



Helping Clients with Part D Appeals – Frequently Asked Questions

1. What does Medicare Part D cover?

Medicare Part D covers outpatient prescription drugs. Each Part D plan has its own formulary, which is a list of drugs that a plan covers. The law requires all Part D plan formularies to include at least two drugs in most categories—or classes—of drugs, and substantially all drugs in the following six classes:

- Immunosuppressants, which are used to prevent an individual's body from rejecting an organ after a transplant
- Antidepressants, which are used to treat depression
- Antipsychotics, which are used for schizophrenia and bipolar disorder
- Anticonvulsants, which are used to treat epileptic seizures
- Antiretrovirals, which are used to treat HIV and AIDS
- Antineoplastics, which are used to prevent the development of tumors

Some drugs are excluded from Medicare coverage by law and cannot be covered by any Part D plan. These include:

- Drugs used to treat anorexia, weight loss, or weight gain; however, Part D may cover drugs used to treat physical wasting caused by AIDS, cancer, or other diseases.
- Fertility drugs
- Drugs used for cosmetic purposes or hair growth
- Drugs that are *only* used to treat cough or cold symptoms
- Drugs used to treat erectile dysfunction
- Drugs that have not been approved by the Food and Drug Administration (FDA)
- Prescription vitamins and minerals, except for prenatal vitamins and fluoride preparations
- Most over-the-counter drugs, like Tylenol[®] and Advil[®]

2. What are some common reasons a plan may deny coverage for a drug?

There are many reasons for why a Part D plan may deny coverage for a prescription drug, but these are some more common reasons:

- **Prior authorization**: a beneficiary must get prior approval from the plan before it will cover a specific drug
- **Step therapy**: the plan requires the beneficiary to try a different or less expensive drug first
- **Quantity limits**: the plan only covers a certain amount of a drug over a certain period of time, such as 30 pills per month

• Off-formulary: the drug is not on the plan's list of covered drugs

If a beneficiary is confused as to why their plan denied coverage of a drug, they should contact their plan.

3. What can a beneficiary do if their plan will not pay for their prescription drug? If a pharmacist tells a beneficiary that their plan will not pay for their prescription drug, the pharmacist should give them a notice titled Medicare Prescription Drug Coverage and Your Rights.

To get more information, the beneficiary should contact their plan to find out the reason it is not covering the drug. When they get this information, they can decide whether to work with their provider to meet the plan's coverage requirements or start an appeal. Keep in mind that at this point, the beneficiary has not received a denial notice from their plan, meaning they cannot start a formal appeal.

Once they have information from the plan about why the plan is not paying for the prescription, they should speak to their prescribing physician or other provider. For example, if the issue is that the medication is not on the plan's formulary, there may be another medication that is on the formulary and is an acceptable substitution. The provider can tell the person whether the medication that is on the formulary would be okay for them to use or not. If not, the beneficiary may wish to appeal. A provider may appeal on a beneficiary's behalf or help with the appeal process, but is not required to do so.

Before they start the formal appeal process, the beneficiary will need to send the plan an exception request or a request for a coverage determination. They should contact their plan for information on where to send it and what information is required. For an exception request, they will need a doctor's letter of support that explains why the plan rule should not apply based on the beneficiary's particular medical needs. Their plan should issue a decision within 72 hours. If the exception request is approved, their drug will be covered. If not, they can proceed with a formal appeal.

4. What are the steps of a Part D appeal?

If the exception request is denied, or the response to a coverage determination request is unfavorable, a beneficiary's plan should send them a **Notice of Denial of Medicare Prescription Drug Coverage**. They can then begin a formal appeal. Here are the steps:

1) Appeal with the plan:

The beneficiary has 60 days from the date listed on the notice to file an appeal with the plan. They should follow the directions on the notice. The plan should issue a decision within seven days. If the plan approves the appeal, their drug will be covered. If it is denied, the beneficiary can proceed to the second level of appeal.

- 2) Appeal with the Independent Review Entity (IRE):
 - A beneficiary must send their appeal to the IRE within 60 days of the date listed on the plan denial. The IRE should issue a decision within 7 days. If the IRE approves the appeal, their drug will be covered. If not, the beneficiary can proceed to the third level of appeal.
- 3) Appeal with the Office of Medicare Hearings and Appeals (OMHA):

If the appeal is denied and the drug is worth at least \$170 in 2020, they can choose to appeal to the OMHA level. They must submit the appeal within 60 days of the date on their IRE denial letter. OMHA should issue a decision within 90 days. If the appeal to the OMHA level is successful, their drug will be covered. If not, the beneficiary can proceed to the fourth level of appeal.

4) Appeal with the Council:

The appeal to the Council must be sent within 60 days of the date on the beneficiary's OMHA level denial letter. The Council should issue a decision within 90 days. If the appeal to the Council is successful, their drug will be covered. If not, the beneficiary may be able to proceed to the fifth level of appeal.

5) Appeal with the Federal District Court:

If the beneficiary's appeal is denied and their drug is worth at least \$1,670 in 2020, they can appeal to the Federal District Court within 60 days of the date on their Council denial letter. There is no timeframe for the Federal District Court to issue a decision about the appeal. If the appeal is successful, their drug will be covered. Often, a beneficiary will want to consult an attorney to decide whether it makes sense to appeal in District Court.

5. A beneficiary needs their drugs as soon as possible. How can they make their appeal go faster?

A beneficiary can request a fast (expedited) exception request if they or their doctor feel that their health could be seriously harmed by waiting the standard timeline for a decision. If their doctor supports the decision to file an expedited exception request, the plan must follow the expedited timeline. A beneficiary can also request an expedited exception request without their doctor's support, but in this case the plan does not have to follow the expedited timeline.

If the plan grants the request to expedite the process, the beneficiary will get a decision within 24 hours of the initial exception request. They can then proceed through the same steps of the formal appeal, but with an expedited timeline:

- 1) At the plan level, the plan should issue a decision on the appeal within 72 hours
- 2) At the IRE level, the IRE should issue a decision within 72 hours
- 3) At the OMHA level, the OMHA should issue a decision within 10 days
- 4) At the Council level, the Council should issue a decision within 10 days
- 5) At the Federal District Court, there is no timeframe for the court to issue a decision

6. What are some tips for filing a successful appeal?

If a doctor is not appealing on a beneficiary's behalf, the beneficiary will usually want to ask their doctor to write a letter of support addressing the plan's reasons for not covering the needed drug. Doctors can confirm medical necessity, whether any of the plansuggested alternative drugs are appropriate, and they may be able to work closely with the patient through the appeals process.

After the IRE level of an appeal, beneficiaries may want to contact a lawyer or legal services organization to help them with later steps of their appeal—but it is not required.

It is important that beneficiaries keep records of the conversations they have with their plan, as well as any documents they receive from their plan, their provider or entities at higher levels of the appeals process.

Persistence is also important. Each level of an appeal is an independent decision, therefore an appeal denied at a lower level may be approved at higher levels without any new or additional information.

7. What can a beneficiary do if their Part D appeal is denied and their plan still does not cover their drug?

If a Part D appeal is denied, and the beneficiary cannot or does not wish to escalate the appeal to a further level, there may be some other options for them to access their prescription drugs.

First, they may want to speak to their doctor. Their doctor may be able to:

- Prescribe generic versions of the drug: Generic drugs are often less expensive than brand-name drugs, and might be covered by the plan or be more affordable if the person chooses to pay out-of-pocket. Their doctor will be able to explain whether the generic version is right for them.
- Provide samples of the medication: This is a temporary solution, as their doctor may not be able to provide samples for very long. If they are using samples, they should be sure to explore other options for getting their drugs covered.
- Discuss other programs: Charity programs may be able to cover some or all of the cost of the drugs

Other resources to consider may be programs from the drug's manufacturer or pharmaceutical assistance programs.

8. What can a beneficiary do if they miss an appeal deadline?

When initially filing an appeal and for each subsequent level, a beneficiary has a limited amount of time to file. That said, after the deadline has passed, if a beneficiary can show good cause for not filing on time, their late appeal may be considered. A beneficiary can request a good cause extension at any level of appeal. Extension requests are considered on a case-by-case basis, so there is no complete list of acceptable reasons for filing a late appeal. Some examples include:

- An appeal notice was mailed to the wrong address.
- A Medicare representative gave a beneficiary incorrect information about the claim they are appealing.
- Illness—either the beneficiary's or a close family member's—prevented the beneficiary from handling business matters.
- The beneficiary filing the appeal is illiterate, does not speak English, or could not otherwise read or understand the coverage notice.

If a beneficiary thinks they have a good reason for not appealing on time, they should send in their appeal as they normally would and include a clear explanation of why their appeal is late. If the reason has to do with illness or other medical conditions, a letter or supporting documentation from the beneficiary's health care provider can be helpful.

9. What is a drug tier?

Medicare prescription drug plans price prescription drugs based upon tiers. Generally, drugs on higher tiers will cost more than drugs on lower tiers, meaning a beneficiary will have a higher copay or coinsurance. Typically, the lowest tiers are for generic drugs, the highest tiers are for specialty drugs, and the middle tiers are for common brand-name drugs.

10. What can someone do if their drug is on a high tier or has unaffordable copays? When a beneficiary's drug is on a high tier and/or has high copays, they may be able to file a tiering exception. For tiering exception requests, the beneficiary or their doctor must show that drugs for treatment of their condition that are on lower tiers are ineffective or dangerous for them. Keep in mind that beneficiaries cannot make a tiering exception request if the drug they need is in a specialty tier.

A beneficiary should ask their plan where to send a tiering exception request. It is usually helpful to include a letter of support from their prescribing physician. This letter should explain why similar drugs on the plan's formulary at lower tiers are ineffective or harmful. The doctor may also fill out the Coverage Determination Request Form to support the request. All plans must accept this form, but some plans may have their own forms that they prefer a person to use, and they also must accept any document that contains all of the required information, even if not on one of these forms. The plan must give a decision within 72 hours of receiving the request.

A beneficiary can request a fast (expedited) appeal if they or their doctor feel that their health could be seriously harmed by waiting the standard timeline for appeal decisions. If the plan grants the request to expedite the process, they will get a decision within 24 hours.

If the plan approves the tiering exception request, their drug will be covered at costsharing that applies in the lower tier. Normally, an approved exception will be good until the end of the current calendar year.

If the plan denies their request, it should send them a Notice of Denial of Medicare Prescription Drug Coverage letter. They can appeal this decision following the steps of the Part D appeal process.

11. What is the Part D late enrollment penalty (LEP)?

If a beneficiary was without Part D or creditable drug coverage for more than 63 days while eligible for Medicare, they may have an LEP when they enroll in Part D. Creditable coverage may include coverage from an employer or union plan, a retiree plan or Veteran's Affairs (VA) benefits. The penalty is 1% of the national base beneficiary premium (\$32.74 in 2020) for every month a beneficiary did not have Part D or creditable drug coverage while eligible for Part D. This amount is added to their monthly Part D premium.

For example, Ms. M turned 65, became eligible for Medicare and did not enroll in Part D. She went 13 months without coverage. She also did not have another form of creditable

drug coverage. When Ms. M enrolls in Part D, in 2020, she will have a \$4.25 penalty that she will pay on top of her monthly premium ($$32.74 \times 1\% = $0.3274 \times 13 = 4.25).

12. How can a beneficiary appeal the Part D LEP?

Beneficiaries have the right to file an appeal regarding their LEP determination. MAXIMUS is the company contracted by Medicare to handle these appeals. They can appeal the penalty (if they think they were continuously covered by a creditable plan) or its amount (if they think it was calculated incorrectly). Beneficiaries should complete the appeal form they received from their plan and attach any evidence they have, including evidence of past coverage like copies of insurance cards or premium bills. They then should mail everything to:

MAXIMUS Federal Services 3750 Monroe Avenue, Suite 704 Pittsford, NY 14534-1302 Customer Service Number: 585-348-3400

Unfortunately, being unaware of the requirement to have prescription drug coverage is unlikely to be a successful basis for an appeal. However, the following may result in the elimination or reduction of a beneficiary's penalty:

- Showing that they have Extra Help
 - Extra Help is a federal program that helps pay for some to most of the outof-pocket costs of Medicare prescription drug coverage. If an individual's income and assets are below a certain amount, they may qualify for Extra Help. Extra Help pays for some of a beneficiary's Medicare drug costs and eliminates their Part D LEP, if they have one.
- They had creditable drug coverage during some or all of the time period in question
 - They should call their former plan, their employer, or union, and ask for a letter proving that they were enrolled in creditable drug coverage. Then, they should attach this letter to their appeal form.
- They had non-creditable drug coverage, but their employer or insurer told them it was creditable or didn't inform them that it was non-creditable
- They were ineligible for Medicare's prescription drug plan (e.g., if they were living outside the U.S. or incarcerated) during the period
- They couldn't enroll into creditable drug coverage because of a serious medical emergency

The appeal deadline is 60 days from the date the beneficiary received the letter informing them about the penalty. Once the appeal is submitted, they can expect a determination from MAXIMUS within 90 days. In the meantime, they should pay the LEP to the plan along with the premium. If the appeal is successful, their plan has to pay them back for the LEP payments they made while the appeal was pending.

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