

Excluded Drugs

Question: Does an enrollee have the right to appeal the denial of a drug that is excluded from coverage under Part D (i.e., is excluded under section 1927(d)(2) of the Act and is not offered by the plan sponsor as a supplemental benefit)?

Answer: The answer to this question depends on how the issue arose initially.

A transaction with an enrollee or physician that involves coverage of a drug that is statutorily excluded from coverage under Part D may be handled as an inquiry, grievance, or a coverage determination, depending on the nature of the transaction. In general, however, complaints about statutorily excluded drugs should not be processed as coverage determinations.

Under 42 CFR 423.566(b)(1), a coverage determination is a decision by a plan sponsor not to pay or provide for a Part D drug that the enrollee believes may be covered by the plan. Drugs excluded from coverage under section 1927(d)(2) of the Social Security Act are not Part D drugs. Thus, strictly interpreted, a decision by a plan sponsor not to cover a drug excluded under section 1927(d)(2) of the Act is not a coverage determination (note that drugs that could be excluded if section 1862(a) of the Act were applied to Medicare Part D are subject to the coverage determination process). However, in some cases, an enrollee may use the coverage determination process to argue that a drug is not statutorily excluded, is not statutorily excluded for a specific indication, or is covered by the plan as a supplemental benefit. These cases must be treated as requests for coverage determinations to ensure that the issue is properly resolved, particularly in cases where a plan has mistakenly classified a covered Part D drug as an excluded drug. Conversely, if an enrollee is not disputing that a drug is excluded, but has a question or general complaint about an excluded drug not being covered, plans should process the transaction as an inquiry or a grievance.

If a drug is excluded, it is never covered by Medicare, regardless of medical necessity. However, an appeal entity may overturn a plan's decision to not cover a drug because it is excluded if the appeal entity determines that the drug is not excluded under section 1927(d)(2), the drug is being used for an indication that isn't excluded under section 1927(d)(2), or the plan sponsor includes the excluded drug as a supplemental benefit.

The following examples illustrate when a transaction should be processed as an inquiry, grievance, or a coverage determination.

Inquiry

Not all transactions that involve excluded drugs should be classified as grievances or coverage determinations. In general, an initial transaction involving an excluded drug should be treated as an inquiry unless the enrollee or the enrollee's physician complains about the policy to exclude the requested drug from coverage, or argues that the drug should be covered on the basis that it is not excluded, is not excluded for the purpose for which it was prescribed, or is covered by the plan as a supplemental benefit.

When a plan sponsor receives an inquiry about an excluded drug, it must provide the enrollee or physician with the following information orally or in writing:

1. The plan sponsor must explain that certain drugs are excluded from coverage under section 1927(d)(2) the Social Security Act;
2. The plan sponsor must explain that the drug the enrollee or physician requested is one of the statutorily excluded drugs and the plan does not offer the drug as a supplemental benefit;
3. The plan sponsor must emphasize that, because the drug is excluded from coverage, the enrollee generally may not obtain it through the coverage determination, exceptions, or appeals processes.
4. The plan sponsor must explain that the enrollee should work with his or her physician to obtain a drug on the plan sponsor's formulary indicated for treating the enrollee's condition; and
5. The plan sponsor must explain that the enrollee or physician has the right to contact the plan sponsor if he or she continues to believe that the requested drug should be covered on the basis that it is not an excluded drug, is not excluded for the purpose for which it was prescribed, or is covered by the plan as a supplemental benefit. The plan sponsor must provide the phone number, address, and fax number designated for receiving such requests.

CMS will develop a model notice for plans sponsors to use when responding in writing to such inquires. The notice will be added to the April 3, 2006 revision of Chapter 18. Until CMS' model notice is available for use, plan sponsors must develop their own notices that satisfy the five requirements listed above and submit their notices for approval through the appropriate CMS marketing procedures.

Example

1. An enrollee calls his or her plan sponsor to determine if Valium is covered for him or her (it doesn't matter if the enrollee has a prescription for the drug or not).
2. The plan sponsor tells the enrollee that certain drugs are excluded from coverage under Part D, and Valium is one of those drugs.
3. The enrollee does not complain about the policy to exclude the requested drug from coverage, or argue that the drug should be covered on the basis that it is not excluded, is not excluded for the purpose for which it was prescribed, or is covered by the plan as a supplemental benefit.
4. The transaction should be treated as an **inquiry**.

Grievance

If an enrollee is not disputing that a drug is an excluded drug, but he/she is complaining about the policy that excludes the drug, the complaint should be processed as a grievance because it's a complaint about the plan sponsor's benefit design structure. This complaint may occur after an inquiry is made, or it may be the initial transaction with the enrollee or physician. Decisions made under a plan sponsor's grievance process are not subject to appeal.

Example

1. An enrollee attempts to fill a Valium prescription. The pharmacist receives an electronic notice indicating that the drug is not covered and provides the enrollee with the Pharmacy Notice.
2. The enrollee calls the plan sponsor to ask why the prescription was not covered. The plan sponsor explains to the enrollee that certain drugs are excluded from coverage under Part D, and Valium is one of those drugs.
3. The enrollee has a general complaint about the drug being excluded, but does not ask the plan to cover it after the plan explains that it is an excluded drug.
4. This request should be treated as a **grievance**.

Coverage Determination

If an enrollee or physician argues that a drug should be covered on the basis that it is not an excluded drug (i.e., the enrollee or physician believes that the drug is not statutorily excluded, is not excluded for the purpose for which it was prescribed, or is covered by the plan as a supplemental benefit), the plan sponsor must process the complaint as a coverage determination, which is subject to appeal. This complaint may occur after an inquiry is made, or it may be the initial transaction with the enrollee or physician. If such a complaint is not processed as a coverage determination (and a plan sponsor mistakenly classifies a covered Part D drug as an excluded drug), the enrollee would not have appeal rights and the issue could not be properly resolved.

If, after receiving the complaint, the plan sponsor verifies that the drug is excluded from coverage, it must issue an adverse coverage determination explaining that certain drugs are excluded from coverage under Part D and the requested drug is one of excluded drugs. As with any adverse coverage determination, the enrollee can appeal the decision (it would not be handled as a grievance). On appeal, the plan sponsor or any subsequent appeal entity will determine if the drug is excluded from coverage. If it is excluded, the appeal entity will uphold the plan sponsor's coverage determination (i.e., the scope of review on appeal is limited to whether the requested drug is excluded, is excluded for purpose for which it was prescribed, or is covered by the plan as a supplemental benefit).

Example

1. An enrollee attempts to fill a Valium prescription. The pharmacist receives an electronic notice indicating that the drug is not covered and provides the enrollee with the Pharmacy Notice.
2. The enrollee calls the plan sponsor to ask why the prescription is not covered. The plan sponsor explains to the enrollee that certain drugs are excluded from coverage under Part D, and Valium is one of those drugs.
3. The enrollee argues that Valium is not excluded, is not excluded for the purpose for which it was prescribed, or is covered by the plan as a supplemental benefit, and requests the plan sponsor to cover the drug.
4. This request must be treated as a **coverage determination**.
5. If the plan sponsor verifies that the drug is excluded, it must issue an adverse coverage determination explaining that the requested drug is excluded. See the Valium example in Chapter 18, section 40.3.3 of the Prescription Drug Benefit Manual for sample language that should be included in this type of decision.
6. The enrollee has the right to appeal this decision and argue that the drug isn't excluded from coverage or is covered by the plan as a supplemental benefit. If the plan sponsor correctly identified the drug as excluded, the appeal entity will issue an adverse decision explaining that the drug is excluded from coverage under part D and is not offered as a supplemental benefit.