DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR BENEFICIARY CHOICES

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To: Part D Plan Sponsors

From: Gary Bailey, Deputy Director
Center for Beneficiary Choices

Subject: FAQs related to model Part D Coverage Determination Request forms, supporting statements from physicians and processing timeframes for exceptions and prior authorizations

Set forth in the attached document are answers to several frequently asked questions (FAQs) on prominent issues involving Part D exceptions and appeals. These FAQs provide guidance to Part D plan sponsors regarding the use of model coverage determination request forms and clarification on how to process coverage determination requests for drugs that have a PA or other utilization management requirement.

We ask that plan sponsors carefully review the attached FAQs and share the document with relevant staff. Thank you for your continuing cooperation.

Frequently Asked Questions

Coverage Determination Request Forms, Physician Supporting Statements & Processing Timeframes for Exceptions and Prior Authorizations

Q1. Are Part D plans required to accept the model Medicare Part D Coverage Determination Request Form and the model Part D Exception and Prior Authorization Request Form?

A1. Yes. The Part D regulations require plans to accept **any** written instrument that is used by an enrollee, the enrollee's appointed representative, or a prescribing physician to request a coverage determination. The model Medicare Part D Coverage Determination request form and model Part D Exception and Prior Authorization Request Form constitute acceptable written coverage determination requests. While plans may have their own coverage determination request forms, they must also accept the model forms.

Similarly, plans are required to accept **any** written instrument that is used by an enrollee's prescribing physician to support an exceptions request. The model Part D Exception and Prior Authorization Request Form constitutes an acceptable written supporting statement from an enrollee's prescribing physician. Thus, an enrollee's prescribing physician may use the model Part D Exception and Prior Authorization Request Form to simultaneously file a written request for an exception on an enrollee's behalf and submit his or her written supporting statement.

The model forms are posted on the CMS website at:

http://www.cms.hhs.gov/center/provider.asp

Q2. When does the adjudication timeframe begin for coverage determination requests that involve a prior authorization (PA) requirement or other utilization management requirement (e.g., quantity limit)?

A2. Requests for coverage determinations that involve PA or other utilization management requirements may be treated differently, depending on whether an enrollee or physician is attempting to satisfy a utilization management requirement or is requesting an exception to the requirement.

Part D plans must determine how to categorize requests that involve a PA or other utilization requirement on a case-by-case basis. If a prescribing physician attempts to satisfy a PA requirement, the request should be processed as a coverage determination that does not involve an exception request and the adjudication timeframe begins when the plan receives the coverage determination request.

If an enrollee or physician submits the Medicare Part D Coverage Determination Request Form or model Part D Exception and Prior Authorization Request Form referenced above, a

plan's PA form, or any other written instrument that includes information demonstrating that the enrollee or physician is attempting to satisfy the PA requirement (e.g., lab results, diagnosis), the plan must notify the enrollee and physician of the decision no later than 24 hours from receiving the request if expedited, or no later than 72 hours from receiving the request if it is not expedited. If the coverage determination request is received without information demonstrating that the enrollee or the physician is attempting to satisfy the PA requirement, the plan should immediately contact the enrollee or prescribing physician and inform them of the PA requirement so that the enrollee or physician has an opportunity to attempt to satisfy the PA requirement. The plan must notify the enrollee and the physician of its decision within either 24 hours (expedited cases) or 72 hours (standard cases) of receiving the coverage determination request. However, if an enrollee or prescribing physician indicates that the enrollee cannot satisfy a PA requirement, the plan should process the case as an exception request and solicit a supporting statement from the prescribing physician. In these situations, the adjudication timeframe for exception requests would apply.

Q3. When does the adjudication timeframe begin for exception requests?

A3. The timeframe for processing an exception request begins when the plan receives the prescribing physician's supporting statement explaining the medical necessity for the drug (e.g., an explanation that the preferred or formulary drug would not be as effective for the enrollee as the requested non-preferred or non-formulary drug, would have adverse effects for the enrollee, or both; an explanation why the utilization management requirement has been ineffective, is likely to be ineffective, or would have adverse effects for the enrollee).

For expedited requests, the Part D plan must notify the enrollee (and physician, as appropriate) of its decision as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the physician's supporting statement. For standard requests, the Part D plan must notify the enrollee (and physician, as appropriate) of its decision as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the physician's supporting statement.

Therefore, if a written exception request contains a supporting statement explaining the medical necessity of the requested drug, the timeframe begins the moment the plan receives the request. For example, the model Part D Exception and Prior Authorization Request Form includes check boxes and a free text field that, when completed by the prescribing physician, serve as the supporting statement. If an enrollee or physician submits the Part D Exception and Prior Authorization Request Form or any other written instrument that includes the supporting statement, the plan must notify the enrollee and physician of the decision no later than 24 hours from receiving the request form if the request is expedited, or no later than 72 hours from receiving the request form if it is not expedited.