

Overview of the Exceptions and Appeals Processes

Introduction

Centocor Ortho Biotech Inc. has developed this guide to help you understand:

1. How to request coverage under a plan's "exception process" (i.e., how to request coverage of a desired medicine when it is not on formulary or otherwise available). When a new drug becomes available, health plans may not always put the drug on their list of covered drugs immediately, and that may prevent you from obtaining new medicines. In these situations, you and your healthcare provider have the right to ask the health plan in advance to consider making the drug available to you as an exception to the plan's policies.
2. How to use the appeals process if your request for coverage is denied after your prescription is filled.

These are commonly used processes and most health plans expect these requests when new unique medicines enter the market.

In addition to an overview of the exceptions and appeals processes, this guide also provides information regarding Medicare Part D, useful resources, and a planning checklist for you and your caregivers.



Exceptions

What is an Exception?

An exception is an initial request for a health plan to reconsider coverage for a prescribed drug therapy or “determination” regarding benefits. For prescription drug benefits, the following may be among the reasons to request an exception:

- A drug is not on formulary
- There are requirements for pre-authorization, dosage or quantity limits, or step-therapy
- A drug is not considered a “preferred” brand and requires a high level of cost sharing

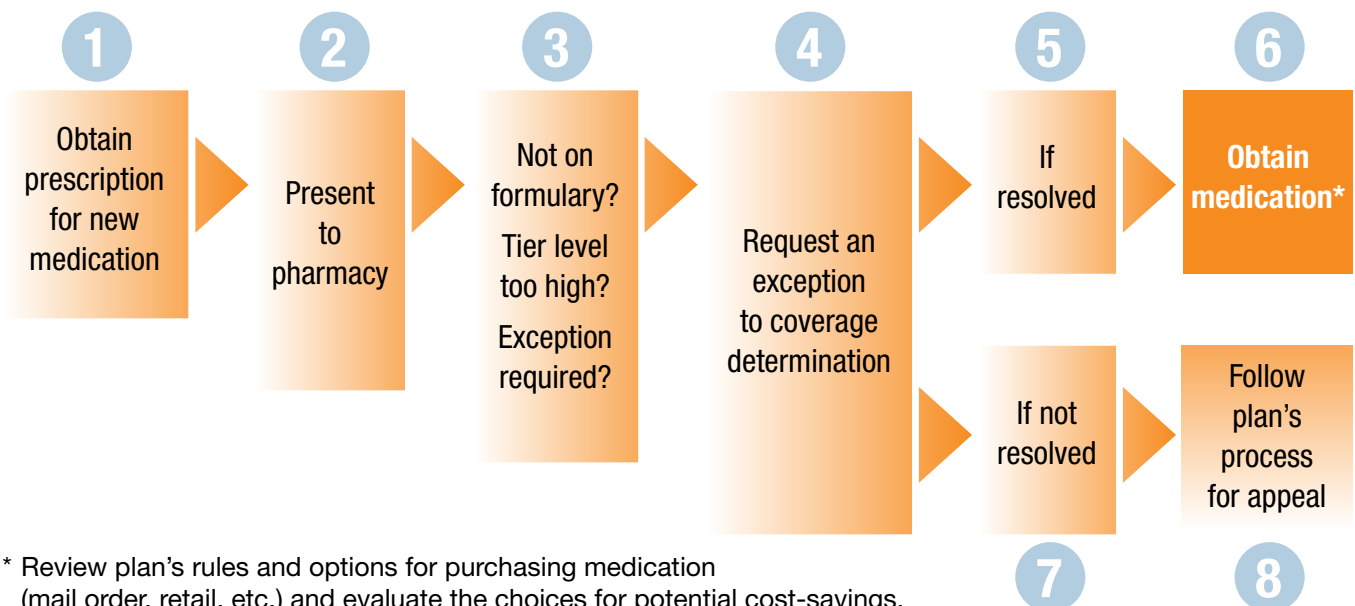
The Exceptions Process

Most health plans have similar general rules regarding exception requests:

- 1) The request must be made in writing (some plans will require use of their specific form, others will specify the type of information to include in a letter requesting an exception)
- 2) A supporting statement from the prescribing doctor must accompany the request
- 3) Expedited processes are available if there is threat to patient life or health

Once the need for an exception is identified, patients or their caregivers should contact their health plan, review the requirements, and obtain any forms that are required for filing the request. The following diagram illustrates the exceptions process:

The Exception and Appeals Process



* Review plan's rules and options for purchasing medication (mail order, retail, etc.) and evaluate the choices for potential cost-savings.

Appeals

What is an Appeal?

An appeal is subsequent request for a health plan to reconsider a coverage decision that was initially denied.

- Patients have the right to an appeal when an exception request has not been granted

The Appeals Process

The appeals process provides patients with additional options to reverse a negative decision regarding their coverage. In most cases this process is progressive, with sequential phases so that failure to reverse a negative decision at any one step leads to a subsequent, higher level appeal. It is important to remember that the steps must be followed in order. Failure to complete the requirements at one level of the appeals process usually prevents patients from moving to the next level of appeal. The appeals process ends when the patient has obtained drug coverage or all available levels of appeal have been exhausted.

Most health plans have similar rules regarding appeals:

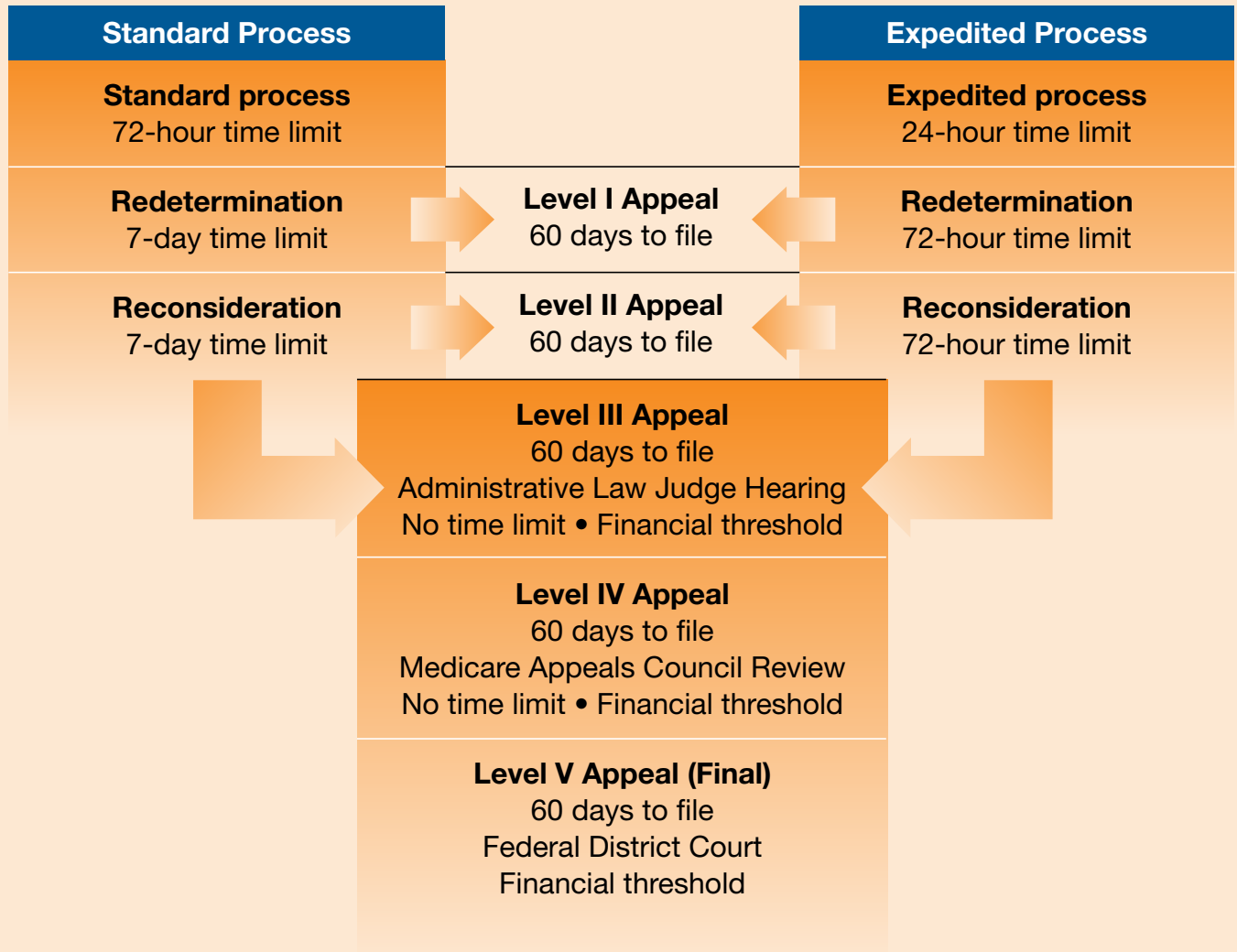
- 1) An appeal is a response to denial of an exception request
- 2) All communication must be in writing
- 3) Supporting documentation, including a doctor's statement, is required
- 4) Expedited processes are available if there is threat to patient life or health
- 5) The steps of the appeals process must be followed in order
- 6) The timelines of each step must be followed

Each private health plan will have an appeals process that is unique to that plan. Upon identifying the need for an appeal, patients should contact their plan, review the requirements and obtain any required forms. The diagram on the right illustrates how the Medicare appeals process follows a denied exceptions request and provides an example of the appeals flow.

Remember that Medicaid and commercial plans may have a different process. Patients and their caregivers should always contact their specific plan for guidance. Calling the member services on your insurance card is usually a good place to start.

Appeals Process for Medicare Part D

Medicare Part D provides five levels of possible appeal (see chart below).



Checklist and Resources

Steps toward obtaining my medication:

Yes No

- | | | | |
|---|--|--------------------------|--------------------------|
| 1 | I have been notified that my medication is not covered because it is not on the formulary or that I will need to pay a high price or meet other requirements before obtaining it. | <input type="checkbox"/> | <input type="checkbox"/> |
| 2 | I have contacted my health plan for guidance in requesting an exception to coverage determination, including what and how to submit the request. . . | <input type="checkbox"/> | <input type="checkbox"/> |
| 3 | I have discussed the situation with my doctor and requested a supporting statement as needed | <input type="checkbox"/> | <input type="checkbox"/> |
| 4 | I have obtained the correct form from my health plan or because I am enrolled in a Medicare Part D plan I will use the “Model Form—Medicare Prescription Drug Exception” available from Medicare | <input type="checkbox"/> | <input type="checkbox"/> |
| 5 | I understand that the timing of a response from my plan will vary by plan and the state in which I live. | <input type="checkbox"/> | <input type="checkbox"/> |
| 6 | If my medication is for chronic use or is classified as a biologic, I have checked with my health plan for any special or required rules for obtaining it. | <input type="checkbox"/> | <input type="checkbox"/> |
| 7 | I am aware of the available options for purchasing my medication (mail order, retail pharmacy, etc.) and have evaluated the choices for potential cost-savings. | <input type="checkbox"/> | <input type="checkbox"/> |

Resource

Phone

Website

Medicare Prescription Drug Coverage: How to File a Grievance, Request a Coverage Determination, or File an Appeal

1-800-633-4227
to order a copy

www.medicare.gov/Publications/Pubs/pdf/11112.pdf
to download a copy

Centers for Medicare & Medicaid Services (CMS)

Medicaid Exceptions and Appeals Processes

Toll free numbers vary
from state to state

www.cms.hhs.gov/MedPrescriptDrugApplGriev

www.cms.hhs.gov/medicaid/consumer.asp
for a list of toll free numbers

AccessOne®

(888) ACCESS-1
(222-3771)

www.centacoraccessone.com

How to Access New Products Under Your Health Plan’s Exceptions and Appeals Process

www.centacoraccessone.com
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Summary

- The exceptions process may be used if a patient's prescribed medication is not on their health plan's formulary or if a patient will have to pay a high cost or meet other requirements before obtaining it.
- Information regarding the exceptions process is available directly from each health plan and may be obtained through your benefits manual, customer service, or the health plan's website.
- If an exception request is denied, a request for reconsideration may be made by using the plan's appeals process.
- Information regarding the appeals process can be obtained from the specific plan involved. Each step must be followed exactly, including making sure all time frames and deadlines are met.
- Once a patient has been granted access to the medication, they should carefully review and select the best option for obtaining it, taking into consideration any limitations the plan may have imposed, as well as convenience and cost.

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