Exceptions and Appeals for Drug Therapies: A Guide for Healthcare Providers

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Additional Considerations

Introduction

This brochure has been developed to help healthcare providers and their patients understand how to request payer coverage for medically necessary drug therapies when:

- Initial requests for coverage are denied
- Patients need a product that would normally be subject to step therapy
- Patients need a product that is not routinely available within a payer's network or service area
- Payers require healthcare providers to support prescriptions with additional information to ensure patient access to therapy

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 are used correctly and only when medically necessary. These include prior authorization, step therapy, and quantity limits.

Overview

Prior authorization (PA) processes require healthcare providers to contact and receive approval from a patient's payer before that payer will cover a certain prescription drug. In these situations the prescriber must substantiate – verbally or in writing – why a particular therapy is medically necessary. Depending upon the payer and specifically requested therapy, the PA decision may be managed by pharmacy staff, medical policy staff, or a designated prior authorization department. Covered drugs that require PA are indicated in the plan's formulary and may also be listed more prominently 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 instance, 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 on 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.)

Quantity Limits

Payers may also 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 and associated administration services (e.g., professional 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 guidelines 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. 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, that detail 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
- Co-morbidities
- The drug is in a protected class[1] 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 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 likely 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.

[1] 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

Overview

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[2]
- **Tiering exception:** used to obtain a non-preferred drug at the cost-sharing terms applicable to drugs in the preferred tier[3]

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.

[2] 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.]

[3] 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[4]

Exception Type	Supporting Information
Formulary	• Preferred drug would not be as effective as the requested drug for treating the condition, or/and • Preferred drug would have adverse effects
Tiering	• Non formulary drug is necessary because all covered drugs on any tier would not be as effective or would have adverse effects • The number of doses under a dose restriction has been or is likely to be ineffective • The alternative listed on the formulary or required to be used in accordance with step therapy has been or is likely to be ineffective

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.

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: http://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.

[4] CMS. Prescription Drug Benefit Manual Chapter 18. §§30.2.1.1; 30.2.2.1. Available at: http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Forms.html.

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. (For a more detailed look at the Medicare appeals process, please refer to Appendix D.)

Steps in the Medicare Part D Appeals Process

Level I Appeal
Redetermination by the Part D Plan Sponsor

↓

Level II Appeal
Reconsideration by the Independent Review Entity

↓

Level III Appeal
Hearing by an Administrative Law Judge

↓

Level IV Appeal
Review by the Medicare Appeals Council

↓

Level V Appeal
Review by a Federal District Court

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 "Medicare Model Coverage Redetermination Request Form" and instructions for use are available for download at: http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Redetermination.html.

Additional resources:

- CMS. Prescription Drug Benefit Manual Chapter 18. Available at: www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.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

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. (Please see Appendix D.)

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. Effective January 1, 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.[5]

[5] Patient Protection and Affordable Care Act. Pub. L. 111-148. §2719(b).

Medicaid

Medicaid is a joint Federal-State program that pays for medical assistance for individuals and families with low incomes and relatively few assets. Although pharmacy coverage is an optional benefit under federal Medicaid law, all States currently provide coverage for outpatient prescription drugs to all categorically eligible individuals and most other enrollees within their Medicaid programs.

Patients that are covered by both Medicare and Medicaid (dual-eligibles) receive their drug coverage under Medicare Part D, and therefore will follow the guidance for Medicare Part D payers. For those Medicaid beneficiaries that are not dually eligible, prescription drug benefits are provided through the individual state program or managed Medicaid payer. Medicaid prescription drug programs differ from state to state. Both the exceptions and appeals guidelines should be obtained from the involved payer and followed accordingly:

- Managed Medicaid: contact the managed care provider
- Traditional Medicaid: contact the state program's customer service department or pharmacy

Although the exceptions and appeals processes are not standardized across states, payers are likely to have similar processes:

- Requests will generally need to be made in writing (required forms may be available)
- Documentation supporting medical necessity will be required from the prescriber
- Adverse coverage determinations may be appealed
- The appeals process will likely consist of successive steps with specific time frames

Veteran's Health Administration[6]

To qualify for the prescription benefit provided by the Veteran's Administration Pharmacy Service, a patient must be enrolled in and receiving health care from the VA healthcare system or be eligible based on one of the exceptions in the law. Only prescriptions written by a VA healthcare provider or a VA-authorized provider can be provided by the VA. Prescriptions from a private healthcare provider will be reviewed by the VA to determine if they can be rewritten by a VA healthcare provider and dispensed from a VA pharmacy or sent to the patient by mail order.

The Veteran's Administration National Formulary (VANF) is the sole formulary for the Veteran's Health Administration (VHA) system. Veterans Integrated Service Networks (VISNs) and local facilities may request additions to the VANF by completing a National Formulary request form, available at the VHA web site (http://www.pbm.va.gov/nationalformulary.asp). A formulary request process, developed and overseen by the facility Pharmacy & Therapeutics (P&T) Committee, is required at each VA facility.

Routine requests for **non formulary agents** ("exception requests") are reviewed by the facility Pharmacy Chief of Service, and the requestor notified of the decision within 96 hours of receipt of such a request. Emergency requests for non formulary agents are immediately addressed by individual(s) identified in the local VA medical center policy. For urgent or emergency situations the drug will be

[6] VHA Handbook. Formulary Management Process.§1808.08. Available at: http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2417.

provided immediately and reviewed afterwards. Specialty non formulary drug requests may be reviewed and approved by the facility Chief of Service for that specialty area (e.g., oncology).

Requests may be approved based on VA approval criteria, such as:

- Contraindication to formulary agent
- Adverse reaction to formulary agent
- Therapeutic failure of alternatives
- Formulary alternative does not exist
- Previous response to non formulary agent
- Risk associated with change
- Compelling, evidence-based rationale

If the exception (non formulary request) is denied, the prescribing physician may appeal. All appeals for disapproved non formulary requests are adjudicated by the facility Chief of Staff.

TRICARE Pharmacy Program[7]

The Department of Defense (DoD) has established a uniform formulary of covered generic and brand-name drugs. The formulary also contains a third tier of medications that are considered "non formulary". Prescriptions for non formulary drugs are available but require an exception or are dispensed at a higher cost to beneficiaries:

- Active duty beneficiaries—provider must file an exception request
- Non-active duty beneficiaries—co-payment is at the higher (Tier 3) level; exception request required to lower the co-payment from Tier 3 (non formulary) to Tier 2 (brand)

The following table summarizes the available types of TRICARE exceptions, by beneficiary status:

Beneficiary Status	Type of Exception Request
Active duty	• Formulary coverage
Non-active duty	• Co-pay tier reduction

Active duty beneficiaries have no co-pay at Military Treatment Facilities. If medical necessity is approved, active duty and other beneficiaries may receive non formulary medications through TRICARE Pharmacy Home Delivery or at retail network pharmacies at no cost.

Exception requests in the TRICARE system are made by establishing medical necessity in compliance with established criteria, such as:

- Contraindication
- Adverse reaction
- Therapeutic failure
- No acceptable alternatives
- Response to previous therapy
- Change is risky

[7] TRICARE Pharmacy Program Handbook. Available at: http://www.military.com/benefits/tricare/tricare-pharmacy-program.

When assessing medical necessity the TRICARE process compares the requested drug against all of the available formulary drugs. Drug specific criteria and forms are available for download and must be completed by the prescriber. Denied claims may be appealed up to 90 days following notice of denial.

To access information on prior authorization, exceptions, medical necessity and obtain required forms, please see:

The Department of Defense Pharmacoeconomic Center at: http://pec.ha.osd.mil/forms_criteria.php

Express Scripts is the TRICARE pharmacy benefits manager and also provides the mail order and specialty pharmacy services (www.express-scripts.com/TRICARE/)

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 issues. Note that although the PBM administers the drug benefit, it may not oversee or approve drug administration services. If the drug in question requires professional administration (e.g., injection or infusion) it may be necessary to authorize those services with the primary payer and not the PBM.

Appendices

Appendix A

Payer Communication Checklist

Activity	✓	Notes
I have developed a clear and simple statement about what my patient needs and why		
I have assembled information adequate to support medical necessity for this request		
For expedited requests: I have assembled adequate information to support the urgency of this request		
I have designated a primary contact for interacting with the payer/PBM on this matter		
I have reviewed the payer's/PBM's website or contacted customer service/provider relations for policy/process information including forms, contacts, etc.		
I have a tracking mechanism in place to log date, time, contact person and outcome of all communication		
I understand 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]

[Medical Director] RE: Patient Name _____

[Insurance Company] Policy Number _____

[Address] Claim Number _____

[City, State, ZIP]

Dear:

I am writing to provide additional information to support my treatment of **[insert patient name]** with **[insert drug name]** for **[insert diagnosis]**. The prescription of **[insert drug name, dosage and route of administration]** for **[insert patient name]** is medically appropriate and necessary and should be a covered and reimbursed service. This letter outlines **[patient's name]** medical history, prognosis, and treatment rationale.

Summary of Patient's History **[describe the patient's medical condition]**

Information that may be helpful to include:

- Patient's diagnosis, history and current status
- Previous therapies the patient has received for this condition
- Patient's response to these therapies
- Brief description of the patient's recent symptoms and current condition
- Rationale for treatment
- Summary (your professional opinion) about the likely outcome of failure to treat with **[insert drug name]**

Given the **[insert patient's name]** history, condition, and the published data supporting use of **[insert drug name]** I believe this treatment is warranted, appropriate and medically necessary.

Please contact my office at **[insert telephone number]** if you require any additional information. I look forward to receiving your timely response and approval of this therapy for my patient.

Sincerely,

[Insert physician's name]

[Insert participating provider number]

Enclosures

[Attach any supporting documentation]

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:	Fax Number:
[Insert plan address(es)]	[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.

Name of prescription drug you are requesting (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)*:

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).**

Signature:	**Date:**

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

☐ **Alternate drug(s) contraindicated or previously tried, but with adverse outcome, e.g., toxicity, allergy, or therapeutic failure** [Specify below: (1) Drug(s) contraindicated or tried; (2) adverse outcome for each; (3) if therapeutic failure, length of therapy on each drug(s)]

☐ **Patient is stable on current drug(s); high risk of significant adverse clinical outcome with medication change** [Specify below: Anticipated significant adverse clinical outcome]

☐ **Medical need for different dosage form and/or higher dosage** [Specify below: (1) Dosage form(s) and/or dosage(s) tried; (2) explain medical reason]

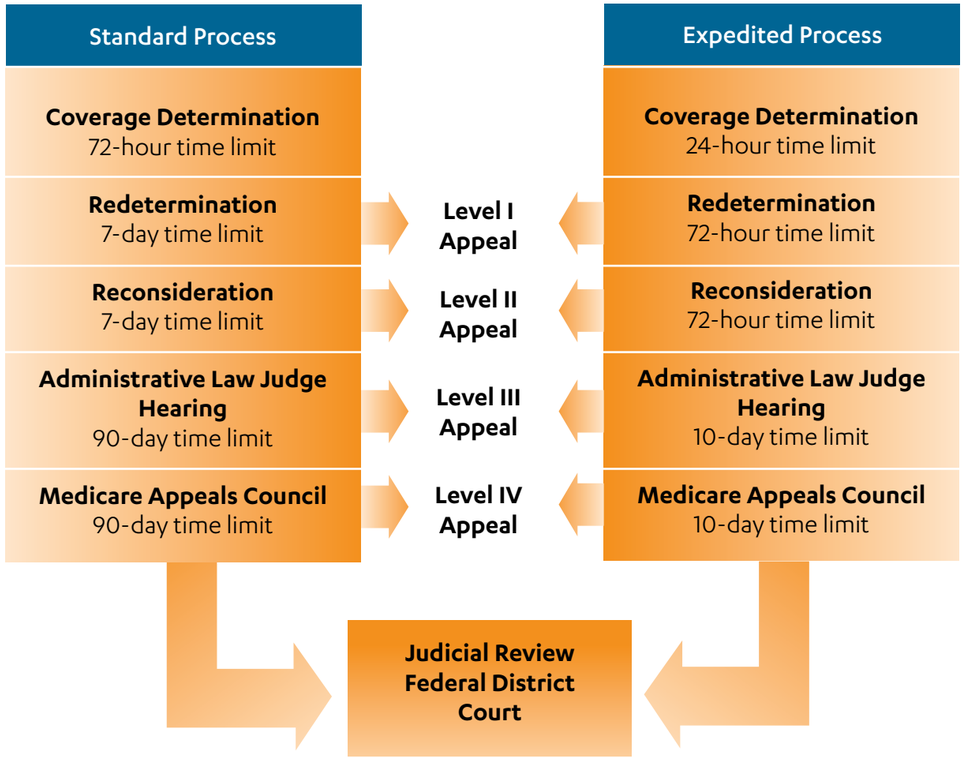
☐ **Request for formulary tier exception** [Specify below: (1) Formulary or preferred drugs contraindicated or tried and failed, or tried and not as effective as requested drug; (2) if therapeutic failure, length of therapy on each drug and adverse outcome; (3) if not as effective, length of therapy on each drug and outcome]

☐ **Other** (explain below)
Required Explanation _____
_____
_____
_____
_____

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

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

Appendix D



Note: Medicaid and commercial payers may not follow the same appeals process. Please check with the specific payer and follow that process.

Source: CMS. Flow Chart: Medicare Part D Appeals Process. Available at: http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/AppealsOverview.html.

Appendix E

Tools and Resources

Resource	Access
CMS Exceptions and Appeals Processes CMS website applicable to Part D exceptions and appeals processes; offers links to resources	www.cms.gov/MedPrescriptDrugApplGriev
How Medicare Prescription Drug Plans and Medicare Advantage Plans with Prescription Drug Coverage (MA-PDs) Use Pharmacies, Formularies, and Common Coverage Rules CMS beneficiary publication providing overview of Medicare Part D; specifically reviews coverage rules	www.medicare.gov/Pubs/pdf/11136.pdf
Forms Website with links to forms applicable to Part D grievances, coverage determinations and exceptions, and appeals processes	www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Forms.html
Medicare Appeals CMS beneficiary publication for all types of Medicare appeals; contains Part D specific information	www.medicare.gov/Pubs/pdf/11525.pdf
Medicaid Exceptions and Appeals Processes Access contact information by state	www.medicare.gov/contacts
Sponsor Grievance, Coverage Determination and Appeals Contacts Download files: contact information for exceptions and appeals responsibility at Medicare Part D plans	www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Exceptions.html
State Health Insurance Assistance Program (SHIP) Obtain state specific contact numbers	www.medicare.gov/contacts
TRICARE Pharmacy Program Link to medical necessity criteria, forms, etc.	www.express-scripts.com/TRICARE/
VA Pharmacy Benefits Management Link to formulary, clinical guidance, etc.	www.pbm.va.gov/

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