

Exceptions and Appeals



Key Points

- The exceptions process may permit access to drugs not on a Medicare prescription drug plan's formulary or reduce the cost-sharing for a drug under certain circumstances.
- Plans must grant exceptions regarding drugs not on the formulary when the plan determines that it is medically appropriate to do so.
- Plans must make their determination on an exception request as expeditiously as an enrollee's health condition requires, but no later than 24 hours for an expedited decision involving enrollees who suffer from serious health conditions, and 72 hours for a standard decision.
- If a plan denies an exception request, the enrollee, or his or her authorized representative (or, in expedited cases, the prescribing physician), may appeal the plan's decision.

General Rules

The drug benefit contains an exceptions and appeals process, which is intended to ensure that beneficiaries have access to prescription drugs they need. It provides a straightforward process for an enrollee to obtain a covered drug that is not on the plan's formulary or to obtain a more favorable cost-sharing level. Plans must provide information about their exceptions and appeals process to beneficiaries who sign up for the plan.

Who can request an exception or an appeal?

- The plan enrollee
- An authorized representative for the enrollee
- The prescriber on behalf of the enrollee

Exceptions

The exceptions process may permit access to drugs not on the plan's formulary or reduce the cost-sharing for the required drug. Prescribers, enrollees, or the enrollee's authorized representative may request an exception of the plan either orally (such as by phone) or in writing.

Non-Formulary Drugs If the enrollee is requesting coverage of a non-formulary drug, the drug may be covered if the prescribing physician determines that all of the drugs on the formulary would not be as effective as the non-formulary drug, or would have adverse effects for the enrollee, or both. If the plan grants the exception, the drug is covered for as long as the beneficiary is enrolled in the plan.

Copayment Reduction If the exception request involves a plan's levels of copayment (also known as tiering), the prescribing physician must determine that the preferred drug for treatment of the condition would not be as effective as the prescribed drug or would have an adverse effect on the enrollee, or both.

Time Frame Plans must make their determinations regarding exception requests as expeditiously as an enrollee's health condition requires, but no later than 24 hours for

expedited decisions involving enrollees who suffer from serious health conditions, and 72 hours for standard decisions. If a plan does not make a coverage determination or redetermination within the appropriate time frames, the decision is automatically forwarded to the independent review entity for consideration.

Immediate Needs While beneficiaries are going through the exceptions process, CMS has encouraged plans to adopt a one-time temporary or emergency supply process to ensure that an enrollee does not have a coverage gap during the exceptions process. This process will vary from plan to plan.

Appeals

If a plan denies an exception request, the beneficiary or his or her authorized representative (or, in expedited cases, the prescribing physician) may appeal the plan's decision. If, at any point in the appeals process, the enrollee receives a favorable decision, the appeals process ends. A beneficiary has the right to appeal adverse decisions up to Federal District Court. There are five levels of appeal and, in the early stages, different time frames established for decisions.

Level	Action	Standard Appeal	Expedited Appeal*
1	Redetermination by Part D Plan	If the Part D plan's initial decision on the exception request is unfavorable, an enrollee may request a redetermination and the plan has up to 7 days to make its decision.	Same as standard, except the plan has up to 72 hours to make its decision.
2	Reconsideration by Independent Review Entity (IRE)	If the Part D Plan's redetermination is unfavorable, an enrollee may request a reconsideration by the IRE (a CMS contractor). The IRE has up to 7 days to make its decision.	Same as standard, except the IRE has up to 72 hours to make its decision.
3	Administrative Law Judge (ALJ)	If the IRE's reconsideration is unfavorable, an enrollee may request a hearing with an ALJ if the cost of the drug meets minimum requirements.	Not applicable.
4	Medicare Appeals Council (MAC)	If the ALJ's decision is unfavorable, an enrollee may appeal to the MAC (in HHS).	Not applicable.
5	Federal District Court	If the MAC's decision is unfavorable, an enrollee may appeal to Federal District Court if the cost of the drug meets minimum requirements.	Not applicable.

*An expedited decision is requested based on the urgency of an enrollee's health condition.

NOTE: The enrollee must decide whether to continue to appeal to the next level.

Information and Monitoring

CMS is requiring that Medicare prescription drug plan network pharmacies and pharmacists provide enrollees with simple and easy-to-understand notices of their rights when they disagree with the information provided by their pharmacists. These notices will advise the enrollees of their right to contact their plans to receive a formal coverage determination that may be appealed if it is unfavorable.

CMS will be monitoring plans and reviewing beneficiaries' complaints to ensure that plans do not engage in discriminatory practices. Enforcement actions will be taken against plans that violate Medicare's requirements.

For additional information contact:

Medicare: 1-800-MEDICARE (1-800-633-4227); TTY 1-877-486-2048

or

www.medicare.gov

Social Security Administration: 1-800-772-1213; TTY 1-800-325-0778

or

www.socialsecurity.gov or www.SSA.gov