

VIII. Coverage Determinations and Appeals

This section covers:

- *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.

A. Coverage Determinations

A coverage determination is a decision by the plan about whether or not to cover a drug. The 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,
- an out-of-network pharmacy furnishes the drug, or
- 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 an exception with the plan, the plan's decision about whether or not to grant the exception is also a coverage determination. *See below for more information on exceptions.*

If coverage for a prescription drug is denied, 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 available at: <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.

For Example: Aretha went to the pharmacy with a prescription for the antibiotic Keflex. When the pharmacist entered the drug into his system, the plan indicated that this brand-name drug is not on the plan's formulary. But the generic form of the drug, cephalexin, is on the formulary. The pharmacist urged Aretha to speak with her prescribing physician about taking the drug in generic form. If the doctor does not approve the generic substitution, Aretha should ask the doctor to request the plan to make an exception to its formulary, on her behalf. The plan's decision on the exception request is a coverage determination.

When requesting a standard coverage determination, the Medicare drug 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 and the steps to appeal the adverse coverage determination.

A coverage determination may be expedited if the physician believes that 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 the physician within 24 hours.

Counseling Tip: If an enrollee is requesting payment for drugs already received, the plan must authorize the payment and send written notice of the decision within 3 calendar days of issuing an oral notice.

For Example: Wilson is enrolled in a PDP called *Plan Dynamite*. The plan has no annual deductible, and at the time of his enrollment, it covered all of his prescribed drugs. Several months after his plan became effective, 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 is not medically necessary for him. This is an example of a "denial," a coverage determination that the plan made on its own initiative. Unlike the determination resulting from an exceptions request, it is not prompted by any action that the beneficiary or prescribing physician takes.

Exceptions

A significant proportion of coverage determinations include requests for exceptions. Part D plan enrollees have the right to request two different types of exceptions from the drug plan, one for coverage of a non-formulary drug (formulary exception) and the other for a reduction in the cost-sharing

Counseling Tip: Plans are not required to fill enrollees' prescriptions while an exception is pending. Long-term care residents, however, must receive their drugs while awaiting a decision from the plan.

amount for a formulary drug (tiering exception). If the plan decides to cover the drug or reduce the cost-sharing amount, the formulary 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 not to renew the exception for the drug. The plan may require the enrollee to submit a new exception 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.

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, and
- a drug with a utilization management restriction (i.e. step therapy, prior approval, quantity limit).

Counseling Tip:
Beneficiaries may not request both types of exceptions for the same drug.

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.

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

For Example: Otis was discharged from the hospital on Friday at 4:30 pm. 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 plan.

B. Appeals Process

When a coverage determination is unfavorable, the enrollee may appeal the 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.

1. Redetermination: A redetermination is a request for the plan to revisit their coverage determination. A request for a standard redetermination must be decided by the plan within seven days, unless the request needs to be expedited, in which case the plan must make a decision within 72 hours of receiving the request.

2. Reconsideration: When the request for a redetermination is unfavorable, **reconsideration** is the next step in the appeals process. This step is a request to the Independent Review Entity (IRE) to revisit the plan's decision. A standard reconsideration must be decided by the IRE within seven days, unless the request needs to be expedited, in which case a decision must be made within 72 hours of receiving the request.

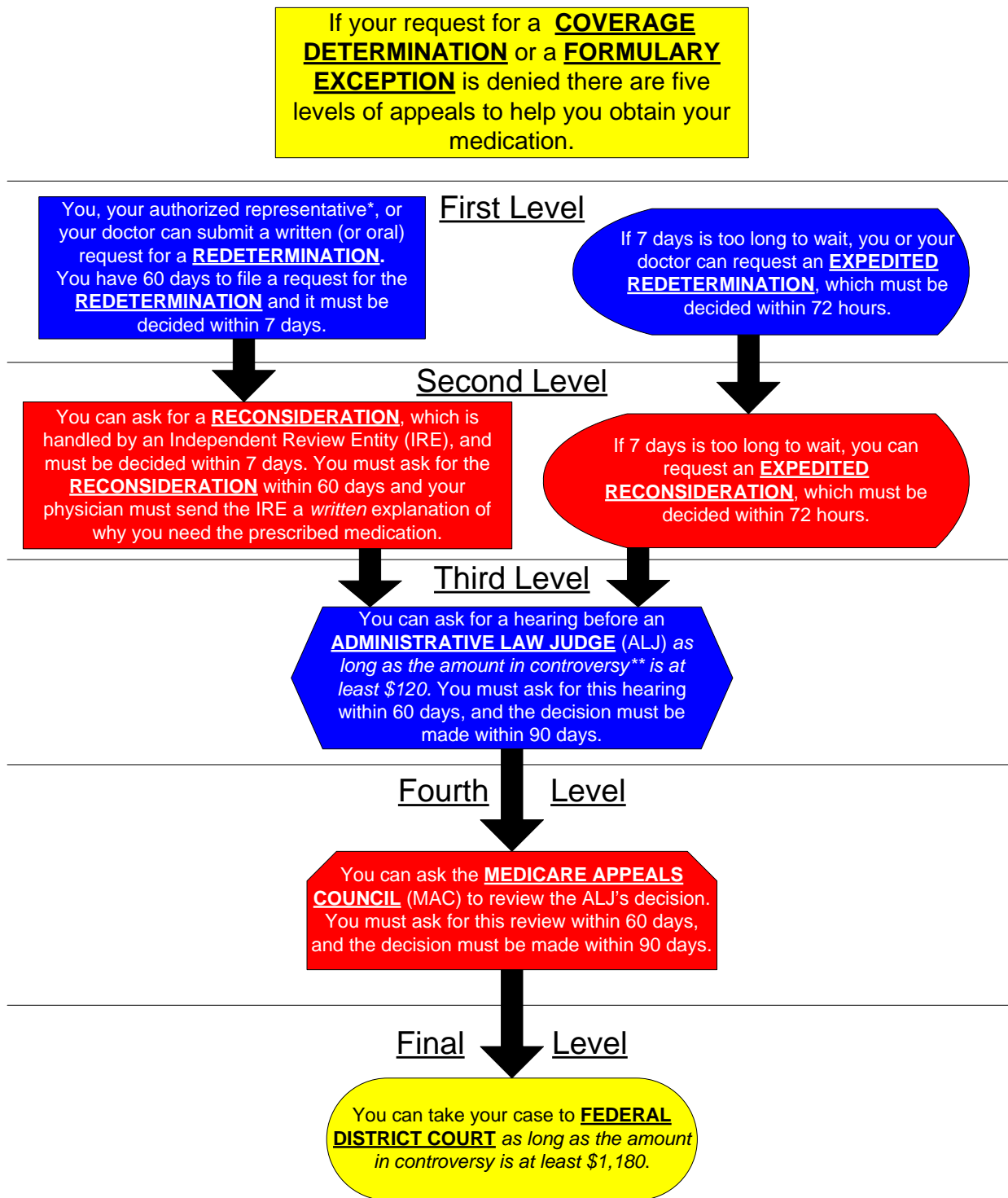
3. Administrative Law Judge (ALJ) Hearing: When the request for reconsideration is unfavorable, the next step in the process is a hearing with an Administrative Law Judge (ALJ), who will review the case thus far. However, the amount in controversy must be at least \$120.00 to request an ALJ Hearing (2008). 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 must be decided within 90 days.

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 be decided within 90 days.

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 \$1,180.00 (2008). 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. *Please refer to the flowchart below, "The Medicare Part D Appeals Process" for a visual depiction of the appeals process.*

The Medicare Part D Appeals Process



* In this flowchart, *you* refers to you the Medicare beneficiary or your authorized representative.

** 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.