be found in the member's or provider's handbook, at the payer's website, or by calling customer service at the number usually located on the back of the member's insurance card. Before initiating or assisting with an appeal it is advisable to review the payer's process, access any required forms and clarify how the payer expects to receive the information: fax, e-mail, phone, etc. Providers will also want to understand how the payer's decision will be communicated and if it will be sent to the prescriber, the patient or both. Retain copies of all correspondence, including the date and time of each step.

Medicare provides an optional model form that may be used to initiate the appeals process with Part D payers. The prescriber's supporting statement can be attached to this form or submitted in another format (e.g., a letter of medical necessity). The "Request for Redetermination of Medicare Prescription Drug Denial" and instructions for use are available for download at: <http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Redetermination.html>.

Additional resources:

- CMS. Medicare Prescription Drug Appeals and Grievances (Medicare Prescription Drug Benefit Manual, Chapter 18). Available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html>
- CMS website: Appeals Overview with links to the steps of the appeals process and resources. Available at: [www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/AppealsOverview.html](http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/AppealsOverview.html)

If a patient pursues appeals at the higher levels of the Medicare Part D process the healthcare provider may be asked to participate. For example, a patient may request their provider to join an Administrative Law Judge Hearing, usually held by phone or video teleconference, less commonly in person, and explain why he or she believes the drug should be covered.

## Time Frames

Payers are required to respond to each step of the appeals process within specific time frames. Both standard and expedited processes are available. As with exception requests the expedited process is reserved for those circumstances in which a delay could cause imminent threat to the patient's life or health. Time frames for filing and payer responses may vary between non-Medicare payers.

Medicare Part D payers must respond within 7 days for a standard redetermination (Level I Appeal) request and 72 hours for an expedited request. If the appeal advances to Level II (Reconsideration), the standard process has a 7-day time limit and the expedited process, 72 hours. Appeals that move beyond Level II are associated with much longer time frames: 90 days for the standard process and 10 days for expedited. Additionally, the enrollee has 60 days to file at each level of appeal, thus it is possible that the process can extend over a long period of time.

## What if the Appeal Is Unsuccessful?

If an unfavorable decision is returned at any level of appeal, it will be accompanied by information about what is required to file a request for the next level. Once all levels of internal appeals have been exhausted the patient may be eligible for an external review. An external review—or external appeal—is a review of the payer's denial by an independent organization. An external review either upholds the payer's decision or may overturn all or a portion of that decision. The payer must accept the decision of the external review. Since 2012, health insurance issuers in all states must participate in an external review process that meets minimum consumer protection standards outlined in the Affordable Care Act.<sup>5</sup>

Contact information for the organization that will handle an external review may be found: 1) in the health plan's notice of final denial after completing the internal appeals process; or 2) by contacting the individual state's department of insurance. To locate state insurance departments go to: [http://www.naic.org/state\\_web\\_map.htm](http://www.naic.org/state_web_map.htm) and select a state from the interactive map.

Note that the external review process does not apply to self-funded plans. Members of self-funded plans should contact their human resources department for guidance.

<sup>5</sup> Patient Protection and Affordable Care Act. Pub. L. 111-148. §2719(b).

# Additional Considerations

## Pharmacy Benefit Managers

Payers often delegate management of their prescription drug benefit to another entity by establishing a contractual relationship between the payer and a Pharmacy Benefit Manager (PBM). When the management of pharmacy benefits is delegated to a third party the direct connection between the healthcare provider and the payer is eliminated and communication occurs directly with the PBM. Today the majority of consumers with pharmaceutical drug benefits receive these benefits through a PBM.

The PBM administers prescription drug benefits according to their agreement with the payer. Tools and techniques used by PBMs are typically aimed at reducing costs, standardizing processes and improving quality, and may include:

- Formulary management;
- Utilization review;
- Cost-sharing with consumers;
- Disease management programs, and
- Others

It is important to understand this arrangement as it will determine who to contact and where to locate information when trying to solve prescription drug access issues. Note that although the PBM administers the drug benefit, it may not oversee or approve drug administration services. If the drug in question is an HCP administered drug, it may be necessary to authorize those services with the primary payer and not the PBM.

# Appendix A

## Payer Communication Checklist

Activity	✓	Notes
Develop a clear and simple statement of patient needs and rationale for request		
Assemble adequate information to support medical necessity for this request		
<b>For expedited requests:</b> Assemble adequate information to support the urgency of this request		
Designate a primary contact for interacting with the payer/PBM on this matter		
Review the payer's/PBM's website or contact customer service/provider relations for policy/process information including forms, contacts, etc.		
Implement tracking mechanism to log date, time, contact person and outcome of all communication		
Identify how and to whom the payer/PBM will communicate their decision		

This request is for:  Prior authorization  Exception request  Appeal

Primary payer/PBM contact: \_\_\_\_\_

Title: \_\_\_\_\_ Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_

## Appendix B

### Sample Format for Letter of Medical Necessity

[Insert physician letterhead]

[Insert Name of Medical Director] RE: Patient Name [ \_\_\_\_\_ ]  
[Insurance Company] Policy Number [ \_\_\_\_\_ ]  
[City, State, ZIP] Claim Number [ \_\_\_\_\_ ]

Dear [Insurance Company]:

I am writing to provide additional information to support my claim for the treatment of **[insert patient name]** with **[insert drug]** for **[insert diagnosis]**. In brief, treatment of **[insert patient name]** with **[insert drug]** is medically appropriate and necessary and should be a covered and reimbursed treatment.

Below, this letter outlines **[insert patient name]**'s relevant medical history, prognoses, treatment history, and treatment rationale.

**Summary of Patient's History [You may want to include]:**

**[Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]**

- **Patient's diagnosis, condition, and history**
- **Previous therapies the patient has undergone for the symptoms associated with their condition**
- **Patient's response to these therapies**
- **Brief description of the patient's recent symptoms and conditions**
- **Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with [insert drug]**

#### Rationale for Treatment

Given the patient's history, condition, and the published data supporting use of **[insert drug]**, I believe treatment of **[insert patient name]** with **[insert drug]** is warranted, appropriate, and medically necessary. The attached copies of clinical, peer-reviewed published literature and package insert document that **[insert drug]** is an effective therapy for patients like **[insert patient name]**.

Please call my office at **[insert telephone number]** if I can provide you with any additional information. I look forward to receiving your timely response and approval of this claim.

Sincerely,

**[Insert Doctor name and  
National Provider Number (NPI)]**

Enclosures

## Appendix C

### Medicare Part D Coverage Determination (Exception) Request Form

This model form was developed in response to requests from outside parties to provide guidance to enrollees and prescribers on requesting coverage determinations (including exception requests) from Part D payers. It is intended to provide basic information on how to ask for a coverage determination from a Medicare drug payer. There are two components to the model form:

- The request (may be completed by the enrollee, appointed representative or prescriber)
- Supporting information\* (completed and signed by the prescriber)

Under the Medicare Part D prescription drug benefit program, a Part D plan enrollee, the enrollee's representative, or the enrollee's doctor/prescriber can request a coverage determination, including a tiering or formulary exception. A request for a coverage determination can be made verbally or in writing. Use of this form is optional. An enrollee, the enrollee's representative, or the enrollee's prescriber may submit a written request for a coverage determination in any format and cannot be required to use this or any other form.

When requesting a coverage determination from a non-Medicare payer, prescribers may be required to use that payer's specific forms. It is important to clarify with each payer the accepted process and format for submitting coverage determination requests. If the payer does not provide specific forms this model may help organize what is likely to be needed. For all payers, both Medicare and non-Medicare, it may be necessary to submit additional information or documentation to support the request.

\* Note: Formulary and tiering exception requests must include a prescriber's supporting statement.

**REQUEST FOR MEDICARE PRESCRIPTION DRUG COVERAGE DETERMINATION**

This form may be sent to us by mail or fax:

Address: [Insert plan address(es)] Fax Number: [Insert plan fax number(s)]

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].

**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. Contact us to learn how to name a representative.

**Enrollee's Information**

Enrollee's Name		Date of Birth
Enrollee's Address		
City	State	Zip Code
Phone	Enrollee's Member ID #	

Complete the following section **ONLY** if the person making this request is not the enrollee or prescriber:

Requestor's Name		
Requestor's Relationship to Enrollee		
Address		
City	State	Zip Code
Phone		

**Representation documentation for requests made by someone other than enrollee or the enrollee's prescriber:**

**Attach documentation showing the authority to represent the enrollee (a completed Authorization of Representation Form CMS-1696 or a written equivalent). For more information on appointing a representative, contact your plan or 1-800-Medicare.**

<b>Name of prescription drug you are requesting</b> (if known, include strength and quantity requested per month):
--

**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 a statement supporting your request. Requests that are subject to prior authorization (or any other utilization management requirement), may require supporting information. Your prescriber may use the attached "Supporting Information for an Exception Request or Prior Authorization" to support your request.**

Additional information we should consider (*attach any supporting documents*):

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**Important Note: Expedited Decisions**

If you or your prescriber believe that waiting 72 hours for a standard decision could seriously harm your life, health, or ability to regain maximum function, you can ask for an expedited (fast) decision. If your prescriber indicates that waiting 72 hours could seriously harm your health, we will automatically give you a decision within 24 hours. If you do not obtain your prescriber's support for an expedited request, we will decide if your case requires a fast decision. You cannot request an expedited coverage determination if you are asking us to pay you back for a drug you already received.

**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).**

<b>Signature:</b>	<b>Date:</b>
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**Supporting Information for an Exception Request or Prior Authorization**

FORMULARY and TIERING EXCEPTION requests cannot be processed without a prescriber's supporting statement. PRIOR AUTHORIZATION requests may require supporting information.

**REQUEST FOR EXPEDITED REVIEW: 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.**

Prescriber's Information		
Name		
Address		
City	State	Zip Code
Office Phone	Fax	
Prescriber's Signature		Date

Diagnosis and Medical Information		
Medication:	Strength and Route of Administration:	Frequency:
New Prescription OR Date Therapy Initiated:	Expected Length of Therapy:	Quantity:
Height/Weight:	Drug Allergies:	Diagnosis:

Rationale for Request
<input type="checkbox"/> <b>Alternate drug(s) contraindicated or previously tried, but with adverse outcome, e.g., toxicity, allergy, or therapeutic failure</b> [Specify below: (1) Drug(s) contraindicated or tried; (2) adverse outcome for each; (3) if therapeutic failure, length of therapy on each drug(s)]
<input type="checkbox"/> <b>Patient is stable on current drug(s); high risk of significant adverse clinical outcome with medication change</b> [Specify below: Anticipated significant adverse clinical outcome]
<input type="checkbox"/> <b>Medical need for different dosage form and/or higher dosage</b> [Specify below: (1) Dosage form(s) and/or dosage(s) tried; (2) explain medical reason]
<input type="checkbox"/> <b>Request for formulary tier exception</b> [Specify below: (1) Formulary or preferred drugs contraindicated or tried and failed, or tried and not as effective as requested drug; (2) if therapeutic failure, length of therapy on each drug and adverse outcome; (3) if not as effective, length of therapy on each drug and outcome]
<input type="checkbox"/> <b>Other</b> (explain below)
<b>Required Explanation</b> _____ _____ _____ _____

This form is also available online at: <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/CoverageDeterminationsandExceptions.html>

Note: Some payers require specific forms for injectable or specialty drugs. Please check with the participating payer for any specific requirements.

# Appendix D

## Tools and Resources

Resource	Access
<p><b>CMS Exceptions and Appeals Processes</b></p> <p>CMS website for Part D exceptions and appeals processes; offers links to resources</p>	<p><a href="http://www.cms.gov/MedPrescriptDrugApplGriev">www.cms.gov/MedPrescriptDrugApplGriev</a></p>
<p><b>How Medicare Prescription Drug Plans and Medicare Advantage Plans with Prescription Drug Coverage (MA-PDs) Use Pharmacies, Formularies, and Common Coverage Rules</b></p> <p>CMS beneficiary publication providing overview of Medicare Part D; specifically reviews coverage rules</p>	<p><a href="https://www.medicare.gov/Pubs/pdf/11136-Pharmacies-Formularies-Coverage-Rules.pdf">https://www.medicare.gov/Pubs/pdf/11136-Pharmacies-Formularies-Coverage-Rules.pdf</a></p>
<p><b>Forms</b></p> <p>Website with links to forms applicable to Part D grievances, coverage determinations and exceptions, and appeals processes</p>	<p><a href="https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/CoverageDeterminationsandExceptions.html">https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/CoverageDeterminationsandExceptions.html</a></p>
<p><b>Medicare Appeals</b></p> <p>CMS beneficiary publication for all types of Medicare appeals; contains Part D specific information</p>	<p><a href="https://www.medicare.gov/Pubs/pdf/11525-Medicare-Appeals.pdf">https://www.medicare.gov/Pubs/pdf/11525-Medicare-Appeals.pdf</a></p>
<p><b>State Health Insurance Assistance Program (SHIP)</b></p> <p>Obtain state specific contact numbers</p>	<p><a href="http://www.medicare.gov/contacts">www.medicare.gov/contacts</a></p>

