



Medicare Part D Prescription Drug Exceptions Process

The following procedures have been established by Preferred Care to ensure that Part D enrollees have access to medically necessary Part D drugs. A Part D enrollee's request for an exception is considered a Coverage Determination. Formulary Tier exceptions and prescription drugs that require Prior Justification will follow the Coverage Determination and Redetermination Processes.

1. Coverage Determination Process:

A. Standard Determinations

- 1) A pharmacist and/or a medical director will review each Pharmacy Coverage Determination request to ascertain clinical appropriateness, policy/benefit interpretation, and approval criteria associated with the drug being requested. If the documentation provided to Preferred Care by the physician substantiates that the enrollee's medical situation meets the criteria, the drug will be approved.
- 2) All Coverage Determinations will be completed and notice provided within 72 hours of receipt of the request. Typically requests received before 3:00 p.m. which include all of the required supporting documentation will be reviewed and a determination will be made by 5:00 p.m. the next day. Requests received after 3:00 p.m., including all required supporting documentation would be reviewed and a determination made by 5:00 p.m. on the second day.
- 3) The physician and enrollee receive notification of the decision. Notification of the physician occurs by phone within 24 hours of the decision. A work item is created by Pharmacy and is routed to Service Recovery to initiate telephone notification of the enrollee within 24 hours. Written notification is issued to the enrollee and the physician the next business day.

The requesting physician may discuss the review with a medical director by contacting the Professional Relations Service Center.

The notice of adverse determination will state the specific reason for the denial, advise the enrollee of the right to Redetermination, and describe the Expedited and standard Redetermination process and the rest of the appeals process.

B. Expedited Determinations

Preferred Care offers an Expedited process for cases where the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

- 1) The enrollee or prescribing physician may submit an oral or written request for Expedited Determination to Preferred Care.
- 2) Preferred Care will determine if the request meets the criteria for an Expedited Determination.
- 3) If the request meets the criteria for an Expedited Determination, Preferred Care will make its determination as expeditiously as the enrollee's health requires, but no later than 24 hours after receipt of the request.
- 4) If Expedited Determination notification is oral, written confirmation will be mailed within 3 calendar days of oral notification.
- 5) If the determination is not favorable to the enrollee, the notice will inform the enrollee of their right to a Redetermination, including description of both the standard and the Expedited Redetermination process.
- 6) If the request does not meet the criteria for an Expedited Determination, Preferred Care will notify the enrollee and the prescribing physician (where appropriate) of the decision.
- 7) Preferred Care will make the Coverage Determination within 72 hours of receipt of the initial request.
- 8) In its notice of Expedited Determination, Preferred Care will provide the enrollee with written notification of their right to an expedited grievance, their right to resubmit the request for an expedited determination with prescribing physician's support, and instructions regarding Preferred Care's grievance process. If the notice of an adverse determination is provided orally, written confirmation to the enrollee will be provided within 3 calendar days. The notice will also advise that Preferred Care will process the request under the 72 hour timeframe for standard determinations.

2. **Tier Exception Process**

Preferred Care will follow the same exception process noted above, including all timeframes for any tier co-payment exceptions. **Co-pay exceptions will only be granted to third tier items.** Additional requirements for an enrollee to be granted a lower tier co-payment include:

- A documented trial of all alternative agents in lower tiers
- A statement of medical necessity from the prescribing physician
- Chart notes corroborating this statement
- If the request is due to an adverse reaction to a prescribed medication, a completed FDA MedWatch form that Preferred Care will forward to the FDA
- If the request is due to a contraindication to take another agent, medical literature documenting that all other agents would have a significant negative impact on morbidity and mortality and the rationale for this determination
- If, in the determination of Preferred Care, the drug is medically necessary and there are no appropriate alternatives available, a tier co-pay exception will be granted

If Preferred Care changes its formulary tier structure during the year, an enrollee using a prescription drug impacted by the change may request review under the Tier Exception Process.

3. **FORMULARY EXCEPTIONS:**

Formulary exceptions are not necessary as Preferred Care utilizes an open formulary for Part D prescription drug plans.

4. **APPEALS (REDETERMINATIONS):**

If a Part D enrollee receives an adverse Coverage Determination, Preferred Care provides the following appeal procedures. Depending on the enrollee's health condition, a standard Redetermination or an Expedited Redetermination may be requested.

A. **Standard Redeterminations**

An enrollee may request a Standard Redetermination of an Adverse Coverage Determination.

- 1) Request for Redetermination must be made within 60 calendar days from the date of the notice of the Coverage Determination.
- 2) If an enrollee shows good cause, Preferred Care may extend the 60-day timeframe for request for Redetermination. Extension requests

must be in writing and state the reason why the request was not filed on time.

- 3) A pharmacist and/or a medical director, who did not review the initial Coverage Determination, will review each request for a Pharmacy Redetermination. Redeterminations for denials based on lack of medical necessity will be made by a physician with expertise appropriate to the field of medicine and services at issue.
- 4) All Redeterminations will be completed with written notice to the enrollee within 7 calendar days of receipt of the request.
- 5) The notice of adverse Redetermination will state the specific reason for the denial, advise the enrollee of the right to reconsideration, and describe the expedited and standard reconsideration process and the rest of the appeals process.

B. Expedited Redeterminations

Preferred Care offers an Expedited Redetermination process for cases where the standard timeframe for Redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

- 1) An enrollee (or prescribing physician where appropriate) may submit an oral or written request for Expedited Redetermination for denials based on medical necessity, network or formulary criteria.
- 2) A pharmacist and/or a medical director, who did not review the initial Coverage Determination, will review each request for an Expedited Redetermination. Redeterminations for denials based on lack of medical necessity will be made by a physician with expertise appropriate to the field of medicine and services at issue.
- 3) Preferred Care will determine if the request meets the criteria for an Expedited Redetermination.
- 4) If Preferred Care requires additional information to make a decision of a Redetermination, the request for additional information must be made within 24 hours of receipt of the request for the Redetermination. Completion time frame of 7 days will still be adhered to.
- 5) If the request meets the criteria for an Expedited Redetermination, Preferred Care will make its Redetermination as expeditiously as the enrollee's health requires, but no later than 72 hours after receipt of the request.
- 6) If Expedited Redetermination notification is oral, written confirmation will be mailed within 3 calendar days of oral notification.
- 7) If the Redetermination is not favorable to the enrollee the notice will inform the enrollee of their right to reconsideration, describe the

Expedited and standard reconsideration process and the rest of the appeals process, including the right to request reconsideration by an independent review entity that contracts with CMS.

- 8) If the request does not meet the criteria for an Expedited Redetermination, Preferred Care will notify the enrollee and the prescribing physician (where appropriate) of the decision.
- 9) Preferred Care will make the Redetermination within 7 days of receipt of the initial request.
- 10) In its notice of denial of Expedited Redetermination, Preferred Care will provide the enrollee with written notification of their right to an Expedited grievance, their right to resubmit the request for an Expedited Redetermination with prescribing physician's support, and instructions regarding Preferred Care's grievance process. If this notice of an adverse Redetermination is provided orally, written confirmation to the enrollee will be provided within 3 calendar days. This notice will also advise that Preferred Care will process the request under the 72 hour timeframe for standard determinations.

5. Failure to Notify in Adjudication Timeframe

If Preferred Care fails to notify the members request in the adjudication timeframe specified for determinations, expedited determinations, redeterminations, and expedited redeterminations, Preferred Care will forward the request to IRE within 24 hours of the expiration of the appropriate adjudication timeframe.