



Medicare Part D Frequently Asked Questions: Exceptions & Appeals¹

This list of “Frequently Asked Questions” regarding the exceptions and appeals processes in the new Medicare Part D prescription drug benefit is designed to both inform advocates and be used as a tool to educate consumers. It is one document in a series that address four different categories: Eligibility & Enrollment, Benefit Design, Exceptions & Appeals, and Administrative Issues. This document will continue to evolve as new questions arise. If you have a question that is not addressed here, please contact NMHA’s Advocacy Resource Center at shcrinfo@nmha.org.

What exceptions processes are required?

PDPs and MA-PDs must have an exceptions process for enrollees to request that a formulary drug be provided at a lower tier for cost-sharing (thereby reducing the co-pay), and that a non-formulary drug be covered by the plan. Because exception requests are coverage determinations and are governed by the rules for coverage determinations, the plan must act within the timeframe for standard coverage determinations (72 hours) or expedited coverage determinations (24 hours).

The plan may grant an exception request to change the cost-sharing tier if it determines that the non-preferred drug is medically necessary and that the preferred drug would not be as effective, or would have adverse consequences. In addition, the exceptions process must address situations where a formulary’s tiered co-pay structure changes during the year and an enrollee is using a drug affected by the change. However, a plan does not have to cover non-preferred drugs at the lower, generic drug co-pay level if the plan maintains a separate tier dedicated to generic drugs. Further, if the plan maintains a formulary co-pay tier in which it places very high cost and unique items (such as genomic and biotech products), it may exclude these very high costs or unique drugs from its exceptions process.

Enrollees may not use a plan’s cost-sharing exceptions process to lower the co-payment for non-formulary drugs for which they have received coverage through the non-formulary drug exceptions process.

The plan must also grant an exception for a drug that is not on the formulary if it determines that the drug is medically necessary, consistent with the physician’s statement, and that the drug would be covered but for the fact that it is an off-formulary drug. For this purpose, “formulary” includes the application of cost-saving tools, such as dose restrictions, step therapy and therapeutic substitution requirements – all of which would result in non-coverage for an otherwise coverable Part D drug.

Although the regulations include some criteria for plans to consider when evaluating an exception request, including a description of the plan’s criteria, consideration of whether the requested drug is therapeutically equivalent to a drug on the plan’s formulary, and consideration of the number of drugs on the formulary within the same class and category as the requested drug; each PDP has the flexibility to

¹ Much of the information within the Exceptions & Appeals FAQ was obtained from materials produced by the Center for Medicare Advocacy. *Medicare Part D Appeals: A Mixed Bag for Enrollees*, Centers for Medicare Advocacy, February 10, 2005, available at http://www.medicareadvocacy.org/Reform_PartDAppeals.htm.

establish its own criteria and develop its own exceptions process. Additionally, the regulations leave it up to a plan's discretion whether it will continue coverage after an exception has been granted into subsequent plan years.

What should a enrollee do if a pharmacist or provider says the drug isn't on the formulary?

Enrollees should contact their plan first when they find out that their drug isn't on the formulary or is in the "non-preferred" cost-sharing tier level to request an exception.

If the plan denies an exception, then the enrollee can appeal the plan's decision. In general, the appeals system follows the Medicare Advantage process, which includes access to independent reviews of plan decisions. Enrollees, prescribing physicians, or enrollees' appointed representatives can begin the appeals process. For more information on the appeals process, see the appeals question below.

Who can request an exception?

You (the enrollee) or your prescribing physician may file a request for an exception. An exceptions request must be filed with an oral or written supporting statement from the prescribing physician that the preferred drug on the formulary is not as effective for you as the requested drug, or that the preferred drug has adverse effects, or both.

Can a drug plan accept a prior authorization request over the phone, or can a plan require a written copy (fax)?

The regulations do not specify requirements for a PDP's drug utilization management activities, such as prior authorization, so long as they are reasonable and appropriate. If a PDP chooses to accept oral requests, the final rule does provide that the PDP may require submission of subsequent written supporting statements.

What are the levels and processes for coverage determinations and appeals?

1. The appeals process begins when the PDP or MA-PD issues a **coverage determination** (see the next question for what constitutes a coverage determination).
2. The plan enrollee may request a **redetermination** of an unfavorable coverage determination; the redetermination will be performed by the PDP.
3. Individuals who remain dissatisfied after the redetermination can request a further review known as a **reconsideration**; the reconsideration will be performed by an "**independent review entity**" (IRE).
4. The enrollee may appeal to an administrative law judge (ALJ) following an IRE review, then to the Medicare Appeals Council, and finally to federal court.

An **expedited review** is available if the standards set out in Medicare Part C (Medicare Advantage program) are met.

Plans must notify enrollees of initial coverage determinations as quickly as the enrollee's health condition requires, but must notify the enrollee no later than 72 hours after receipt of the request. Plans then have seven days in which to notify enrollees of a redetermination decision. Plans must act on requests for expedited coverage determinations no later than 24 hours after receiving the request, and must act on expedited redeterminations within 72 hours.

An enrollee must file a request for a reconsideration with the PDP or MA-PD. The plan then forwards the enrollee's request to the IRE within 24 hours if it does not act in a timely manner on the redetermination request. The Part D regulations require the IRE to issue its reconsideration decision within the same timeframes noted above for issuing a redetermination.

What triggers a right to appeal?

Coverage determinations that trigger appeal rights include a PDP's decision not to pay for or provide a medication because the drug: (1) is not on the plan's formulary, (2) is not considered medically necessary, (3) is furnished by an out-of-network pharmacy; or (4) is not a drug for which Medicare will pay under Part D. An individual may also appeal when a coverage determination is not provided in a timely manner, when that delay would adversely affect the health of the enrollee; a request for an exception is rejected, and; if the individual is dissatisfied with a decision regarding the co-payment required for a drug.

What qualifies as a coverage determination?

A coverage determination does not occur when a beneficiary goes to the pharmacy to fill a prescription and the pharmacist tells them that the drug is not covered. If this occurs, a beneficiary must call their plan and get confirmation that the plan will not cover the drug. This is important because a beneficiary cannot make an exception request or go through the appeals process without first getting a coverage determination directly from their Part D prescription drug plan.

Does a coverage determination have to be in writing?

If a PDP decides to deny a drug it must give the enrollee written notice of the coverage determination. The notice must state the specific reason for the denial and also inform the enrollee of their right to a redetermination and describe the redetermination process. For expedited coverage determinations, the PDP may first orally notify the enrollee of an adverse decision, but must mail written confirmation of the decision within three days.

Who defines medical necessity?

The Medicare law and regulations fail to define "medical necessity" so it is up to the plans to define the term. Plans do not have to make their definitions public.

Can my provider or other person assist me with an appeal?

Yes, you may receive assistance from your provider, a family member, or other person to assist with an appeal.

Will a dual eligible have the same due process rights under Medicare Part D as Medicaid?

The Medicare Part D regulations do not contain the current Medicaid protection that allows for continued coverage of a prescription pending an appeal. Some plans may choose to give their enrollees a 60-day supply of a prescription when there is a formulary change, instead of sending notice 60 days in advance. Since the pharmacy will only be required to post notice or give a general notice to call the plan for further information, it appears that enrollees who want the 60-day supply will have to first contact the plan and then return to the pharmacy to get their medicine.