

IF YOUR MEDICARE DRUG PLAN MAKES A DECISION YOU DISAGREE WITH, WHAT CAN YOU DO?

By the Minnesota Disability Law Center

January 2006

If you are now enrolled in Medicare Part D, and you find yourself not being able to get medications you need, you can challenge a decision your drug plan makes. The purpose of this fact sheet is to explain when you have a right to challenge a denial by your drug plan, and how to do so. NOTE: YOUR PHARMACY *DOES NOT* MAKE DECISIONS ABOUT YOUR MEDICATIONS. YOU MUST DEAL WITH YOUR DRUG PLAN WHEN A DRUG IS DENIED.

A. What decisions by my drug plan can I challenge?

You may not be able to get a drug you need for several reasons. Here are the kinds of plan decisions that you can contest through the “exceptions and appeals” process:

1. The plan says the drug is not medically necessary.
2. The plan says the drug has to have prior authorization.
3. The plan says other medications must be shown to not work well before they will approve the one you are asking for (“step therapy”).
4. The plan does not agree with the dosage, manner of medication (for example, liquid or pill), type (generic versus brand name) or number of refills your doctor is requesting.
5. The plan only offers the drug to persons on a different premium tier than you.
6. Your cost-sharing amount is higher than that of a different tier of the plan.
7. The plan says it does not offer that drug on its formulary, or used to offer it but no longer does.
8. The pharmacy that filled the prescription is not in the plan’s network.

B. What information does my doctor need to give to my plan?

Your doctor has several important roles to play in helping you get needed medications. If your doctor requests an “expedited” 24-hour process to speed up the time the plan has to make a decision, the plan *must* agree to expedite. Your doctor will have to give the plan a verbal or written statement explaining why 72 hours is too long and how it could “jeopardize life or health or the ability to regain maximum function”. The clock doesn’t start ticking until the plan receives a statement from your doctor explaining why you need this drug.

Doctors are the key to getting a particular drug. If the issue is medical necessity, your doctor needs to give the plan an oral or written explanation of why the drug is medically necessary, and why other drugs won’t work. For example, you may be asking for an “exception” to the formulary available to you, such as a drug not on the formulary, or one that is on a plan formulary for those paying a higher premium. Your doctor will have to show that the plan’s drugs are not as effective and/or may cause adverse effects. If you

want to get a drug without having to show first that other, cheaper drugs are not as effective (“step therapy”), your doctor will have to explain why it is important for you to skip step therapy. If your plan has a limit on dosage or number of refills, you will need your doctor’s help in getting the limits set aside. Your doctor’s help is crucial to reversing a denial of a medication by your drug plan.

C. What is the “exceptions and appeals” process?

To get a particular medication, you may need to ask your drug plan to make an “exception” to its formulary or rules for getting drugs. You may be asking for an “exception” to get a drug that is not on your plan’s formulary. You may ask for an “exception” when the drug is offered on a different tier of the plan than the one you are on. You may also want to appeal other plan decisions, for example, a decision that a drug that is on your formulary is not medically necessary or that you have to “step” up to that drug by trying other, cheaper drugs first.

The steps in the exceptions and appeals process are: the initial decision or determination, the redetermination, the independent review process, the Administrative Law Judge appeal, the Medicare Appeals Council, and federal district court. This fact sheet will mostly focus on the steps up to the Administrative Law Judge (“ALJ”) hearing. By the ALJ step, most disagreements should be resolved. Also, if you ask for an ALJ hearing, you may want the help of a lawyer.

In the first two steps, your drug plan is the decision maker. The federal law does not set out many rules for the plans to follow, so these first two steps are mostly based on the plan’s own procedures, criteria and document requirements. For example, the federal law did not define “medical necessity” so each drug plan sets up its own requirements for how you show that a drug is medically necessary. You will need a statement from your doctor in these steps. That statement can be oral, but a written statement is best.

- 1. Step one—determination:** If you are not able to get a drug you need, **the first step is to ask for a *written coverage determination from your plan***. You have 60 days to ask for a determination, but since the drug is important to your health, you don’t want to wait that long. When you ask for a coverage determination, the plan has 72 hours to respond. The 72 hours starts when the plan receives a statement from your doctor. If you can’t wait that long for health reasons, you or your doctor can ask for an expedited determination, but your doctor will need to explain how waiting longer might endanger your health. The drug plan must then make a decision within 24 hours. Because of the short timeline, the plan can let you and your doctor know orally of its decision and then follow up in writing. Without a statement from your doctor, the plan can decide to use the 72-hour time frame instead.

If you get a favorable written coverage decision, that decision is good for the plan year. Your plan can choose to extend it into the next plan year. If you get an unfavorable decision, **the information you get from your plan should also explain how**

to challenge the unfavorable decision. To challenge an unfavorable decision, you need to ask for a redetermination.

- 2. Step two—Redetermination:** A redetermination is the drug plan’s review of its own coverage determination. You have up to 60 days to request a redetermination, but in most cases, you shouldn’t wait that long.

When you request redetermination, a decision must be made *within 7 days*, or if your doctor says the decision need to be *expedited, within 72 hours*. Your doctor is the one who decides whether the process needs to be expedited. An expedited redetermination decision can be made orally to your doctor and confirmed in writing to you within 3 days.

If you get a favorable decision at this stage, the decision is good for the plan year. If you get another unfavorable decision, you can then ask for an independent review.

- 3. Step Three—Independent Review Entity:** Step three takes you out of the plan’s process and into a decision made by an outside reviewer, which has been hired by the federal government. This is the Independent Review Entity, which makes its own decision on whether you should be able to get the drug you are asking for. The current Independent Review Entity, or IRE, is an organization called Maximus. Your drug plan is required to tell you how to appeal to Maximus for a review and a new decision.

You must make a written request within 60 days. The IRE usually has 7 days to review your case and make a written decision. However, if your case is an expedited one, the IRE has only 72 hours to make a decision. The IRE process is not a hearing. It is a review of the plan’s decisions and the information you provided to the plan. The IRE is required to contact your doctor. The IRE must make sure that all information important to the question of why you need the medication is in the record and is considered by the IRE when it makes its decision. If the IRE decision is in your favor, it is good for the plan year. If the decision is unfavorable, the IRE will give you information about how to appeal your case to the next level, the Administrative Law Judge hearing.

- 4. Step four-- the Administrative Law Judge (ALJ) hearing.** The ALJ step is a hearing conducted by an Administrative Law Judge, who works for Medicare. You must make a request for an ALJ hearing within 60 days of receiving a decision from the IRE. **To get an ALJ hearing, your case or “claim” must be worth at least \$110 in the year 2006. In figuring the worth of your claim, you look at the total cost of the drug, including refills, not just your share of the cost.** For example, if the drug you are trying to get costs your drug plan \$25 per refill and your doctor is prescribing 6 refills ($\$25 \times 6 = 150$), then you meet the requirement of having \$110 at issue, even if your co-pay is only \$1 per refill.

The ALJ has 90 days to grant your request for a hearing and 90 days to make a decision. You will be entitled to present evidence and witnesses and to make arguments in your

favor to the ALJ. Because there are very few locations for in-person hearings, most ALJ hearings will be done by video teleconferences. The ALJ will make a decision on whether or not you should be able to get the drug you are asking for. If you lose, the written decision will explain your next step for appealing to the Medicare Appeals Council.

- 5. Step five —Medicare Appeals Council . Step five** is an appeal is to the Medicare Appeals Council (MAC). This step is a review of the ALJ hearing and decision. It does not include another hearing. You have 60 days to request a review by the MAC. The MAC has 90 days to make a decision. If the decision is unfavorable, **Step six** is an appeal to federal court. The written decision from the MAC will explain how you can appeal to federal court.

- 6. Step six—federal court review.** This is the last step in the appeal process. You have 60 days from the date of the MAC decision to file in federal court. **However, to go to federal court, you must have an amount in controversy that totals \$1050 in 2006.** This includes the projected annual cost for the year. You are also allowed to combine appeals to meet this amount, so if you had one drug at issue that cost the drug plan \$600 for all the refills for the year, and another drug at issue that cost \$500, you would meet the amount in controversy requirement. But, if you are appealing a drug worth \$150 including refills, like the example at the ALJ stage, you would not meet the amount in controversy requirement for going to federal court. Court requirements and rules can be hard to follow, so it is a good idea to get a lawyer at this stage if you don't have one already.

D. What if I have been unsuccessful in the appeal steps I have taken? If you have been unsuccessful in the appeals steps you have taken, you should talk to your doctor about other medications you might try that are on your plan's formulary. There may be drug manufacturer programs that provide the drug for free or reduced cost. You can also contact the Minnesota Linkage Line at 1-800-333-2433; TTY 1-800-627-3529. The Linkage Line may be able to tell you if there are other programs that can help you pay for your drugs.