



Medicare Rights Center

Medicare Part D Appeals:

An advocate's manual to navigating the
Medicare private drug plan appeals process

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Medicare Rights Center
800-333-4114
www.medicarerights.org

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Table of Contents

Introduction.....	3
Why would you need to appeal?.....	4
Before you begin your appeal.....	4
Part D Appeals: An outline.....	5
Pre-Appeal: Requesting a coverage determination.....	6
Beginning the appeals process: Requesting a redetermination.....	8
Getting the Independent Review Entity to review your appeal.....	9
Administrative Law Judge hearing.....	10
Medicare Appeals Council.....	11
Requesting a reopening.....	12
Federal court.....	12
When your plan must implement a reversed decision.....	13
Appendix 1: Case Examples	
1. The plan does not return a decision within the required timeframe.....	14
2. The plan says the drug is excluded from Medicare coverage.....	15
3. The plan says the drug is covered by Part B, not Part D.....	16
4. The plan wants you to try a “preferred” drug before it will cover your prescribed medication.....	17
5. The plan says the drug is not a “Part D drug”.....	18
6. The plan says the drug is not “medically necessary” for you.....	19
7. The plan says the prescribed dose exceeds “standard” guidelines.....	20
Appendix 2: Sample protocol for advocates.....	21
Appendix 3: Glossary of terms.....	22
Appendix 4: Part D Appeals Toolkit.....	24

Introduction

The Medicare drug benefit, also known as Medicare Part D, began January 1, 2006, as the largest benefit added to Medicare coverage in 40 years. However, unlike Original Medicare, Part D drug coverage is offered exclusively through private plans that contract with Medicare. That means that many administrative complaints and problems must be addressed first through each individual private plan, rather than through Medicare.

What is a Medicare Part D appeal? An appeal is a request for coverage you make when you disagree with your Medicare private drug plan's decision not to cover a prescribed medication or to limit the amount of a medication it will cover. Part D appeal procedures are the same whether you are in a stand-alone drug plan or get all your health and drug benefits through a Medicare private health plan (Medicare Advantage plans like Medicare HMOs and PPOs).


Advocates can help people with Medicare undertake the Part D appeals process, which differs from Original Medicare because you must appeal first to your private plan instead of to Medicare. In addition, each of the hundreds of private plans that offer Medicare drug coverage has its own phone numbers and departments for submitting appeals, making it hard for even sophisticated consumers to appeal a Medicare drug plan's coverage denial successfully. Sometimes it can be difficult for even experienced advocates to determine what stage a client has reached in the appeals process if the client has tried to appeal on her own and has not kept copies of the paperwork she has submitted to or received from her Medicare drug plan. (See consumer tip sheet on Part D appeals in [Appendix 4](#)).

People with Medicare who need to appeal their plan's decision often need to find an advocate to become their legal representative to navigate the appeals system on their behalf, work with the prescribing doctor, and negotiate with the Exceptions and Appeals department of their drug plan (see [Appendix 4](#) for a form your clients can use to designate you as their legal representative).

This manual is designed to help advocates navigate the Medicare Part D appeals process to make sure their clients get the medications they need.

Throughout this manual we will:



- **Identify important terms** commonly used in the Part D appeals process with this symbol (). Becoming familiar with these terms will help you successfully navigate the appeals process. An appeal can get derailed due to the use of the wrong term (see [Case Example #1](#)). Look in the Glossary at the end of this manual for definitions.
- **Refer to “you” as the person with Medicare** to simplify language.
- **Show where you can find appeals rules and rights in federal statutes, regulations, and CMS guidance** with the symbol to the right. To find the regulations online, go to [Appendix 4](#).



Why would you need to appeal?

According to the rules implemented by the Centers for Medicaid and Medicare Services (CMS), the federal agency that oversees Medicare, prescription drug plans must develop formularies (📖). A formulary is essentially a list of drugs, along with approved dosages, that the plan will cover for its members. According to federal regulations, every formulary must include at least two drugs in every major class of drugs (📖). Formularies are also divided into different cost-sharing tiers (📖), which will determine the amount of the co-payment (📖) or coinsurance (📖) for a given drug. Still, because formularies do not include every medication, there will inevitably be times when you will need:

- a drug that is not on the formulary;
- a drug that is excluded from Medicare coverage by law;
- a drug that is not “preferred” by your Medicare private drug plan;
- a dosage amount or formulation that is not approved on the formulary;
- a lower co-payment coinsurance for a particular drug.

Because of these potential problems you may face, federal law requires plans to have an appeals process. (See [Case Examples in Appendix 1](#) for specific strategies for different types of appeals.)

Before you begin your appeal!


Doctors need to know how important they are to the process. The only way to succeed with a Part D appeal is to make sure that the prescribing doctor submits a clear statement of medical necessity (📖) and states that only the prescribed medication will work for you, or that the prescribed medication works best for you. If the doctor believes that switching to a drug covered by the plan would work as effectively and would not harm you, you may be able to avoid going through the appeals process by having your prescription changed. (See handout for doctors in [Appendix 4](#)).

TIPS:

- **Be persistent!** You may encounter a lot of red tape and bureaucratic obstacles as you try to find out where and how to file your appeal. For contact information, look on the plan’s Coverage Determination Request form or Explanation of Benefits (EOB).
 - **Know your terminology.** To get the right contact information, you have to know exactly what you need and use terms the plan will understand. See the glossary for common Part D terms.
 - **Your private drug plan’s decision is not the final word.** Do not take “no” for an answer. Take the time to go through the appeals process. It can be successful.
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The Part D appeals process: An outline

Coverage Determination or Prior Authorization (page 6)

- Your medication is not covered by your Medicare private drug plan or requires permission from the plan before it can be prescribed (prior authorization). You can request a coverage determination from your plan at any time.
- Your plan must decide whether to cover your drug—and notify you of its decision—within 72 hours of receiving your doctor's statement explaining why the drug is medically necessary (24 hours if it is an expedited request ()).



Plan Redetermination (Appeal) (page 8)

- You must request a redetermination within 60 days of receiving a denial of your request for a coverage determination (adverse coverage determination).
- Your drug plan has seven days to make and notify you of its decision (72 hours for an expedited appeal).
- Amount in question does not matter.



Reconsideration (Review by the Independent Review Entity) (page 9)

- You must request a reconsideration within 60 days from the date you receive an affirmation of denial from your drug plan.
- The IRE, Maximus Federal Services, has seven days to make and notify you of its decision (72 hours for an expedited appeal).
- Amount in question does not matter.



Administrative Law Judge (ALJ) Hearing (page 10)

- You must request an ALJ hearing within 60 days of getting a denial from the IRE.
- Amount in question must be at least \$120 in 2009.
- CMS maintains that the ALJ has no time limit within which to respond.



Medicare Appeals Council (MAC) Review (page 11)

- You must request a MAC hearing within 60 days of getting a denial from the ALJ.
- Amount in question does not matter.
- The MAC maintains that it has no time limit within which to respond.



Judicial Review (Federal District Court) (page 12)

- You must request judicial review within 60 days of getting a denial from the MAC.
- Amount in question must be at least \$1,180 in 2009.
- The federal district court has no time limit within which to respond.



The deadline to file an appeal at any level may be extended if you can demonstrate “good cause.” Examples of “good cause” may include, but are not limited to: having a serious illness; experiencing a death or serious illness in the immediate family; or losing important records in a fire or natural disaster. See 42 C.F.R. § 405.942(b)(2) and (b)(3).



Pre-Appeal Requesting a coverage determination

Most of the time you will find out your Medicare private drug plan does not cover your medications when you try to fill your prescription at the pharmacy. When the pharmacist tells you your plan will not cover the prescribed drug, the first thing you need to do is **request a written coverage determination** (📖) from your drug plan. **You need the written coverage determination from your plan before you can start the appeals process.** Getting a “no” at the pharmacy is **not** considered a coverage determination.

A **coverage determination** is your Medicare drug plan’s initial decision on whether it will cover your medication—the answer to your request for coverage (which may be referred to as an “exception request”). You must submit a coverage determination form to your drug plan **with a doctor’s statement explaining the medical necessity of your prescription.** While the plan must accept any written request and cannot require you to use a specific form, it is best to **use the coverage determination request form provided by Medicare** (see [Appendix 4](#) to download the form). The doctor’s statement may go directly on the form or on the doctor’s letterhead. You may want to attach additional information supporting medical necessity, such as lab results.



If your plan does not grant your request for prior authorization (📖), **then that denial counts as a coverage determination.** You can then request a redetermination. See Prescription Drug Benefit Manual, Chapter 18, § 30.1.

Who can request a coverage determination?

Below is a list of who can request a coverage determination. However, be aware that no matter who actually makes the request, your **doctor** must still submit a supporting statement to your plan.

- **You** can request a coverage determination. However, you will still need a supporting statement from your prescribing doctor. **The Medicare Rights Center recommends that people with Medicare get help or advice on how to begin the process from an advocate familiar with the Part D appeals system.**
- Your prescribing **doctor** can request a coverage determination—standard or expedited.
- An **advocate** who legally represents you. (See [Appendix 4](#) for a legal rep form.)
- Your **guardian or surrogate** who is recognized under state law.

How do you request a coverage determination?

It is generally better to submit a **written request** rather than an oral request because calls are harder to document. The plan must respond to your request for a coverage determination within **72 hours.** Your doctor can also ask—either orally or in writing—for an **expedited determination** (📖) when your “life, health or ability to regain maximum function” is in jeopardy. **Plans must respond to expedited determination requests within 24 hours** of

receiving your doctor's statement of medical necessity. These are **clock hours, not business hours**. Your plan should contact you, but if you do not hear in the timeframe above, you should call and ask for the plan's decision.




- **The appeals clock only starts ticking once the plan receives the coverage determination request AND the doctor's statement.** It is best if the physician writes a supporting letter on letterhead. The plan must also accept a statement written directly on the coverage determination request form, but these requests are often denied.
- **Keep all written evidence of communication with your plan, including fax transmittals, registered mail receipts and call logs.**

When you request a coverage determination, submit as much supporting evidence as possible. Your doctor's letter must assert that the prescribed drug is medically necessary and:

1. Any drug on the formulary would not be as effective and/or would be harmful to you.
2. All other drug or dosage alternatives on the plan's formulary have been ineffective or caused harm, or based on sound clinical evidence and knowledge of the patient, are likely to be ineffective or cause harm.

If the doctor's statement does not address one of the two claims above, your drug plan can extend the timeline it has to return a written coverage determination by claiming that the coverage determination request is incomplete. Sending the plan as much relevant information as possible in the beginning of the process also improves your chances of getting a favorable coverage determination (see [Appendix 4](#) for a letter template your doctor can use to submit the request). Your plan may still ask to see a full medical history or more information from the doctor, but must make any such requests immediately.

TIPS:

- **Use correct language to request a coverage determination.** If your plan classifies your request as a grievance () , you will not start the appeals process. Say explicitly, "I am requesting coverage for Drug X." (See [Case Example #1](#)).
- **Not all excluded drugs are equal.** Some excluded drugs are **always** excluded, no matter what (such as benzodiazepines and barbiturates). However, other drugs are excluded only for certain uses. **Show that your doctor prescribed your medication for a use that is not explicitly excluded.** See Case Examples [#2](#) and [7](#).



For, example, over-the-counter cold medication prescribed for Chronic Fatigue Syndrome may be covered. See Prescription Drug Benefit Manual, Chapter 6, § 20.1

- **Show the "whole picture" of your physical and mental health.** If the plan's "preferred" drug interacts with other medications you are taking or if it will impact other illnesses you have, you have a stronger case. **Submit as much documentation as possible**, especially if you already tried one of the drugs your drug plan is requiring you use before the prescribed drug, and it didn't work or caused other health problems. Submit medical records that prove your case. See Case Examples [#2](#) and [5](#).



If you are dissatisfied with your plan's customer service or your plan does not respond within the designated time frame, **you can and should file a grievance**. Be sure to file your grievance separately from your appeal, as plans have been known to misclassify appeals as grievances, which may delay processing of your request for coverage. See Prescription Drug Benefit Manual, Chapter 18, §§ 10.3 and 20.2. For a tip sheet on how to file a grievance, see www.cms.hhs.gov/partnerships/downloads/PartnerTipSheetPartDComplaints081706.pdf.

Appeal Level 1

Beginning the appeals process: Requesting a redetermination

Once your plan has responded **in writing** that it has decided **not** to cover your drug with a letter entitled, "Notice of Denial of Medicare Drug Coverage," you can begin the appeals process. **The first level of appeal is requesting a redetermination** from your plan. If your doctor has not done so already, she should also include additional documentation, such as medical records or peer-reviewed journal articles, showing that no other drug or dosage will be effective for you and/or that other drugs would be harmful to your health (See [Appendix 4](#) for a letter template you can use to request a redetermination from your plan).

In general, the more documentation your doctor submits, the stronger your case will be.

For instance, if your doctor can show that she tried three other medications and none controlled your symptoms as well as the prescribed medication, the appeal will be much stronger. This is especially true considering that the plan has the right to rebut the doctor's argument with its own evidence about the safety and efficacy of the prescribed medication.

If you paid for any medications out of pocket while your appeal was pending, you should submit all receipts at every stage of the appeals process. That way your Medicare drug plan will know how much it must reimburse you

Plans must respond to redetermination requests within **seven days**. However, if your "life, health or ability to regain maximum function" is in jeopardy, you can ask your doctor to request an **expedited review** that the plan must respond to within **72 hours** (See 42 C.F.R. § 423.590(d)). (The plan may turn down a request for expedition if you request it without a doctor's support.)

Generally, a plan should grant coverage of a drug when it determines that the medication is medically necessary, based on the evidence submitted. However, often plans will rubber-stamp their initial denials even though your doctor supports the medical necessity of your prescription.

If your plan approves coverage at the redetermination level, your coverage of that prescription should last through the rest of the plan year, although some plans offer to provide coverage for one calendar year from the date of approval. **If you decide to stay with the plan the following year, you should ask if the coverage will continue or if you will have to go through the appeals process again.** Try to get the plan's decision in writing before the end of the year so you can switch to another plan during the Annual Coordinated Election Period (November 15 to December 31 each year).

If coverage of your prescription is again denied, you can continue the appeals process by getting the Independent Review Entity, Maximus Federal Services, to review your case.

TIPS:


- If your doctor cannot or will not help, try contacting her nurse or physician's assistant.
 - Send your doctor a list of other drugs in the same class as the prescribed drug that are included in your plan's formulary. This way the doctor can directly counter the plan's claim that you could easily take another drug on its formulary or in a "preferred" tier.
 - Make sure your doctor responds to the plan's denial with a freshly dated letter and sends it to the Grievance and Appeals Department. (The address will be on the denial letter.)
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Appeal Level 2

Getting an independent review of your appeal

The second level of the appeals process is conducted by the Independent Review Entity (IRE), a private company that contracts with Medicare to review Part D appeals. Currently, the IRE is Maximus Federal Services, which should provide an objective review of your Medicare drug plan's decision. You may also hear the IRE referred to as a Qualified Independent Contractor or QIC. Maximus has a Part D appeals web site at www.medicarepartdappeals.com/.

When your Part D plan sends you an adverse redetermination notice, it is also required to provide a "Request for Reconsideration of Medicare Prescription Drug Denial" form. This form will include instructions on how to appeal to the IRE and the timeframe in which you must submit your appeal (**60 days** from the date on the denial letter).

When the IRE reviews a case, it will look at the prescribing doctor's statement explaining why you need the prescribed drug. **Your doctor should submit as much additional medical support as possible at this time.** Federal law requires the IRE to employ doctors with some expertise in various areas of medicine, so that they will be able to review the wide range of cases that arise. When reviewing your case, the IRE will generally check certain compendia () to see if your doctor's prescription is supported by established medical research. The IRE's review of an appeal is called a **reconsideration**. You should receive a written reconsideration decision within seven days of submitting your appeal (72 hours for expedited requests).



It helps to be familiar with Medicare rules and regulations to ensure the IRE provides accurate information. For example, the IRE told one caseworker that her client's doctor would have to actually **demonstrate** that a certain drug on the plan's formulary would have harmful effects or would be less effective than the prescribed drug. However, the regulations allow doctors to **predict** that these effects would occur since demonstrating it could harm the patient. See 42 C.F.R. § 423.578(a)(4)(iii) and [Case Example #4](#).

TIPS:

- While the IRE (currently Maximus Federal Services) generally makes fair decisions, they can make mistakes. Keep copies and records of everything you send the IRE. **If the IRE's decision is based upon faulty evidence, you can request that it reopen your case** (see Prescription Drug Benefit Manual, Chapter 18, § 120). See [page 12](#) for more information.
- At this stage, it may be beneficial to have a lawyer or other advocate help you appeal. However, you can also appeal yourself; the process is no different or more difficult than appealing to your plan.

The Medicare Rights Center has caseworkers ready to assist you at this level. Call our Appeals Hotline at 888-466-9050 for assistance.



The difficulty with the higher levels of the appeals process is that the Administrative Law Judge (ALJ), Medicare Appeals Council (MAC), and federal court can take months to issue their decisions. **If your client urgently needs a medication, but loses in the early levels of the appeals process, it is not likely that an ALJ, the MAC, or a federal court will act quickly, if review is granted at all.** Lawyers and other advocates may be eager to pursue an appeal in the hopes of setting a precedent or shaping policy. If your health is threatened, however, getting the proper medication should be the first concern. As a result, you might be forced to pay for your medications out of pocket or switch to a covered drug, simply to preserve your own health and well-being. If the appeal is denied, you will not be reimbursed for your costs. However, health should come first.

Appeal Level 3

Administrative Law Judge Hearing

The third level of the appeals process is conducted before an Administrative Law Judge (ALJ) with the Office of Medicare Hearings and Appeals (OMHA). Appeals can only be made if the amount of money you would have to spend to get the prescription drug is \$120 or more (in 2009). This amount of money is called the “amount in controversy” and may be added together if you are appealing for coverage of several different drugs or requesting coverage for the drug for an entire year. (See 42 C.F.R. § 423.610 and Prescription Drug Benefit Manual, Chapter 18, § 90.2).

A written request for ALJ review must be submitted within **60 days** of receiving an unfavorable decision from the IRE. Generally, ALJs will allow you to submit additional evidence before the hearing. Be sure to submit any evidence, including written arguments, you want the ALJ to consider within 10 days of the date you receive your “Notice of Hearing” from the ALJ’s office.

An ALJ may hear arguments from you, your drug plan, and possibly even the IRE. Such arguments are generally made via telephone conference call or video teleconferencing.



Additionally, it may be possible to appear before the ALJ in person. Because both you and your plan may present evidence to the ALJ, subpoenas may be requested to ensure access to people and documents.

TIPS:

- There are four regional OMHA offices. Your denial notice should indicate to which one you should send your appeal. You can also go to www.hhs.gov/omha/offices.html to find the field office that has jurisdiction over your area.
 - Try to arrange for your prescribing physician to testify at your hearing. Before scheduling the hearing, check with your doctor to determine when she is available, and give her your hearing date and time as soon as you have it.
 - Before the hearing, call your ALJ's assistant to make sure you know who will be present at your hearing, and that you receive copies of any evidence submitted by your plan or any other parties.
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Appeal Level 4 Medicare Appeals Council

If your appeal to the ALJ is unsuccessful, you can appeal to the Medicare Appeals Council (MAC). The MAC is an entity within the U.S. Department of Health and Human Services (HHS), and it will review your case based on the documents that you and any other parties submitted to the ALJ. Both you and your drug plan can file additional written arguments. MAC review will generally be granted under certain conditions, namely when there is a question of fairness during the ALJ hearing or a Medicare policy issue is at stake, such as disputing CMS's interpretation of the role Food and Drug Administration guidelines play in defining medical necessity (see 42 C.F.R. § 423.620).

A request for a MAC review must be filed by writing a letter to the MAC. You can file a written request with HHS by either completing Form DAB-101: "Request for Review of Administrative Law Judge (ALJ) Medicare Decision/Dismissal," available at www.hhs.gov/dab/DAB101.pdf, or by submitting a written request that includes the following:

1. Your name and address
2. Your Medicare number
3. The item(s) in dispute
4. The date(s) of the item(s)
5. The date of the ALJ's final action (if any)
6. Your name and signature (and that of any person serving as your advocate)

The appeal request must identify the parts of the ALJ's decision with which you disagree and explain why you disagree. For example, if you believe that the ALJ's decision is inconsistent with a statute, regulation, CMS guidance, or other authority, you should explain why the ALJ's

decision is inconsistent with that authority. The written request must be submitted directly to the MAC within **60 days** of receiving a denial from the ALJ.

Requesting a Reopening

If you feel that a denial at any level (except federal court) was based upon a clear error, or if you have **new** evidence that supports your case (like additional medical records or an expanded letter of medical necessity), you can request that the last entity that reviewed your appeal reopen your case (see 42 C.F.R. § 423.634).

With the exception of appeals at the plan level, you will often be better off requesting a reopening instead of proceeding to the next stage of appeal. This is because as you proceed through the appeals process, timeframes for decision-making become longer. For instance, requesting a reopening at the IRE level will typically result in a decision within a few weeks, whereas ALJ review can take months.

However, it is important to not let the time limit for continuing your appeal lapse. The clock keeps ticking while you wait for the decision on whether the appeal entity will reopen your case. If the entity refuses to reopen your case, that decision cannot be appealed and you will need to start the appeals process over if the deadline for taking your appeal to the next level has passed.

Reopening requests must be made in writing and are generally approved if the entity made an obvious error based on the evidence included in your appeal or new evidence would result in a different conclusion (see Case Examples 1 and 3 for examples of successful reopenings).



There are timeframes for requesting reopenings. For more information on reopenings, see Prescription Drug Benefit Manual, Chapter 18, § 120.

Appeal Level 5 Federal Court

The fifth level of review is conducted in federal court. You can request judicial review if:

- The MAC denied your request for review; or
- The MAC upholds the denial and you believe that CMS's interpretation of Part D regulations is inconsistent with the federal statute or arbitrary or capricious; and
- The amount in controversy is at least \$1,180 (in 2009). That sum increases slightly every year.

Once a federal court has heard your case, the appeals process is exhausted. However, it may be possible to appeal an adverse federal district court decision to a federal court of appeals, and ultimately, to the Supreme Court of the United States.

After Your Appeal

When your plan must implement a reversed decision

You won your appeal! Congratulations! Now when must your plan begin covering your drug?

- **If your plan reverses its decision** about covering or paying for your medication, it must provide coverage within **seven days** and issue reimbursement within **30 days**.
- **If a reversal is made at a higher level of appeal**, your plan must provide coverage within **72 hours** and issue reimbursement **within 30 days**.

The decision must be retroactive to the date you requested an initial coverage determination. If you paid for any medications out of pocket while your appeal was pending and submitted receipts with your appeal, your plan should send you a check automatically.

If you did not submit receipts at the time of your appeal, you can submit a reimbursement request to your plan. You will have to submit copies of your receipts (or a print out from your pharmacy) as well as any other paperwork your plan may require.

If you win at the IRE level (Maximus) or a higher level of appeal, the entity that reversed the plan's decision is responsible for ensuring that your plan complies with its decision. Contact the appeal entity if your plan refuses to either provide coverage or issue reimbursement. You can also contact your regional CMS office (see [Appendix 4](#) for contact information).

If you decide to stay with your drug plan the following year, you should ask if the coverage you won through your appeal will continue or if you will have to appeal again. Get the plan's decision in writing before the end of the year so you can switch to another plan during the Annual Coordinated Election Period (November 15 to December 31 each year).



See 42 C.F.R. § 423.636 for further regulations on how plans must implement reversed decisions.

Appendix 1: Case Examples

1. The plan does not return a decision within the required timeframe
2. The plan says the drug is excluded from Medicare coverage
3. The plan says that your drug is covered by Part B, not Part D
4. The plan wants you to try a “preferred” drug before it will cover your prescribed medication
5. The plan says the drug has been prescribed for an “off-label” use
6. The plan says the drug is not “medically necessary” for you
7. The plan says the prescribed dose exceeds “standard” guidelines

1 The plan does not return a decision within the required timeframe

Under Part D law, you are entitled to receive timely decisions from your Part D plan during the appeals process, with specific timeframes for each stage (see 42 C.F.R. § 423.562). Regardless, many plans routinely find ways to avoid meeting these requirements.



Part D plans are not required to process a request for a formulary exception until the prescribing physician provides a supporting statement of medical necessity. Therefore, it is crucial that all requests for coverage include a supporting statement by the prescribing physician (see Prescription Drug Benefit Manual, Chapter 18, § 30.2.2).

Problem:

Mr. P’s Medicare drug plan required him to try the generic form of Oxycontin before it would cover the brand name. Mr. P asked two of his physicians to submit letters of medical necessity explaining that Mr. P was allergic to the generic form of the medication. His drug plan denied his physicians’ requests, stating that Mr. P must try another version of the generic before the plan would cover Oxycontin. Mr. P’s advocate submitted a redetermination request. Several weeks later, Mr. P’s plan still had not responded, even though federal regulations require Medicare drug plans to issue redetermination decisions within seven days (see 42 C.F.R. § 423.590). Mr. P’s advocate resubmitted the redetermination request four times, but the plan still refused to issue a redetermination.

What to do:

Mr. P’s advocate forwarded the appeal to the IRE (Maximus), explaining that Mr. P’s plan had not responded to the redetermination request. The IRE dismissed the case, stating that it could not review the case until the plan issued a redetermination. Mr. P’s advocate requested a reopening of the IRE’s decision, including documentation of her multiple attempts to send the redetermination request, along with all of the required information, to the drug plan. The IRE finally overturned the plan’s denial.



If a Medicare drug plan fails to meet the legal timeframe for making a decision, it must forward the case to Maximus within 24 hours of the expiration of the timeframe (see 42 C.F.R. § 423.568(e) and 42 C.F.R. § 423.590(c)). However, since many Medicare private drug plans do not process appeals or make coverage determinations in a timely manner, they cannot be counted on to forward cases. Advocates should themselves escalate (📖) coverage determination and appeal requests to the IRE (Maximus) when timeframes have elapsed—with documented evidence of their attempts to obtain a decision from the plan.

TIP:

- In cases where plans fail to abide by coverage determination or appeal timeframes, you should also submit grievances to the plans. If CMS finds that a plan has a pattern of not returning decisions within the requisite timeframes, the plan may be found in breach of its Medicare contract and/or subject to sanctions (see Prescription Drug Benefit Manual, Chapter 18, § 40.4). For a tip sheet on how to file a grievance, see [Appendix 4](#).
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2 The plan says the drug is excluded from Medicare coverage

Some drugs are explicitly **excluded** from Medicare coverage by law. However, while Medicare will not pay for these drugs, plans themselves can choose to cover them as part of an enhanced benefit package. These excluded drugs include:

- Drugs for*:
 - Anorexia, weight loss or weight gain
 - Fertility
 - Cosmetic purposes or hair growth
 - Relief of the symptoms of colds, like a cough and stuffy nose
 - Erectile dysfunction
- Prescription vitamins and minerals (except prenatal vitamins and fluoride preparations)
- Non-prescription drugs (over-the-counter drugs)
- Certain anti-anxiety drugs (barbiturates and benzodiazepines)



*Prescription drugs that will not be covered for the treatment of the conditions listed above may be covered if they are being prescribed to treat other conditions. For example, prescription medications for the relief of cold symptoms may be covered by Part D if prescribed to treat something other than a cold, such as shortness of breath from severe asthma. See 42 C.F.R. § 423.100, Prescription Drug Benefit Manual, Chapter 18, § 20.2.4.

Problem:

Mrs. V has a disability and takes several different medications to treat pain, Chronic Fatigue Syndrome (CFS) and anemia. She had seen the same doctor for 10 years and had tried a variety of drug regimens to treat her conditions. To treat her CFS, her doctor prescribed Duratuss, a combination of a prescription-strength Sudafed and Guaifenesin. Her Medicare drug plan denied her claim for Duratuss because Sudafed is typically used to treat cold symptoms.

What to do:

Mrs. V's advocate spoke with Mrs. V's prescribing doctor. Her doctor prepared a letter detailing Mrs. V's medical condition. In the letter, the doctor:

- stated that he prescribed Duratuss to treat Mrs. V's CFS;
- described how Duratuss helped Mrs. V's CFS;
- explained that Mrs. V had already tried other medications, none of which was as effective as Duratuss;
- asserted that other drugs Mrs. V could take, such as more expensive and potentially addictive amphetamines, would be harmful to her health.

The doctor signed the letter and printed it on his practice's letterhead. The advocate then faxed and mailed the letter, along with an additional cover letter requesting a redetermination (see [Appendix 4](#)) to Mrs. V's plan. Three days later, Mrs. V's plan called the advocate to let her know that the plan had approved coverage. Mrs. V was able to get her medication.

3 The plan says your drug is covered under Part B, not Part D

Many people (even plan representatives) are confused about which part of Medicare will cover particular drugs. To answer this question, follow these general rules of thumb:

- **Part B** will continue to cover drugs administered by a doctor or at a dialysis facility, but the doctor or facility, **not the patient**, must buy the drugs. Part B also covers a limited number of outpatient prescription drugs. **Outpatient drugs paid for by Part B before Part D began in 2006 will continue to be paid for by Part B.** Part D cannot pay for any drugs that are covered by Part B.
- **Part D** covers outpatient drugs through Medicare private drug plans. Your Medicare drug plan should cover most prescriptions your doctor writes for you to fill at the drugstore.

For more information on Part B vs. Part D issues, see:



- Medicare Interactive:
http://www.medicareinteractive.org/ext_url.php?url=http://www.medicareinteractive.org/uploadedDocuments/mi_extra/partbvspartdchart.html
- Chapter 6, Appendix C of the Prescription Drug Benefit Manual
www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp

Problem:

Mrs. G had Medicaid when she got a transplant in January 2000. She enrolled in Medicare in July 2002, two years after her transplant. Before she started receiving drug coverage through her Medicare drug plan in 2006, New York Medicaid had covered all of her prescription drugs, including two immunosuppressants, which are necessary to ensure a patient's body does not reject a transplanted organ. Mrs. G's drug plan refused to cover her immunosuppressants, claiming that they should be covered under the Medicare Part B benefit. **This would be true only if Medicare had covered her transplant, which it did not.**

What to do:


Mrs. G's advocate called the New York Medicaid office and asked them to cover her immunosuppressants while she pursued an appeal with the Medicare drug plan. The Medicaid office agreed. The advocate then contacted Mrs. G's doctor who had performed the transplant to fax her medical records and a letter to support Mrs. G's appeal.

Mrs. G's plan returned an adverse coverage determination. At the redetermination level, the plan again claimed that Mrs. G's drugs should be covered by Part B because her transplant was covered by Medicare, even though Mrs. G's medical records clearly stated that she did not have Medicare at that time. Mrs. G's advocate appealed to the Independent Review Entity (IRE) which affirmed the plan's decision. The advocate requested that the IRE reopen the case since it was clear that neither the plan nor the IRE had adequately reviewed Mrs. G's medical records. The IRE agreed and subsequently approved Mrs. G's immunosuppressants for coverage by her Part D plan because her transplant was not in fact covered by Medicare.



For rules on how to request that a review agency reopen a case, see the Prescription Drug Benefit Manual, Chapter 18, § 120.

4 The plan wants you to try a “preferred” drug before it will cover your prescribed medication

Medicare drug plans can place certain restrictions, such as prior authorization, step therapy or quantity (dosage) limits () on their coverage of particular drugs. These are called utilization management (UM) requirements or cost utilization tools (See 42 C.F.R. § 423.153(b); Prescription Drug Benefit Manual, Chapter 18, § 30.2.2). However, you can bypass these restrictions by requesting a coverage determination as long as your doctor believes that:

- Any drug on any tier of the plan's formulary would not be as effective as the prescribed drug or would be harmful to you (prior authorization); **or**
- The number of doses allowed by the plan has not been as effective; **or**, based on sound medical evidence, your physical and mental characteristics, and known effects of the drug regimen, would not be as effective or would be harmful to you (quantity limit); **or**

- The preferred drugs listed on your plan formulary have been ineffective **or** have been or are likely to be harmful for you, **or** have been or are likely to be ineffective (step therapy).

Problem:

Ms. B’s doctor prescribed Byetta to treat her Type 2 diabetes. However, her plan wanted her to try Lantus, a “preferred” drug on its formulary.

What to do:

Ms. B’s doctor and advocate requested a coverage determination to bypass this step-therapy requirement because her doctor believed that Lantus would not be as effective for her. Ms. B’s plan denied her request.

Ms. B’s advocate requested a redetermination, but the plan affirmed its denial because Ms. B had not yet tried the “preferred” drugs Avandia, insulin, or a sulfonylurea agent.


Ms. B’s doctor wrote another letter to the IRE demonstrating that Ms. B had already tried and failed insulin and a sulfonylurea agent. In addition, he provided medical journal articles showing that Byetta is a unique drug to treat Ms. B’s particular medical circumstances and that no other drugs on the plan’s preferred list would work. To respond to the plan’s requirement that she try Avandia, Ms. B’s advocate provided CMS guidance that states that a plan may not require a doctor to show that **all** “preferred” drugs would be harmful or ineffective in every situation. The IRE approved coverage and overturned the plan’s decision.




See 70 Fed. Reg. 4353 for written guidance that doctors do not have to prove that **all** drugs proposed by your drug plan have been harmful or ineffective for you.

5 The plan says the drug is not a “Part D drug”

CMS regulations state that a **Part D drug** is one that is used for a “medically-accepted indication.” For all drugs, except anti-cancer medications, this means:

1. The use is approved by the Food and Drug Administration (FDA); **or**
2. The use is approved for inclusion in one of the three compendia () approved by CMS.

A **Part D anti-cancer drug** is also one that is used for a “medically-accepted indication,” but the definition is broader. This means:

1. The use is approved by the Food and Drug Administration (FDA); **or**
2. The use is approved for inclusion in one of the compendia () approved by CMS; **or**
3. The use is approved for inclusion in one of the peer-reviewed medical journals approved by CMS.

Uses that are not approved by the FDA are called “off-label” uses (.



Rules on “medically-accepted indication[s]” can be found at: 42 U.S.C. § 1396r-8(k)(6) and (g)(1); 42 U.S.C. § 1927(k)(6); and 42 C.F.R. § 423.100,

Problem:

Ms. G was prescribed Carimune to treat her severe asthma. Before this medication, she had undergone numerous therapies, none of which had alleviated her symptoms, and had been hospitalized several times for acute, life-threatening episodes. In addition, the drugs she tried before Carimune increased her blood-sugar levels and blood pressure, exacerbating her hypertension. Her plan denied her exception request, stating that treating asthma is not a medically accepted use of Carimune and therefore her prescription could not be covered.

What to do:

After the plan returned an adverse coverage determination and redetermination, Ms. G’s doctor and advocate appealed to the IRE. Ms. G’s doctor supplied a full medical history, demonstrating her long history of trying and failing other therapies for her condition. Her doctor stated that she would not be a good candidate for the alternative therapies suggested by her drug plan. In addition, the doctor demonstrated that the use of Carimune to treat severe asthma is supported by at least one of the Part D-approved compendia, satisfying the requirements for it to be covered under Part D. The IRE found in Ms. G’s favor and instructed the plan to cover her treatment.

TIPS:

- If the drug you need is not approved by the FDA **or** supported by any of the approved compendia, your appeal will be more difficult to pursue. Call the Medicare Rights Center at 888-466-9050 for guidance.
 - It can be difficult to access the Part D-approved compendia, as they are not publicly available. Your doctor may have access to one or all of the compendia through her hospital or a university. If your doctor cannot check the compendia, try asking any other doctors or other health care providers you may know, or even a medical student.
-

6 The plan says that the drug is not “medically necessary” for you

A Medicare drug plan may counter a doctor’s statement that a drug is medically necessary using its own medical and scientific evidence on a particular medication’s safety and efficacy in treating certain conditions.

Problem:



Mr. R was undergoing treatment for hepatitis C. The treatment, however, caused anemia, making him too weak to endure the regimen. In order to boost his red blood cell count, his doctor prescribed Procrit injections. His drug plan rejected both his exception request and redetermination request due to a prior authorization requirement that stated that the plan only covered Procrit for people who had HIV, non-myeloid cancer, myelodysplastic syndrome, or chronic renal failure.

What to do:

Mr. R's advocate continued to appeal to the IRE and his doctor submitted a statement explaining that Mr. R's red blood cell count had fallen to a level where it was no longer safe for him to continue the treatment for hepatitis C, endangering his overall health. The IRE agreed with Mr. R's doctor that Procrit was medically necessary in this case and approved coverage.

7 The plan says the prescribed dose exceeds "standard" guidelines

Problem:

Ms. L lives with severe depression. Her psychiatrist had tried numerous treatments and had settled on a specific combination of Wellbutrin, Mirtazepine and Cymbalta. However, her Medicare drug plan would not cover the prescribed quantities, stating that they exceeded the standard number of doses and that there was no significant clinical data that could justify the use of non-FDA approved doses. The IRE agreed with the plan, further claiming that the prescribed doses were not covered under Part D because they were not supported by the compendia.

What to do:

Ms. L's advocate pursued the appeal to the ALJ level. Working with Ms. L's doctor, the advocate argued three main points:

1. The treatment was medically necessary to treat her depression.
2. The fact that the prescribed dosage does not meet the definition of a Part D drug—i.e. it is not supported by the FDA label or the compendia—does not necessarily mean that it is an excluded drug.
3. CMS policy states the importance of providing continuity of care.

Luckily, Ms. L's doctor had kept meticulous notes of his attempts to find the right combination of drugs to treat Ms. L's depression, demonstrating that any change could have harmful effects on Ms. L's condition. In addition, an expert physician from the American Psychiatric Association was able to provide supporting testimony. The ALJ ordered the plan to cover the drug regimen prescribed by Ms. L's doctor.



- CMS has stated that a drug may be considered a Part D drug even if the prescribed **dosage** is not approved by the FDA or included in the compendia. See Prescription Drug Benefit Manual, Chapter 6, § 10.6)

- CMS' support of continuity of care can be found in § 3.C of its Formulary Guidance (www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CY07FormularyGuidance.pdf).
- The American Psychiatric Association's (APA) practice guidelines recommend that for the treatment of both schizophrenia and major depressive disorder, psychiatrists are specifically recommended to adjust dosages (titrate) based on the responses of individual patients. (American Psychiatric Association, *Practice Guideline for the Treatment of Patients with Major Depressive Disorder*, 2nd Edition, 2000.)

Appendix 2: Sample protocol for advocates

A. Determine if an appeal is appropriate

1. Make sure the prescribed drug is a Part D covered drug. Should it be covered under Part B? Is it excluded from Medicare coverage by law?
2. Find out if the client has other insurance that may pay for the drug (such as a state pharmaceutical assistance program (SPAP) or Medicaid).
3. Find out if the client has appealed for Part D coverage of this prescription in the past, under this or another drug plan. If so, what was the result of that appeal? If the client won, and still has a copy of the favorable decision, you can try submitting the previous decision instead of starting over from scratch.
4. Call the client's doctor to explain the situation and request cooperation. Ask if there is any other drug on the plan's formulary that will work for your client. Be prepared to give the doctor the names of other drugs in that drug class on the plan's formulary. If the doctor says the prescribed drug is the only one that will work for the client, ask if she can provide medical records/information in support of the coverage request.

B. Get a coverage determination / initial decision

1. Ask the client if s/he has gotten a written coverage determination from the drug plan.
 - If the client has received a written determination and was denied, skip to "C. Appeal."
 - If not, get important information: drug plan, physician, and pharmacy information.
2. Have your client sign an HHS Appointment of Representative form (unless the appeal is coming from the prescribing physician).
3. Fax a cover letter, the coverage determination form and doctor's statement of medical necessity to the plan (see tip sheet for doctors in [Appendix 4](#)).

C. Appeal

1. If the plan denies coverage in its initial coverage determination, call the doctor to ask if she can provide additional medical records/information in support of the appeal, if she has not already done so. If necessary, ask the doctor to requesting expedited review.
2. Have the client sign an Appointment of Representative form, if not yet already done.
3. Find out if employees of the plan led the client to believe the plan would cover her prescription before she enrolled. If so, include this information in your appeal request.
4. Put together materials and fax appeal (redetermination request) to the plan.



If the appeals process is unsuccessful or your client urgently needs coverage for her medications, she may be eligible for a **Special Enrollment Period** to switch plans to one

that will cover her medications. This may be a more effective solution, especially if the plan does not respond to the appeal requests in a timely manner (see [Appendix 4](#)).



Appendix 3: Glossary of terms

Appeal: A request that you make when you disagree with your insurer’s decision not to cover a service or item you believe you need and should be covered. The ability to appeal Part D denials is guaranteed by law and the process is regulated by CMS.

Class of drugs: A “therapeutic class” contains drugs that are similar based on the disease they treat or on the way they affect the body.

Compendium: A medical compilation used to provide clinicians with information on well-researched off-label uses of prescription drugs that are effective in the treatment or management of specific conditions. Off-label prescriptions may only be covered by Part D if they are supported in one of the following compendia:

- American Hospital Formulary Service Drug Information;
- United States Pharmacopoeia Drug Information;
- DRUGDEX Information System.

Coinsurance: A percentage of the cost of each prescription you buy through your Medicare private drug plan that you are responsible for paying. For example, your Medicare private drug plan may charge you 20 percent of the price of your brand-name medication. What you pay may vary as the price of the drug changes.

Copayment: A flat fee that you are responsible for paying for each prescription. Some plans may charge a \$5 or \$10 copayment for generic drugs. This amount should stay the same throughout the year.

Cost-sharing tier: Medicare private drug plans structure their formularies to contain different cost-sharing tiers. That means your out-of-pocket costs for each prescription you fill depends on which “tier” the drug is in. Lower tiers have lower out-of-pocket costs and usually include generic versions of drugs. Higher-tier drugs will cost you more and usually include brand-name drugs. Plans can have multiple tiers. Plans can also have one specialty tier containing drugs that cost more than \$500. You can request that the plan lower the cost-sharing of the drug you take—provided it is on your plan’s formulary—to a lower cost-sharing tier (see “Tiering Exception”). The plan can decide whether it allows such requests on a specialty-tier drug.

Coverage determination: A Medicare drug plan’s initial decision on whether it will cover your medication—the answer to your request for coverage (also referred to as an “exception request”).

Escalated appeal requests: A request that your appeal be permitted to “skip” a level and move up to the next level if the previous level did not act on the appeal within the statutory or regulatory timeframe. For example, if the IRE does not act on your appeal within its seven-day time limit, you can request that your appeal be escalated to the ALJ level without waiting any longer for the IRE to make a decision.

Expedited determination or appeal requests: A request that your plan or the IRE respond to your coverage determination request or appeal faster than the normal timeframe. You can ask for an expedited coverage determination or appeal when your “life, health or ability to regain maximum function” is in jeopardy. (Plans must expedite requests if your doctor certifies your health requires it.)

Formulary: A list of drugs that the plan will cover for its enrollees. The formulary must list approved dosages and any restrictions on coverage (see Prior Authorization, Step Therapy and Quantity Limits). According to federal regulations, every formulary must include at least two drugs in every major class of drugs. Formularies are usually divided into cost-sharing tiers.

Formulary Exception: A type of coverage determination that addresses formulary issues. You would request a formulary exception in order to get coverage for a drug that requires a prior authorization, step therapy, or quantity limit restriction, as well as to obtain coverage of an off-formulary prescription.

Grievance: A complaint you file with your Medicare drug plan about its operations or behavior. For example, you may file a grievance if you are dissatisfied with the plan’s customer service or how it managed your appeal. You should always file a grievance if your plan fails to follow appeals timeframes. Plans must report the number of grievances they receive to CMS, and CMS is supposed to sanction plans that are repeat offenders. However, be aware that **an appeal**, not a grievance, is **the only way to request a reversal of a denial of coverage of your medication**.

Medical necessity: To demonstrate the medical necessity of a prescription under Part D, your doctor must show that the prescription is either more effective or less harmful than the medications on your plan’s formulary. Even if your doctor can prove medical necessity, your prescription may not be covered by your plan if it is otherwise excluded from Part D coverage.

Off-label use: A use of a drug that is not listed on the Food and Drug Administration label. Drug makers seek FDA approval for specific uses of their products and conduct trials to test their drugs' safety and effectiveness in patients with specific conditions. If the FDA approves the drug for those conditions, the drug manufacturer has to sell the medications with a label that lists the FDA-approved uses for that drug. Any use outside of that is referred to as “off-label.”

Prior authorization: A requirement that you get permission from your plan before it will cover a particular medication.

Quantity limit: A limit on the amount or dosage of a particular medication that a plan will cover, which may be less than the prescribed dosage.

Step therapy: A requirement that you try other drugs and find them harmful or less effective for you (also referred to as “fail first requirements”) before your plan will cover your prescribed medication.

Tiering Exception: A request that a particular non-preferred drug that is medically necessary for you be covered at a lower cost-sharing tier. You may only request a tiering exception for non-preferred drugs. “Specialty” and preferred drugs are exempt from these exceptions.



Appendix 4: Part D Appeals Toolkit

Where to find Part D appeals law

If a plan disagrees with you in your appeal, it is often helpful to provide the plan with the relevant federal laws, regulations and guidance on Part D coverage, as well as appeals rules and procedures.

1. The federal statute is the law written by Congress and is the most authoritative text on Part D rules. You can find the Part D statute in Section 1860D of the Social Security Act, online at www.ssa.gov/OP_Home/ssact/title18/1800.htm.
2. Federal regulations, written by CMS, explain how the statute will be implemented. Part D regulations are in Title 42 (Public Health), Part 423 (Voluntary Medicare Prescription Drug Benefit). You can access the federal regulations online at www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1 and see Title 42, Part 423 at www.access.gpo.gov/nara/cfr/waisidx_06/42cfr423_06.html.
3. CMS guidance provides further details on how CMS is implementing the laws and regulations. Prescription Drug Benefit Manuals can be found on the CMS website at: www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp

For Part D appeals rules, see the Prescription Drug Benefit Manual, Chapter 18: “Part D Enrollee Grievances, Coverage Determinations, and Appeals.” For details about coverage for prescription medications under Parts B and D, see Chapter 6: Part D Drugs and Formulary Requirements.

- a. Some guidance is cross-referenced with guidance on Medicare private health plans. However, the Managed Care Manual explicitly states that the rules on Part D appeals apply to people who are enrolled in either a Medicare private health plan like an HMO or PPO (also called Medicare Advantage plans) or a stand-alone prescription drug plan (PDP). See Chapter 13, Section 10 of the Managed Care Manual: www.cms.hhs.gov/manuals/downloads/mc86c13.pdf.

Part D appeal forms, contact information and handouts

- **Medicare Rights Center advocates:** MRC has a team of caseworkers and volunteer lawyers to help with Part D appeals. Call our Appeals Hotline at 888-466-9050.
- **Legal Representation forms:** <http://www.cms.hhs.gov/cmsforms/downloads/cms1696.pdf>. Federal regulations allow you to appoint someone to legally represent you when you appeal. See 42 CFR § 423.570(c)(3); Prescription Drug Benefit Manual, Chapter 18, § 10.4.
- **Request for Coverage Determination forms:** www.cms.hhs.gov/MLNProducts/Downloads/Form_Exceptions_final.pdf. Plans must accept any oral or written request, but using a standard form may get your request processed more quickly. See Prescription Drug Benefit Manual, Chapter 18, § 40.1.
- **A tip sheet for your doctor:** www.medicarerights.org/tips_physician_appeals.pdf
- **A tip sheet for consumers:** www.medicarerights.org/pdf/get_the_most_out_of_drug_plan.pdf
- **A tip sheet for consumers on requesting redeterminations:** www.medicarerights.org/appeal_partd.pdf
- **A model cover letter for redetermination request** that you can attach to your doctor's statement of medical necessity. www.medicarerights.org/pdf/sample-redetermination-cover-letter.pdf
- **Information of filing grievances and CMS Regional Offices that help troubleshoot Part D appeals:** (see page 2) www.cms.hhs.gov/partnerships/downloads/PartnerTipSheetPartDComplaints081706.pdf
- **Special Enrollment Period Chart:** See if your client is eligible to switch Medicare private drug plans outside of normal enrollment periods at: www.medicarerights.org/sep_chart.pdf
- **Part B vs. Part D drug coverage issues chart on Medicare Interactive:** http://www.medicareinteractive.org/ext_url.php?url=http://www.medicareinteractive.org/uploadedDocuments/mi_extra/partbvspartdchart.html