Part D Coverage Determinations, Appeals & Grievances

Web-Based Training (WBT) Course

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Sponsors

The Part D Coverage Determinations, Appeals & Grievances Web-Based Training (WBT) course is brought to you by the Centers for Medicare & Medicaid Services (CMS) Medicare Learning Network® (MLN)

Introduction

Although this course is designed for Medicare Part D plans, it was made available through the assistance of the **Medicare Learning Network® (MLN)**.

Welcome to the **MLN** – Your Medicare education and information resource!

The MLN is the home for education, information, and resources for the health care professional community. The MLN provides access to the Centers for Medicare & Medicaid Services (CMS) program information you need, when you need it, so you can focus on providing care to your patients.

Serving as the umbrellas for a variety of CMS education and communication activities, the MLN offers:

1. MLN Educational Products, including MLN Matters ®Articles;
2. Web-Based Training (WBT) Courses (many offering Continuing Education Credits)
3. MLN Connects™ National Provider Calls;
4. MLN Connects™ Provider Association Partnerships;
5. MLN Connects™ Provider eNews; and
6. Provider Electronic Mailing Lists.

Part D Coverage Determinations, Appeals & Grievances WBT Course

This WBT course consists of a Pre-Assessment, course content, review questions, Post-Assessment, and course evaluation. Successfully completing this course requires completing the Pre-Assessment, course content, course evaluation, and achieving a cumulative score of 70 percent or higher on the Post-Assessment.

This course uses cues at various times to provide additional information. The cues are hyperlinks, buttons, and rollovers. For information on using these cues, as well as suggested browser settings, click the “HELP” button in the right-hand corner.

After successfully completing the course, you will receive instructions on how to print your certificate.

Click the “Disclaimers” button below for the disclaimers pertaining to this WBT course.

DISCLAIMERS

Welcome to the Part D Coverage Determinations, Appeals & Grievances WBT Course

The Part D Coverage Determinations, Appeals & Grievances WBT course was created by CMS to educate health care and plan professionals about Part D coverage determinations, appeals & grievances.

Course Objectives

Upon completing this course, you should be able to correctly:

- Identify the basic definitions of terms related to Part D coverage determinations, appeals & grievances;
- Recognize requirements for coverage determinations;
- Recognize requirements for appeals;
- Recognize requirements for effectuation;
- Recognize requirements for grievances; and
- Identify some common problems encountered by plans.

Part D Coverage Determinations, Appeals & Grievances WBT Course Overview

After completing the Pre-Assessment, you will be able to access the course lessons. This course is divided into four lessons.

Lesson 1: Basic Definitions covers certain basic definitions you should know when fulfilling the requirements for Part D coverage determinations, appeals & grievances.

Lesson 2: Coverage Determinations provides an overview of coverage determinations, including how to make a request, the time frames for processing, and notification requirements.

Lesson 3: Appeals & Grievances discusses requirements for redeterminations, appeals, effectuation, and grievances.

Lesson 4: Common Problems reviews common plan errors identified by CMS based on audit findings and plan oversight efforts.

You do not have to complete the course in one session; however, you must complete at least one lesson before exiting the course. Do not click the "X" button in the right-hand corner of the window as this will cause you to exit the WBT course and the system will not record your progress. The entire course can be completed in about 60 minutes. Following the lessons, you will complete a Post-Assessment and course evaluation.

Click the "MAIN MENU" button to test your current knowledge of Part D Coverage Determinations, Appeals & Grievances.

Welcome to Lesson 1: Basic Definitions

This lesson introduces the basic definitions you should know when fulfilling the requirements for Part D coverage determinations, appeals & grievances. The following pages review these key terms. It should take you about 10 minutes to complete this lesson.

> **NOTE:** For a quick overview of the Medicare Part D Program, view the "Part D Understanding Medicare" video at http://www.youtube.com/watch?v=iAIA41j4Ubc on the Internet. For more information about Part D coverage determinations, appeals & grievances, visit http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev on the Centers for Medicare & Medicaid Services (CMS) website.

Lesson Objectives

Upon completing this lesson, you should be able to correctly:

- Identify the basic definitions of terms related to Part D coverage determinations, appeals & grievances.

Basic Definitions: Enrollee

An enrollee is a Part D eligible individual who has elected a plan offered by a Part D plan sponsor.

Basic Definitions: Coverage Determination

A coverage determination is any decision made by, or on behalf of, a Part D plan sponsor regarding payment or benefits to which an enrollee believes he or she is entitled.

This can include:

- Pre-benefit decisions; and
- Reimbursements of claims for drugs already purchased.

Basic Definitions: Appeal

An appeal is any of the procedures which deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under the Part D plan the enrollee believes he or she is entitled to receive, including any cost sharing amounts the enrollee must pay for the drug coverage.

These procedures include the five levels of appeals on the next page.

Basic Definitions: Appeal Procedures

JOB AID A

Click here for a printable PDF

Appeal procedures may include the five levels of the appeals process:

1	Redeterminations	Redeterminations by the Part D plan sponsor;
2	IRE Reconsiderations	Reconsiderations by the Independent Review Entity (IRE);
3	ALJ Hearings	Administrative Law Judge (ALJ) hearings;
4	MAC Review	Review by the Medicare Appeals Council (MAC); and
5	Judicial Review	Judicial review by a Federal District Court.

Basic Definitions: Redetermination

A redetermination is the first level of the appeal process. Redeterminations involve a Part D plan sponsor reevaluating an adverse coverage determination, the findings upon which it was based, and any other evidence submitted or obtained.

Basic Definitions: Independent Review Entity (IRE)

The IRE is an independent entity contracted by CMS to review Part D plan sponsor denials of:

- Coverage determinations; and
- Redeterminations.

Basic Definitions: Effectuation

Effectuation is compliance with:

- A favorable determination; or
- A complete or partial reversal of a Part D plan sponsor's initial adverse coverage determination.

Compliance may entail:

- Payment of a claim; or
- Authorization for, or provision of, a benefit.

Basic Definitions: Grievance

A grievance is any complaint or dispute, other than a coverage determination or Late Enrollment Penalty (LEP) determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested.

A grievance may also include a complaint that a Part D plan refused to expedite a coverage determination or redetermination, or invoked an extension of the time frame for making a decision.

Grievances may include complaints regarding the timeliness, appropriateness, access to, and/or setting of a provided item.

Review Questions

You've just learned the basic definitions you should know when fulfilling the requirements for Part D Coverage Determinations, Appeals & Grievances. The following pages present review questions to help reinforce your new knowledge.

Click the "NEXT" button to proceed to the review questions.

JOB AID B

Click here for a summary of basic definitions in a printable PDF

Review Question 1 of 3

Select the correct answer.

Which of the terms below refers to any complaint or dispute, other than a coverage determination or a Late Enrollment Penalty (LEP), expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested?

A. Redetermination

B. Grievance

C. Reconsideration

Review Question 2 of 3

Select the correct answer.

Which of the terms below refers to the first level of the appeal process that is conducted by the plan sponsor?

A. Redetermination

B. Grievance

C. Reconsideration

Review Question 3 of 3

Select the correct answer.

Which of the terms below refers to the second level of the appeal process that is conducted by an Independent Review Entity (IRE)?

A. Redetermination

B. Grievance

C. Reconsideration

Congratulations!

You've completed Lesson 1: Basic Definitions.

Now that you've learned the basic definitions related to Part D coverage determinations, appeals & grievances, let's look at the requirements for coverage determinations in detail. Lesson 2: Coverage Determinations, provides an overview of coverage determinations, including how to make a request, the time frames for processing, and notification requirements.

Click the "MAIN MENU" button to return to the Web-Based Training (WBT) course Main Menu. Then select "Lesson 2: Coverage Determinations" to begin Lesson 2. Do not click the "X" button in the right-hand corner of the window as this will cause you to exit the WBT course and the system will not record your progress.

Welcome to Lesson 2: Coverage Determinations

This lesson provides an overview of coverage determinations. It discusses how to make a request, the time frames for processing, and notification requirements. It should take you about 10 minutes to complete this lesson.

Lesson Objectives

Upon completing this lesson, you should be able to correctly:

- Recognize the requirements for coverage determinations.

Coverage Determinations

Coverage determinations may involve:

- A decision about whether to **provide** or **pay** for a Part D drug that the enrollee believes may be covered by the plan;
- A decision concerning a tiering exception request;
- A decision concerning a formulary exception request;
- A decision about the amount of cost sharing for a drug;
- A decision about whether an enrollee has, or has not, satisfied a prior authorization or other utilization management request; or
- Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee (this constitutes an adverse coverage determination).

Coverage Determinations (continued)

For more information about each type of coverage determination, refer to 42 Code of Federal Regulations (CFR) 423.566 at http://www.ecfr.gov/cgi-bin/text-idx?SID=481da968ea8d735aa4aed92cfc996c36&node=42:3.0.1.1.10&rgn=div5#42:3.0.1.1.10.13.5.5 on the Internet. For tiering exceptions, refer to 42 CFR 423.578(a). For formulary exceptions, refer to 42 CFR 423.578(b).

Additionally, you may refer to the “Medicare Prescription Drug Benefit Manual,” Publication 100-18, Chapter 18, at http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev on the CMS website.

Coverage Determination Requests

The enrollee, the enrollee's representative, or the enrollee's prescriber may request a coverage determination.

If the request involves Part D drug benefits that an enrollee has not yet received, the request may be made verbally, in writing, or electronically through the plan's website. If the request is for reimbursement for a drug the enrollee has already received, the request **must** be made in writing (unless the sponsor allows oral requests).

> **NOTE:** When a coverage determination request is subject to the exceptions process (either tiering or formulary), a supporting statement from the prescriber must be submitted.

Coverage Determination Requests (continued)

Plan sponsors must:

- Accept any request made in writing by an enrollee, prescriber/physician, or an enrollee's representative;
- Not require an enrollee or physician or other prescriber to make a written request on a specific form;
- Document the **date** and **time** they receive the request; and
- Maintain a system for tracking when an enrollee and prescriber, as appropriate, must be notified of the plan's decision.

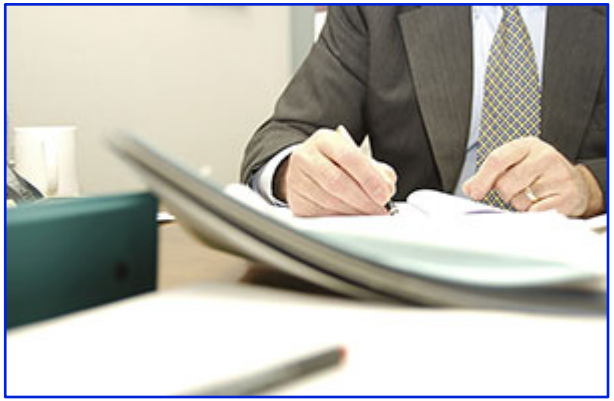
Coverage Determination Request Adjudication Time Frame

Plan sponsors must make a determination and notify the enrollee within the adjudication time frame. If the decision is favorable to the enrollee, the plan must authorize or provide the benefit within the appropriate adjudication time frame.

The coverage determination request adjudication time frame begins when the plan or its delegated entity first receives the request. The request could be received by a telephone call to the plan, a fax to the Pharmacy Benefit Manager (PBM), or any other method of requesting coverage.

When a coverage determination request is subject to the exceptions process (either tiering or formulary), the adjudication time frame begins when the plan or its delegated entity receives the prescriber's supporting statement. While tolling an exception request received without a prescriber's supporting statement, the plan must make reasonable and diligent outreach attempts to the prescriber in order to obtain the missing information. If it is not received within a reasonable period of time, despite the plan's efforts, the plan must make a decision as to whether the requested drug is medically necessary based on the information available.

Coverage Determination Request Adjudication Time Frame (continued)



The plan examines the request and determines:

- What is being requested; and
- Which adjudication time frame applies.

The next page shows the types of requests and the adjudication time frame for each type of request.

NOTE: If a plan fails to make a decision within the required time frame, it must auto-forward the case to the IRE and notify the enrollee that the case was forwarded. The only exception to this rule is for fully favorable decisions made within 24 hours of the missed time frame.

Coverage Determination Request Adjudication Time Frame (continued)

Type of Request	Adjudicate No Later Than
Expedited Pre-Benefit*	24 hours from receipt of request
Expedited Pre-Benefit Exception*	24 hours from receipt of prescriber's supporting statement

*The medical exigency standard requires plan sponsors to make all coverage decisions as expeditiously as the enrollee's health condition requires.

Coverage Determination Request Adjudication Time Frame (continued)

Type of Request	Adjudicate No Later Than
Standard Pre-Benefit *	72 hours from receipt of request
Standard Pre-Benefit Exception*	72 hours from receipt of prescriber's supporting statement

*The medical exigency standard requires plan sponsors to make all coverage decisions as expeditiously as the enrollee's health condition requires.

Coverage Determination Request Adjudication Time Frame (continued)

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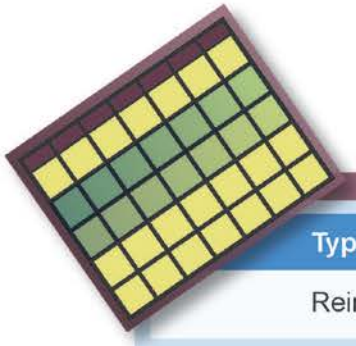
Click here for a printable PDF of all three adjudication time frame tables



Type of Request	Adjudicate No Later Than
Reimbursement	14 days from receipt of request

Coverage Determination Request Adjudication Time Frame (continued)

Reimbursement Request:

When a plan sponsor receives a request for payment, the plan sponsor must make a decision, notify the enrollee of the decision, and make payment (if favorable) within 14 calendar days of the receipt of the request.

For reimbursement involving exception requests, the time frame is not tolled pending receipt of a physician's or prescriber's supporting statement.

There are no expedited reimbursement requests.

Coverage Determination Request Processing: Plan Policies and Procedures

Plan sponsors should develop clear and compliant policies and procedures for processing coverage determination requests.

Plans must have a Medical Director who is involved in designing, approving, and overseeing those policies and procedures related to the adjudication of coverage determination requests.

Coverage Determination Request Processing: Gathering Information

Plans must gather as much information as possible from the initial coverage determination request. Plans should start by determining what information they need to make a decision:

- Is this drug on formulary?
- Are there any utilization criteria?
- Is the enrollee trying to satisfy a Utilization Management (UM) requirement or request an exception from it?
- Is a prescriber's supporting statement needed?
- What information is needed (what outreach should be done)?

Coverage Determination Request Processing: Conducting Reasonable Outreach

Once the plan sponsor identifies the type of request and what information it needs to make a decision, the plan should begin outreach to the prescriber to obtain missing information immediately after receiving a coverage determination request.

Part D plans must conduct reasonable outreach to obtain missing information and the prescriber's supporting statements, including:

- Determine what is "reasonable" outreach on a case-by-case basis, depending on the circumstances of the request and the enrollee's health condition;
- Use telephone calls, fax attempts, etc.;
- Make calls at reasonable times (for example, during business hours or the physician's or other prescriber's office hours); and
- Clearly state what information is missing or needed in order to approve a request.

Coverage Determination Request Processing: Involving Physician or Other Licensed Health Care Professionals in Review

If a Part D plan sponsor expects to issue a partially or fully adverse medical necessity decision based on the initial review of the request, the coverage determination must be reviewed by a physician or appropriate licensed health care professional before the plan sponsor issues the decision.

Coverage Determination Request Processing: Notification

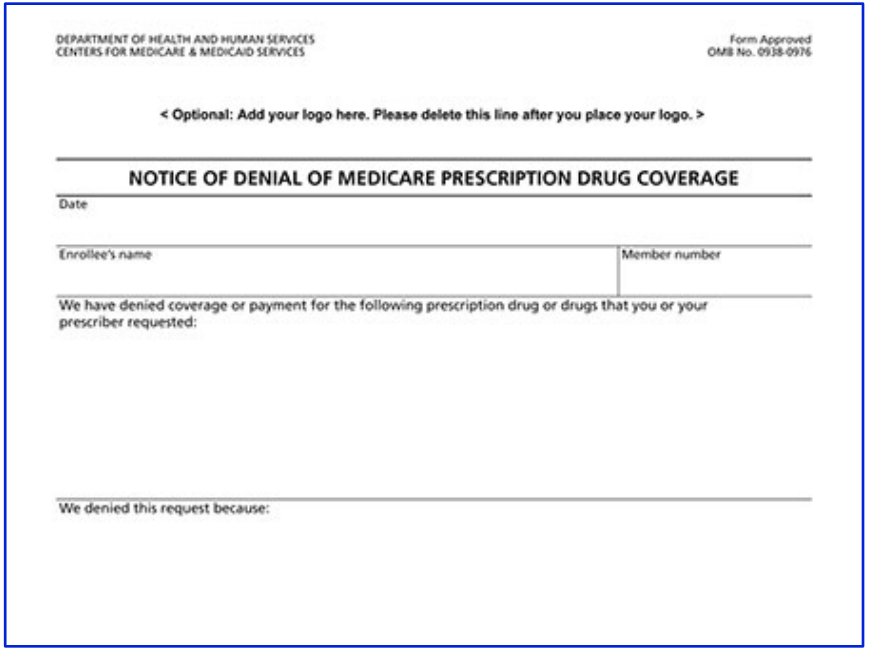
All coverage determinations require **written** notification of the decision to the enrollee.

Verbal notification may also be needed in order to meet the adjudication time frames.

Coverage Determination Request Processing: Notification of Fully or Partially Adverse Decisions

All adverse decisions (any decision not fully favorable to the enrollee) require a standardized denial notice using Form CMS-10146, “Notice of Denial of Medicare Prescription Drug Coverage.”

To obtain the form, visit http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms10146.pdf on the CMS website.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0976

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NOTICE OF DENIAL OF MEDICARE PRESCRIPTION DRUG COVERAGE

Date

Enrollee's name | Member number

We have denied coverage or payment for the following prescription drug or drugs that you or your prescriber requested:

We denied this request because:

Coverage Determination Request Processing: Notification of Fully or Partially Adverse Decisions (continued)

The denial rationale must:

- Contain the **specific reason for the denial** that takes into account the enrollee's presenting medical conditions, disabilities, and special language requirements, if any;
- Contain a description of any applicable Medicare or plan coverage rule upon which the denial decision was based, including any specific formulary criteria that must be satisfied for approval;
- Be written in clear, understandable language; and
- Include a copy of the CMS model form "Request for Redetermination of Medicare Prescription Drug Denial," with applicable sections pre-populated.

To obtain the form, visit https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/ModRedRequestFormandInstructions508.zip on the CMS website.

Coverage Determination Request Processing: Notification of Fully Favorable Decisions

All favorable decisions require a readable and understandable written notice that explains the conditions of the approval. The notice will include:

- The duration of the approval;
- Any associated limitations; and
- Any coverage rules applicable to subsequent refills.

Review Questions

You've just learned the requirements for coverage determinations. The following pages present review questions to help reinforce your new knowledge.

Click the "NEXT" button to proceed to the review questions.

Review Question 1 of 3

Select the correct answer.

An enrollee requests Drug X which is not on the plan's formulary. What should the plan do next?

A. Initiate a coverage determination request and wait for the enrollee to contact the prescriber.

B. Toll the case indefinitely while waiting for the prescriber's supporting statement.

C. Initiate a coverage determination request, begin reasonable outreach attempts to the prescriber, and toll for a reasonable amount of time while making those outreach attempts.

Review Question 2 of 3

Select the correct answer.

An enrollee calls the plan grievance line on Tuesday at 4:59 p.m. to request coverage for a drug. Customer service sends the request to the correct department. The department logs it on Wednesday at 8:15 a.m. and calls the prescriber for additional information to satisfy a prior authorization. The supporting information is faxed to the plan on Wednesday at 6:50 p.m. When was the coverage determination initiated?

A. Tuesday at 4:59 p.m.

B. Wednesday at 6:50 p.m.

Review Question 3 of 3

Select the correct answer.

A standard pre-benefit coverage determination must be adjudicated no later than _____ from receipt of the request.

A. 24 hours

B. 72 hours

C. 14 days

Congratulations!

You've completed Lesson 2: Coverage Determinations.

Now that you've learned about the requirements for coverage determinations, let's look at appeals and grievances in detail. Lesson 3: Appeals & Grievances discusses requirements for redeterminations, appeals, effectuation, and grievances.

Click the "MAIN MENU" button to return to the Web-Based Training (WBT) course Main Menu. Then select "Lesson 3: Appeals & Grievances" to begin Lesson 3. Do not click the "X" button in the right-hand corner of the window as this will cause you to exit the WBT course and the system will not record your progress.

Welcome to Lesson 3: Appeals & Grievances

This lesson discusses requirements for redeterminations, appeals, effectuation, and grievances. It should take you about 10 minutes to complete this lesson.

Lesson Objectives

Upon completing this lesson, you should be able to correctly:

- Recognize requirements for appeals;
- Recognize requirements for effectuation; and
- Recognize requirements for grievances.

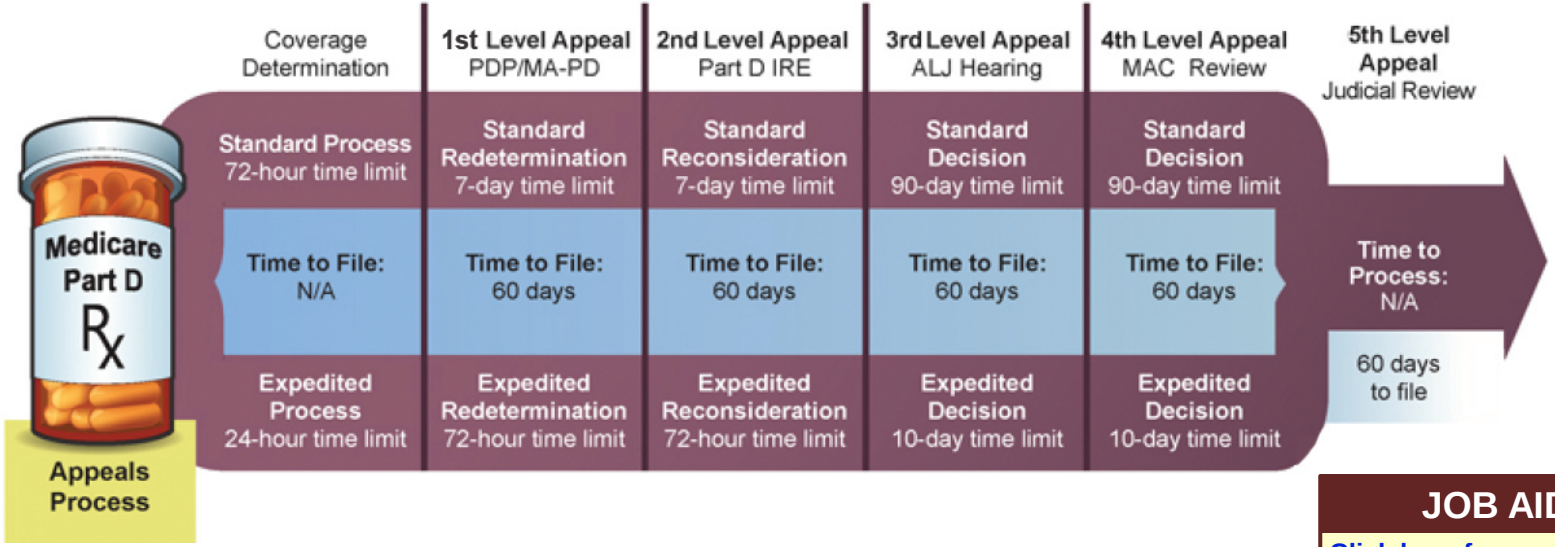
Five Levels of Appeals

The table below describes the five levels of appeals.

Level	Appeal	Time to File Appeal	Amount in Controversy (AIC)	Time to Process Appeal—Standard	Time to Process Appeal—Expedited
1	Part D Plan Sponsor Redetermination	60 days after coverage determination	Any	7 days	72 hours
2	Independent Review Entity (IRE) Reconsideration	60 days after redetermination	Any	7 days	72 hours
3	Administrative Law Judge (ALJ) Hearing	60 days after reconsideration	Yes*	90 days	10 days
4	Medicare Appeals Council (MAC) Review	60 days after ALJ decision	N/A	90 days	10 days
5	Judicial Review	60 days after MAC decision	Yes*	N/A	N/A

* The AIC is subject to change on an annual basis. For this year's AIC, visit http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/ALJHearing.html and http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/FederalCourtReview.html on the Centers for Medicare & Medicaid Services (CMS) website.

Medicare Part D Appeals Process



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Click here for a printable PDF

First Level of Appeal: Redetermination

A redetermination is the first level of appeal. The Part D plan sponsor conducts the review, but the actual person conducting the review must be someone other than the person involved in making the initial coverage determination. If the original denial was based on a lack of medical necessity, a physician with expertise in the field of medicine appropriate to the drug at issue must conduct the review.

For more information, refer to 42 Code of Federal Regulations (CFR) 423.580-590 at http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR on the Government Printing Office (GPO) website. Before selecting the title and section you must select the year based on the annual update schedule described on the page.

Additionally, you may refer to the "Medicare Prescription Drug Benefit Manual," Publication 100-18, Chapter 18, Section 70 at http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/partdmanualchapter18.pdf on the CMS website.

Finally, you may visit http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Redetermination.html on the CMS website.

First Level of Appeal: Redetermination—Making a Request

To make a redetermination request, file the request within 60 calendar days after the date printed or written on the coverage determination denial notice.

The following people may request redeterminations:

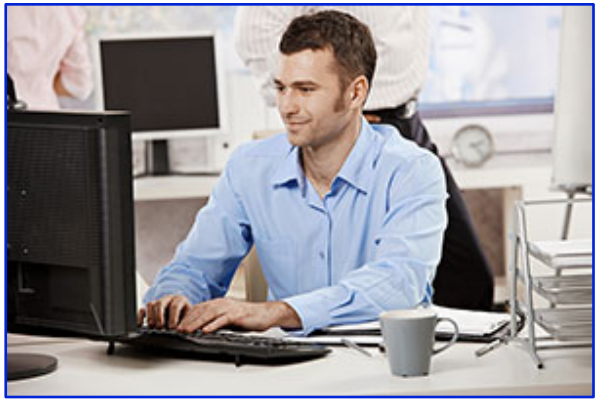
- The enrollee;
- The enrollee's representative; or
- The enrollee's prescriber.

There are two types of redetermination requests: standard and expedited. Standard requests should be filed in writing to the plan sponsor (the plan sponsor may choose to accept verbal requests). Expedited requests may be submitted verbally or in writing to the plan sponsor.

First Level of Appeal: Redetermination—Adjudication Time Frame

A standard redetermination request decision must be made no later than 7 calendar days after the receipt of the request. An expedited decision must be made no later than 72 hours after the receipt of the request.

If a plan fails to make a decision within the required time frame, it must auto-forward the case to the IRE and notify the enrollee that the case was forwarded. The only exception to this rule is for fully favorable decisions made within 24 hours of the missed time frame.

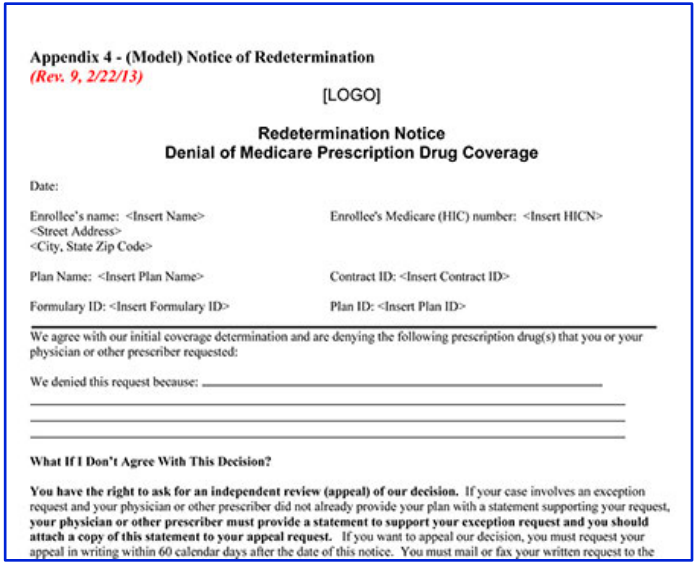


First Level of Appeal: Redetermination—Notification Requirements

All redeterminations require written notification of the decision to the enrollee or the enrollee's representative. The notification must be written in clear, understandable language.

All adverse decisions require the plan sponsor to send either:

- The CMS-approved "(Model) Notice of Redetermination" at http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/PlanNoticesAndDocuments.html on the CMS website; or
- A notice created by the plan that meets the requirements of 42 CFR 423.590(g) at http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR on the GPO website. Before selecting the title and section you must select the year based on the annual update schedule described on the page.



Appendix 4 - (Model) Notice of Redetermination
(Rev. 9, 2/22/13)

[LOGO]

Redetermination Notice
Denial of Medicare Prescription Drug Coverage

Date:

Enrollee's name: <Insert Name>
<Street Address>
<City, State Zip Code>

Enrollee's Medicare (HIC) number: <Insert HICN>

Plan Name: <Insert Plan Name>

Contract ID: <Insert Contract ID>

Formulary ID: <Insert Formulary ID>

Plan ID: <Insert Plan ID>

We agree with our initial coverage determination and are denying the following prescription drug(s) that you or your physician or other prescriber requested:

We denied this request because: _____

What If I Don't Agree With This Decision?

You have the right to ask for an independent review (appeal) of our decision. If your case involves an exception request and your physician or other prescriber did not already provide your plan with a statement supporting your request, **your physician or other prescriber must provide a statement to support your exception request and you should attach a copy of this statement to your appeal request.** If you want to appeal our decision, you must request your appeal in writing within 60 calendar days after the date of this notice. You must mail or fax your written request to the

First Level of Appeal: Redetermination—Notification Requirements for Adverse Decisions

The denial rationale must contain the **specific reason for the denial** and take into account the enrollee's:

- Presenting medical conditions;
- Disabilities; and
- Special language requirements, if any.

The notification must contain a description of any applicable Medicare or plan coverage rules upon which the denial decision was based, including specific formulary criteria that must be satisfied for approval.

The notification must contain appeal rights in the denial notice.

First Level of Appeal: Redetermination—Notification Requirements for Favorable Decisions

All favorable decisions require written notice which explains the conditions of the approval in a readable and understandable form. Favorable decisions must also include:

- The duration of approval;
- Any associated limitations; and
- Any coverage rules applicable to subsequent refills.

Second Level of Appeal: Reconsideration

An enrollee, enrollee's representative, or enrollee's prescriber may request a reconsideration from an IRE within 60 days of the unfavorable redetermination.

When the IRE requests a case file from the plan sponsor, the plan sponsor must send a hard copy of the file within:

- 24 hours for expedited reconsiderations; or
- 48 hours for standard reconsiderations.

The hard copy file should include all applicable documents listed in the "Medicare Prescription Drug Benefit Manual," Publication 100-18, Chapter 18, Section 70.30 at http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/partdmanualchapter18.pdf on the CMS website.

For more information, refer to the "Part D QIC Reconsideration Procedures Manual" at http://www.medicarepartdappeals.com/Resources/MA-PDPDPPlans/ProceduresManual.aspx on the Internet or http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Reconsiderations.html on the CMS website.

Third Level of Appeal: ALJ Hearing

If the reconsideration is unfavorable, an enrollee or enrollee's representative may appeal the adverse reconsideration to an ALJ within 60 days of the denial.

For more information, visit http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/ALJHearing.html on the CMS website.

Fourth Level of Appeal: MAC Review

If an ALJ issues an unfavorable/adverse decision, an enrollee or enrollee's representative may appeal to the MAC within 60 days of the denial.

For more information, visit http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/MedicareAppealsCouncil.html on the CMS website.

Fifth Level of Appeal: Federal District Court Review

If the MAC issues an unfavorable/adverse decision, the final appeal stage is the Federal District Court.

For more information, visit http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/FederalCourtReview.html on the CMS website.

Proper Effectuation

Proper effectuation of an approval includes authorizing (or paying for) the benefit so that an enrollee can obtain the approved drug.

This must happen within the required time frames (for example, 24 hours for an expedited pre-benefit coverage determination or 72 hours for a standard pre-benefit coverage determination). Proper effectuation includes authorizing a pre-service benefit correctly in a plan's claims processing system to prevent any delay for the enrollee's access.

For exception requests, the effectuation must be through the end of the plan year. For all other requests, the plan must follow its CMS-approved formulary to determine the length of approval.

Proper Effectuation—Favorable Decisions From Another Review Entity

If a plan receives a favorable decision from another review entity (that is, the IRE, ALJ, MAC, or a Federal District Court):

- The plan must authorize or provide the benefit within 24 hours for an expedited request or 72 hours for a standard request from the date it receives notice from the appeal entity reversing the determination;
- For payment requests, the plan must authorize the payment within 72 hours and make payment within 30 days; and
- The plan must send a statement attesting to the effectuation to the IRE.

Grievances

A grievance is any complaint or dispute, other than one that constitutes a coverage determination. It may be filed verbally or in writing within 60 days from the date of the incident.

The plan must notify the enrollee of the decision no later than 30 days after receiving the request, unless an extension is taken. If the complaint involves a plan's refusal to grant an enrollee's request to expedite a determination, the plan must respond within 24 hours.

If the request was submitted verbally, the response may be verbally or in writing. The plan must respond in writing if:

- The request was submitted in writing;
- The request was submitted verbally and the enrollee requested a written response; or
- The request involves a quality of care grievance.

For quality of care grievances, the response must include a description of the enrollee's right to file a complaint with the Quality Improvement Organization (QIO).

Grievances Resources

For more information, refer to 42 CFR 423.564 at http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR on the GPO website. Before selecting the title and section you must select the year based on the annual update schedule described on the page.

Additionally, you may refer to the “Medicare Prescription Drug Benefit Manual,” Publication 100-18, Chapter 18, Section 20, at http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/partdmanualchapter18.pdf on the CMS website.

Finally, you may visit http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Grievances.html on the CMS website.

Review Questions

You've just learned the requirements for appeals and grievances. The following pages present review questions to help reinforce your new knowledge.

Click the "NEXT" button to proceed to the review questions.

Review Question 1 of 3

Select the correct answer.

An enrollee receives an adverse redetermination decision from a plan and wishes to appeal for reconsideration. The enrollee must submit the request for reconsideration within _____ days after the date printed on the redetermination.

A. 7 days

B. 60 days

C. 90 days

Review Question 2 of 3

Select the correct answer.

For exception requests, proper effectuation must be through the end of the plan year.

A. True

B. False

Review Question 3 of 3

Select the correct answer.

Plans must respond to grievances in writing in which of the following situations?

A. The request was submitted to the plan in writing

B. The request was submitted verbally and the enrollee requested a written response

C. The request involves a quality of care grievance

D. All of the above

Congratulations!

You've completed Lesson 3: Appeals & Grievances.

Now that you've learned about the redeterminations, appeals, and grievances, let's look at some common problems. Lesson 4: Common Problems, explores common problems that plans encounter based on Centers for Medicare & Medicaid Services' (CMS) audit findings and plan oversight efforts.

Click the "MAIN MENU" button to return to the Web-Based Training (WBT) course Main Menu. Then select "Lesson 4: Common Problems" to begin Lesson 4. Do not click the "X" button in the right-hand corner of the window as this will cause you to exit the WBT course and the system will not record your progress.

Welcome to Lesson 4: Common Problems

This lesson explores common plan errors identified by the Centers for Medicare & Medicaid Services (CMS) based on audit findings and plan oversight efforts. It should take you about 10 minutes to complete this lesson.

Lesson Objectives

Upon completing this lesson, you should be able to correctly:

- Identify some common problems encountered by plans.

Common Problems

Common problems include:

- Untimely effectuation or inappropriate effectuation of approved coverage determinations or appeals in claims systems and plan databases;
- Requests for coverage determinations or appeals misclassified as grievances;
- Inappropriately processing appeals as initial coverage determination requests;
- Untimely notifications;
- Insufficient or inaccurate denial notices;
- Failure to auto-forward untimely cases to the Independent Review Entity (IRE) appropriately; and
- Failure to properly oversee and monitor delegated entities.

Common Problems: Untimely or Inappropriate Effectuation

One common problem is untimely or inappropriate effectuation of approved coverage determinations or appeals in claims processing systems and databases.

For example:

- A benefit is not authorized within 24 hours for an expedited coverage determination; or
- An approved exception request is not authorized for the remainder of the plan year.

Remember!

Effectuations must follow standard and expedited notification time frames. For exception requests, the authorization must be through the end of the plan year. For all other requests, the plan must follow its CMS-approved formulary to determine the length of approval.

Common Problems: Request for Coverage Determination or Appeals Misclassified as Grievances

Another common problem that CMS found among plans is when a request for a coverage determination or an appeal is misclassified as a grievance.

For example:

- An enrollee calls the plan and says “I want to file a complaint. You denied my request for Drug A, but I need it because I am allergic to the alternative Drug B.” The plan misclassifies this statement as a grievance.

Remember!

Even if an enrollee calls to “complain,” if the complaint is also a request for a drug, it must be processed as a coverage determination or appeal, as appropriate. In the example above, because the statement is an attempt to receive approval for Drug A, it should be handled as an appeal and not as a grievance.

Common Problems: Request for Coverage Determination or Appeals Misclassified as Grievances (continued)

For example:

- An enrollee calls the plan and says “I am unhappy with this plan, you charged me a co-pay of $15 but my explanation of benefits (EOB) says I should have been charged $10.” The plan classifies this statement as a grievance and not as an initial coverage determination.

Remember!

In this case, the enrollee is arguing he or she should not have paid as much as they did. This should be treated as a coverage determination. If the enrollee called to complain that the price of a drug was too high, but was not disputing the actual cost, then it would be treated as a grievance.

Keep in mind that multiple requests can come in concurrently. If there is both a grievance and a coverage determination request in the same telephone call, each issue should be processed separately and simultaneously under the proper procedure.

Common Problems: Inappropriately Processing Appeals as Initial Coverage Determination Requests

Another common problem occurs when a plan inappropriately processes an appeal as an initial coverage determination request. This can include overusing the reopening process.

For example:

- An enrollee or physician submits “new evidence” disputing an adverse decision within the 60-day appeal window. The plan inappropriately processes the information as an initial coverage determination.

Remember!

New evidence submitted within the 60-day appeal window (or later with good cause) and related to adverse coverage determinations should generally be processed as an appeal. Reopenings are remedial actions taken to change a binding determination or decision, and frequent use of the reopening process can indicate that a plan is not following CMS’ requirements for initial coverage determinations. If a plan reopens a coverage decision, it must follow Subpart U guidance. If an enrollee has filed a valid appeal request, the plan does not have jurisdiction to reopen.

For more information on reopenings, refer to the “Medicare Prescription Drug Benefit Manual,” Publication 100-18, Chapter 18, Section 120 at http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/partdmanualchapter18.pdf on the CMS website.

Common Problems: Untimely Notifications

Another common problem is untimely notifications sent to enrollees or their physicians.

Remember!

Notices must be sent in accordance with the standard and expedited time frames found in the “Medicare Prescription Drug Benefit Manual,” Publication 100-18, Chapter 18 at http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/downloads/partdmanualchapter18.pdf on the CMS website.

Verbal notification should be made and **documented** if necessary to meet the time frames. Letters must follow the verbal notification within 3 calendar days.

Common Problems: Insufficient or Inaccurate Denial Notices

Another common problem is denial notices that do not contain sufficient rationale for the denial, or that are not tailored to the specific case.

For example:

- The plan sends a denial notice that states, “Not enough information was received to make a decision.” This statement by the plan does not constitute sufficient rationale for the denial.

Remember!

Denial notices must be specific to the enrollee and the situation. The notice must clearly explain why the drug was denied, and the next steps an enrollee or prescriber should take. For example, when explaining why a drug is being denied, the plan could tell the enrollee that they must try and fail the following alternatives before Drug A can be approved—alternatives are: Drug B and Drug C.

Common Problems: Failure to Auto-Forward Untimely Cases to the IRE Appropriately

Another common problem is failure by the plan to auto-forward cases to the IRE, or failure to forward those cases in a timely manner.

Remember!

If a plan misses the adjudication time frame it must immediately auto-forward the case to the IRE. The plan loses jurisdiction over the case and cannot issue a decision after the time frame has passed. A limited exception applies if the plan issues a fully favorable decision within 24 hours of the required time frame.

For more information please see the “Medicare Prescription Drug Benefit Manual,” Chapter 18, Sections 40.4, 50.6, and 70.10.

Common Problems: Failure to Properly Oversee and Monitor Delegated Entities

Another common problem is failure by the plan to properly oversee and monitor delegated entities.

Remember!

The plan is ultimately responsible for all coverage determinations, appeals, and grievances, even if the day-to-day responsibility is delegated to another entity (such as a Pharmacy Benefit Manager [PBM]).

Plans should consistently monitor and audit the delegated entity to ensure correct processing of requests.

Review Questions

You've just learned some common problems that plans encounter based on CMS' audit findings and plan oversight efforts. The following pages present review questions to help reinforce your new knowledge.

Click the "NEXT" button to proceed to the review questions.

JOB AID E

Click here for a summary of common problems that plans encounter in a printable PDF

Review Question 1 of 3

Select the correct answer.

New evidence submitted to the plan 10 days after a coverage determination decision is made should be processed as a reopening.

A. True

B. False

Review Question 2 of 3

Select the correct answer.

The plan sends a denial notice that states, “Not enough information was received to make a decision.” This statement by the plan does not constitute sufficient rationale for the denial.

A. True

B. False

Review Question 3 of 3

Select the correct answer.

A plan receives a call from an irate enrollee. The enrollee was unable to obtain her medication at the pharmacy. The plan representative looks at the formulary online and determines that the drug in question requires prior authorization. The enrollee states that she is unhappy and needs the drug. What should the plan do?

A. Open a coverage determination request

B. Open a grievance

C. Treat the call as an inquiry

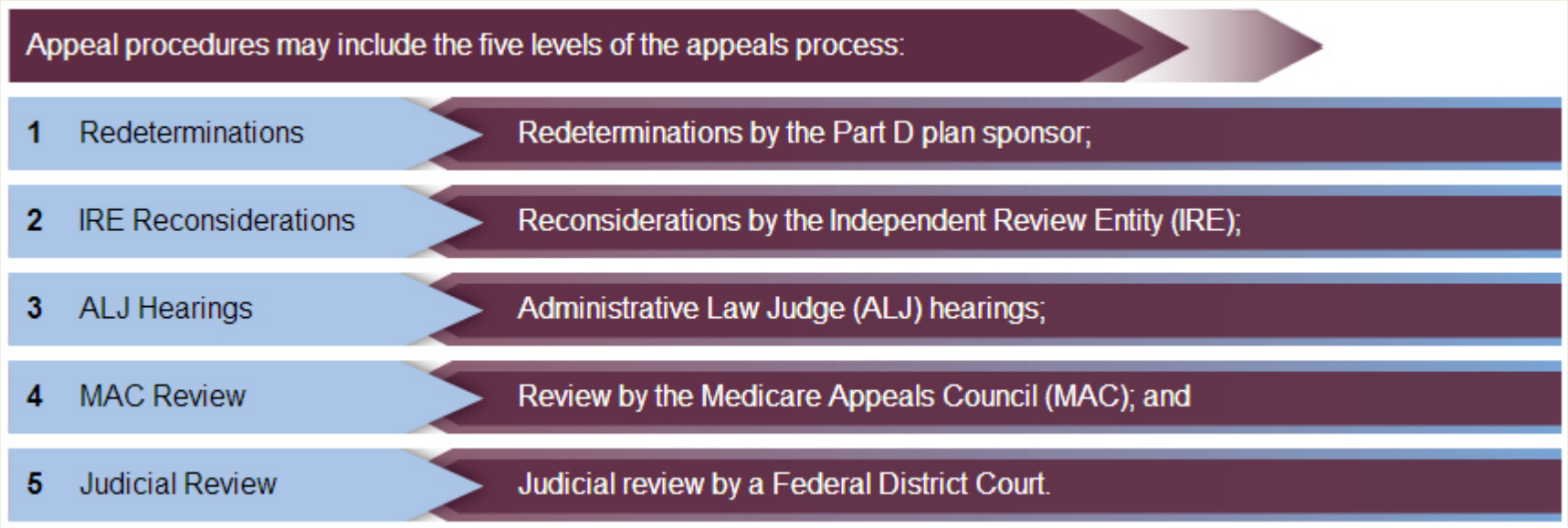
Congratulations!

You've completed Lesson 4: Common Problems.

Click the "MAIN MENU" button to return to the Web-Based Training (WBT) course Main Menu. Then select "Post-Assessment" to begin the Post-Assessment. Do not click the "X" button in the right-hand corner of the window as this will cause you to exit the WBT course and the system will not record your progress.

Job Aid A

Appeals Procedures



Job Aid B

Basic Definitions

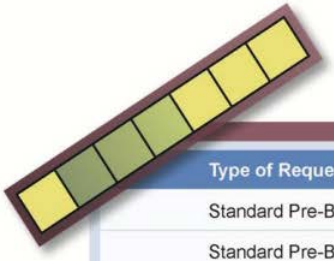
Term	Definition
Appeal	An appeal is any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits or on any amounts the enrollee must pay for the drug coverage.
Coverage Determination	A coverage determination is any decision made by, or on behalf of, a Part D plan sponsor regarding payment of benefits to which an enrollee believes he or she is enrolled.
Effectuation	Effectuation is compliance with: •A favorable determination; or •A complete or partial reversal of a Part D plan sponsor's original adverse coverage determination.
Enrollee	An enrollee is a Part D eligible individual who has elected a plan offered by a Part D plan sponsor.
Grievance	A grievance is any complaint or dispute, other than a coverage determination or Late Enrollment Penalty (LEP) determination, expressing dissatisfaction with any aspect of operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested. A grievance may also include a complaint that a Part D plan refused to expedite a coverage determination or reconsideration, or invoked an extension of the time frame for making a decision. Grievances may include complaints regarding the timeliness, appropriateness, access to, and/or setting of a provided item.
Independent Review Entity (IRE)	The IRE is an independent entity contracted by the Centers for Medicare & Medicaid Services (CMS) to review Part D plan sponsor denials of coverage determinations and redeterminations.
Redetermination	A redetermination is the first level of the appeal process. Redeterminations involve a Part D plan sponsor reevaluating an adverse coverage determination, the findings on which it was based, and any other evidence submitted or obtained.

Job Aid C

Coverage Determination Request Adjudication Time Frame

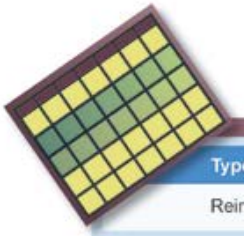
Type of Request	Adjudicate No Later Than
Expedited Pre-Benefit*	24 hours from receipt of request
Expedited Pre-Benefit Exception*	24 hours from receipt of prescriber's supporting statement

*The medical exigency standard requires plan sponsors to make all coverage decisions as expeditiously as the enrollee's health condition requires.



Type of Request	Adjudicate No Later Than
Standard Pre-Benefit*	72 hours from receipt of request
Standard Pre-Benefit Exception*	72 hours from receipt of prescriber's supporting statement

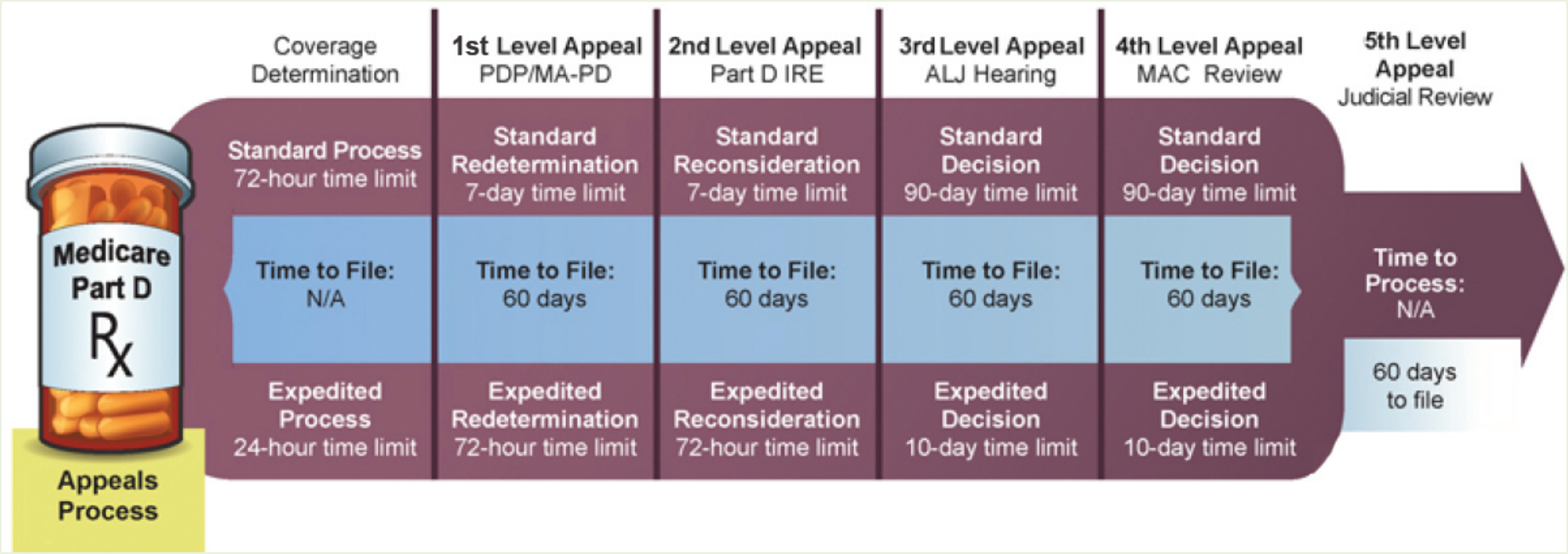
*The medical exigency standard requires plan sponsors to make all coverage decisions as expeditiously as the enrollee's health condition requires.



Type of Request	Adjudicate No Later Than
Reimbursement	14 days from receipt of request

Job Aid D

Medicare Part D Appeals Process



Job Aid E

Part D Coverage Determinations, Appeals, and Grievances Common Problems

Common Problem	Remember
Untimely or Inappropriate Effectuation	Effectuations must follow standard and expedited notification time frames. For exception requests, the authorization must be through the end of the plan year. For all other requests, the plan must follow its Centers for Medicare & Medicaid Services (CMS)-approved formulary to determine the length of approval.
Request for Coverage Determination or Appeals Misclassified as Grievances	Even if an enrollee calls to "complain," if the complaint is also a request for a drug, it must be processed as a coverage determination or appeal, as appropriate. Keep in mind that multiple requests can come in concurrently. If there is both a grievance and a coverage determination request in the same telephone call, each issue should be processed separately and simultaneously under the proper procedure.
Inappropriately Processing Appeals as Initial Coverage Determination Requests	New evidence submitted timely and related to adverse coverage determinations should generally be processed as an appeal. Reopenings are "remedial actions." Frequent use of the reopening process can indicate that a plan is not following CMS' requirements for initial coverage determinations. If a plan does "reopen," it must follow Subpart U guidance. There are no time frames for reopening decisions, but there are notification requirements. For more information on reopenings, refer to the "Medicare Prescription Drug Benefit Manual," Publication 100-18, Chapter 18, Section 120 at http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/partdmanualchapter18.pdf on the CMS website.
Untimely Notifications	Notices must be sent in accordance with the standard and expedited time frames found in the "Medicare Prescription Drug Benefit Manual," Publication 100-18, Chapter 18, at http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/partdmanualchapter18.pdf on the CMS website. Verbal notification should be made and **documented** if necessary to meet the time frames. Letters must follow the verbal notification within 3 calendar days.

Job Aid E (continued)

Part D Coverage Determinations, Appeals, and Grievances Common Problems

Common Problem	Remember
Insufficient or Inaccurate Denial Notices	Denial notices must be specific to the enrollee and the situation. The notice must clearly explain why the drug was denied, and the next steps an enrollee or prescriber should take.
Failure to Auto-Forward Untimely Cases to the Independent Review Entity (IRE) Appropriately	If a plan misses the adjudication time frame it must auto-forward the case to the IRE. The plan losses jurisdiction over the case and cannot issue a decision after the time frame has passed. A limited exception applies if the plan issues a fully favorable decision within 24 hours of the required time frame.
Failure to Properly Oversee and Monitor Delegated Entities	The plan is ultimately responsible for all coverage determinations, appeals, and grievances, even if the day-to-day responsibility is delegated to another entity (such as a Pharmacy Benefit Manager [PBM]). Plans should consistently monitor and audit the delegated entity to ensure correct processing of requests.