

## GRIEVANCES, COVERAGE DETERMINATIONS, AND APPEALS

This section covers:

- Grievances
- Coverage Determinations (Including Exceptions)
- Appeals

Because each Medicare drug plan has a different formulary, as well as different rules regarding access to drugs, some enrollees may have problems getting all of their prescriptions filled through their Part D plans. The MMA establishes specific rules and processes for beneficiaries who are having difficulty obtaining their prescriptions. Understanding the reasons for the plan's denial of coverage and learning what to do about it are important steps in obtaining a drug from the Part D plan.

### GRIEVANCES

All Medicare drug plans must have processes in place to hear and resolve grievances filed by Part D plan enrollees. Here are several examples of situations that Part D plans should process as grievances:

- Complaints about copayment amounts
- Complaints about an enrollee's enrollment or disenrollment
- Complaints about a change in premiums or cost-sharing amounts from one contract year to the next
- Complaints about wait times on the plan's toll-free number for members
- Complaints about the quality of care or benefits provided
- Complaints about the plan's written communications
- Complaints about timeliness of services provided

CMS requires that Part D grievance procedures include the following elements:

- Plans must accept information and evidence about grievances orally and in writing up to at least 60 days after the event.
- Plans must accept any information or evidence concerning the grievance.
- Plans must respond within 24 hours to expedited grievances related to a plan's refusal to grant a request for an expedited coverage determination or an expedited redetermination if the enrollee has not yet received the drug at issue
- Plans must transmit in a timely manner all grievances to the appropriate decision-makers

- Plans must take prompt, appropriate action, including a full investigation of complaints
- Plans must notify results of their investigations to all concerned parties, as expeditiously as the enrollee's case requires, but no later than 30 days after the plan receives the oral or written grievance
- Plans must inform enrollees of the results of the grievance as follows:
  - Plans must respond in writing to those grievances submitted in writing
  - Plans may respond either orally or in writing to grievances submitted orally, unless the enrollee requests a written response.
  - Plans must be responded to in writing to all grievances related to quality of care, regardless of how the grievance is filed. The response also must include information about the enrollee's right to file a written complaint with the QIO.
- Plans must have procedures for tracking and maintaining records about the receipt and disposition of grievances. They also must disclose grievance data to Medicare enrollees upon request.

All enrollees in Part D plan are entitled to receive written materials about the plan's grievance procedures. Plans must make written information available about enrollees' right to file expedited grievances when plans deny the enrollees' requests for expedited appeal or organization determination or when the Part D plan takes an extension on a coverage determination or appeal.

**EXAMPLE** *Susan recently called her SHIP office to talk about a problem she had with her Part D plan's customer service call center. She reports that she was on hold for 30 minutes and that a service representative was rude and unable to answer her questions. Susan is upset and wants to know what she can do.*

*Susan has the right to file a grievance (i.e., a complaint) with her Part D plan within 60 days of the incident. She can refer to her plan's Evidence of Coverage booklet for instructions on how to file a grievance. After submitting her grievance, Rachel should receive a response from the Part D plan within 30 days.*

## COVERAGE DETERMINATIONS

A coverage determination is a decision by a Medicare drug plan about whether or not to cover a prescribed medication under the Part D program. In most cases, drug plans determine that prescribed medications are medically necessary and approve coverage. But a plan may decide not to cover a drug for several reasons:

- The drug is not on the plan's formulary.
- The plan determines the drug to be not medically necessary.
- The plan restricts coverage to a specific dosage of the drug.

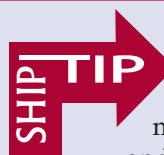
- The drug is subject to prior authorization, step therapy, or another utilization management restriction.
- The drug is covered under Medicare Part A or Part B.
- An out-of-network pharmacy furnishes the drug.
- The plan sponsor determines that the drug is excluded from Part D coverage.

These types of coverage determinations are generally made by the plan behind the scenes, and do not require an enrollee to take action to receive a coverage determination. There is, however, a type of coverage determination – called an exception – that only occurs after an enrollee takes action. When a beneficiary files a request for a formulary exception with the plan, the plan’s decision about whether to grant the exception is also a coverage determination.

If a plan denies coverage for a prescription drug at the pharmacy counter, the beneficiary, an appointed representative, or the beneficiary’s physician may request a coverage determination. An appointed representative is a person asked by a beneficiary to assist in the coverage determination process. To become an appointed representative, this person can complete a standard CMS form (<http://new.cms.hhs.gov/cmsforms/downloads/cms1696.pdf>). The form is valid for one year after it is signed, and must be submitted with each request for a coverage determination. Because the MMA gives physicians the authority to request a coverage determination on behalf of a beneficiary, it is not necessary for the physician to be an appointed representative.

**EXAMPLE** *Aretha went to the pharmacy with a prescription for the antibiotic Keflex. When the pharmacist entered the drug into his computer system, the plan indicated that this brand-name drug is not on the plan’s formulary. But the drug’s generic form, cephalexin, is on the formulary. The pharmacist called Aretha’s prescribing physician about dispensing the generic instead of the brand-name drug. If the doctor does not approve the generic substitution, Aretha can talk to her SHIP about getting help to request a formulary exception from the plan. The plan’s decision on the exception request is a coverage determination.*

Medicare drug plans make coverage determinations on standard and expedited time frames. When someone requests a standard coverage determination, the Part D plan must make its decision and respond to the beneficiary and the prescribing physician (if the physician requested the coverage determination) within 72 hours after receiving the request. If the plan denies coverage for the prescribed medication, the plan must give the beneficiary a written notice describing the reason for the denial along with instructions to appeal the adverse coverage determination.



If an enrollee is requesting payment for drugs already received, the plan must authorize the payment and send written notice of the decision within three calendar days of issuing an oral notice.

A drug plan will make an expedited coverage determination if the physician believes that a delay will place the enrollee's life, health, or ability to regain maximum function in serious jeopardy. Expedited requests are completed according to the plan's rules, usually by phone or fax. The plan must respond to the beneficiary and physician within 24 hours.

**SHIP TIP** Plans are not required to fill prescriptions for most enrollees while an exception is pending. Long-term care residents, however, must receive their drugs while awaiting a plan's decision.

**EXAMPLE** *Wilson is enrolled in a PDP. Until recently, the plan covered all of his prescribed drugs. Last month, Wilson's doctor prescribed a new brand-name drug for his arthritis. Wilson went to a preferred pharmacy to fill the prescription, but the pharmacist told him that the plan denied coverage for the drug because it has a prior authorization. Wilson should work with his pharmacist and doctor to fulfill the prior authorization requirement of the plan to receive coverage. Wilson's doctor faxed in his relevant medical records, and his PDP began to provide coverage within three days.*

## Exceptions

A significant portion of coverage determinations are requests for exceptions. Part D plan enrollees have the right to request two different types of exceptions from their drug plans, one for coverage of a non-formulary drug (formulary exception) and the other for a reduction in the cost-sharing amount for a formulary drug (tiering exception). If the plan decides to cover the drug or reduce the cost-sharing amount, the exception lasts for the remainder of the plan year. If an enrollee remains in the same plan for the next year, the plan can decide anew about an exception for the drug. The plan may require the enrollee to submit a new exception request for the coming plan year. Note that Medicare rules do not require the drug plans to process an enrollee's exception request until the prescribing physician provides the plan with an oral or written supporting statement.

**SHIP TIP** Beneficiaries may not request both types of exceptions for the same drug.

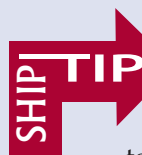
## Formulary Exceptions

Exceptions that fall under this category include requests for:

- A drug that is not on the plan's formulary
- A drug that is on the plan's formulary, but not in the dosage or form prescribed by the physician
- A drug with a utilization management restriction (i.e., step therapy, prior approval, quantity limit)

## Cost-Sharing (Tiering) Exceptions

Beneficiaries may request exceptions to lower their cost-sharing amounts for non-preferred, brand-name drugs. Plans with cost-sharing tiers assign some medications to a more costly non-preferred drug tier and others to a more affordable, preferred status tier. Beneficiaries who cannot take the preferred drug in a class or category may request an exception to lower the cost-sharing amount of their non-preferred drug to that of the preferred group.



If a plan has a separate tier for generic drugs, an enrollee cannot request an exception to reduce the copayment of a brand-name drug to that of a generic drug.

**EXAMPLE** *Otis was discharged from the hospital on a Friday afternoon. While in the hospital, he received prescriptions for three new drugs. His daughter went to the pharmacy that evening to fill the prescriptions, and learned that one of the drugs was not on his Part D plan's formulary. The daughter immediately called the attending physician to ask if there was an alternative drug that her father could take. The physician said no, but agreed to call Otis's plan to request an expedited exception for his non-formulary drug. The physician also spoke with the pharmacy to arrange for a two-day supply of the drug. On Saturday afternoon, the physician received notice of the plan's favorable coverage determination, granting a formulary exception. As a result, Otis was able to fill his prescription with coverage through his drug plan. The exception lasts for the remainder of the plan year, provided that Otis stays with the same plan.*

## APPEALS PROCESS

When a coverage determination is unfavorable, or “adverse,” the enrollee may appeal the drug plan's decision. There are five steps in the appeals process. In each step, beneficiaries must make their request for further action within 60 days of receiving notice of the prior, unfavorable response.

### Step 1. Redetermination

A redetermination is a request for the Part D drug plan to revisit an unfavorable coverage determination. A request for a standard redetermination must be decided by the plan within seven days. If the beneficiary's request must be expedited, the plan must make a decision within 72 hours of receiving the request.

### Step 2. Reconsideration

When the drug plan gives an adverse decision on a redetermination request, reconsideration is the next step in the appeals process. This step is a request to the Part D Qualified Independent Contractor (QIC), a Medicare contractor also known as an Independent Review Entity (IRE), to review the Part D plan's adverse redetermination decision. The Part D QIC must decide on standard reconsideration requests within seven days and within 72 hours of receiving an expedited reconsideration request.

The Part D QIC is Maximus Federal Services. For details on reconsideration procedures, see the Part D Reconsideration Manual at the Part D QIC's appeals website at <http://www.MedicarePartDAppeals.com>. The QIC's office in King of Prussia, Pennsylvania handles reconsiderations coming from the stand-alone PDPs, while its office in Victor, New York reconsiders denial decisions by MA-PDs.

In 2007, the last year for which a report is available, the Part D QIC received 11,033 reconsideration requests. Thirty-eight percent of these appeals involved a utilization management tool dispute including, for example, step therapy restrictions. In some types of appeals, the Part D QIC reversed the drug plan's adverse decision—and ordered coverage for the drugs—at fairly high rates. It reversed drug utilization management tool denials in 59 percent of the cases and out-of-network coverage denials at a 47 percent rate. With respect to exceptions requests, the Part D QIC overturned 48 percent of the off-formulary exception request denials, and 26 percent of denials for tiering exception requests.

### **Step 3. Administrative Law Judge (ALJ) Hearing**

When the request for reconsideration is unfavorable, the next step in the process is a hearing with an Administrative Law Judge (ALJ), who will review the case thus far. However, the amount in controversy must be at least \$130 (2010) to request an ALJ Hearing. The amount in controversy is defined as the projected amount of money that a beneficiary would spend during the plan year directly related to the Part D drug in question. ALJ Hearings generally must be decided within 90 days. It may take longer than 90 days for in-person hearings.

### **Step 4. Medicare Appeals Council (MAC)**

When the request for an ALJ Hearing is unfavorable, the next step is the Medicare Appeals Council (MAC). The MAC reviews the ALJ decision. The MAC must make a decision within 90 days in most cases.

### **Step 5. Federal District Court**

The Federal District Court is the final step in the appeals process. To request a review by the Federal District Court, the amount in controversy must be at least \$1,260 (2010). The amount in controversy is defined as the projected amount of money that a beneficiary would spend during the plan year directly related to the Part D drug in question.

As this section illustrates, there are specific rules and processes set forth by the MMA for beneficiaries who are having difficulty obtaining their prescriptions. Some beneficiaries may be able to resolve their access issue relatively easily, while others may need to take a series of steps to hopefully resolve their issue.

See Appendix P for *Part D: Appeals Process* flowchart.