DEPARTMENT OF HEALTH & HUMAN SERVICES
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Center for Medicare

**DATE:** July 24, 2018

**TO:** All Prescription Drug Plan Sponsors

**FROM:** Jerry Mulcahy, Director, Medicare Enrollment & Appeals Group

John Scott, Acting Director, Medicare Parts C & D Oversight and Enforcement Group

**SUBJECT:** Documentation to Support Part D Exception Requests

This guidance is designed to remind plans of tools they have available to lower drug costs for Medicare beneficiaries. Under the Part D prescription drug program, formularies are a critical tool in the efficient management of the program. Part D enrollees may request an exception to a plan sponsor's formulary or tiered cost-sharing and their request must be accompanied by a written or oral supporting justification from the prescriber. The Part D sponsor must determine if the exception request meets the Part D drug benefit program requirements for exception requests. The purpose of this guidance is to remind Part D plan sponsors of the processes explained in the Prescription Drug Benefit Manual Chapter 18 section 30.2 – Exceptions. This section of the manual describes the rights and responsibilities of Part D enrollees, their providers and Part D sponsors in requesting and processing exception requests.

The requirements related to obtaining a prescriber's supporting statement will be reviewed with the Part D IRE and the Part D Coverage Determinations, Appeals and Grievances (CDAG) audit teams to ensure consistent understanding and application of these rules. For CY2019, CMS CDAG auditor methods of evaluation will be updated to eliminate the tolling timeliness test since the policy is only defined in our guidance as a reasonable, but not indefinite, period of time. In addition, the Part D IRE will be re-trained regarding the exceptions requirements and plan sponsors' ability to require appropriate documentation from providers when considering tiering and formulary exceptions.

If an enrollee wishes to obtain an exception, (e.g. if a prescription for a non-formulary brand name drug is written when an equivalent generic is on formulary), his or her prescribing physician or other prescriber must provide the plan sponsor with a statement. The supporting statement criteria for each type of exception follows:

Tiering Exceptions – Prescriber Supporting Statement Criteria

The physician's or other prescriber's supporting statement must indicate that the drug in the lower cost-sharing tier for the treatment of the enrollee's condition--

(1) Would not be as effective as the requested drug in the higher cost-sharing tier; and/or

(2) Would have adverse effects.

Formulary Exceptions – Prescriber Supporting Statement Criteria

The physician's or other prescriber's supporting statement must indicate that the requested prescription drug should be approved because:

(1) All covered Part D drugs on any tier of a plan's formulary would not be as effective for the enrollee as the non-formulary drug, and/or would have adverse effects;

(2) The number of doses available under a dose restriction for the prescription drug:

(a) Has been ineffective in the treatment of the enrollee's disease or medical condition or,

(b) Based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(3) The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements:

(a) Has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(b) Has caused or, based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee.

If an enrollee or an enrollee's prescriber is requesting an exception, the normal timeframes for resolving coverage determination requests does not begin until the enrollee's prescribing physician or other prescriber provides the required supporting statement as detailed above. Once the required supporting statement, satisfying the factors above, is received, the normal 24 hour (expedited request) or 72-hour (standard request) or 14 calendar days (reimbursement requests) coverage determination processing timeframes begin.

Example:
On June 1, an enrollee requests a drug that is not on formulary. Neither the enrollee nor the provider submitted a statement supporting why the formulary exception should be granted. The normal coverage determination timeframes do not start.
On June 2, the plan sponsor sends a request to the enrollee and the provider for the required supporting statement.
June 3, the plan sponsor sends another request.
June 4, the plan sponsor sends another request.
June 6, the plan sponsor has never received the supporting statement so the sponsor denies the request using the standard coverage determination denial process including the right to appeal the denial.

In the absence of the prescribing physician's or other prescriber's supporting statement, the plan should not leave the request open indefinitely. If no evidence exists to support the exception request, the plan should deny the request for lack of medical necessity.

If the physician or other prescriber provides a written statement that includes the required information detailed above, but the plan sponsor believes it needs additional information to support one of those factors (e.g., lab tests), the plan sponsor must clearly identify the type of information that should be submitted. The plan sponsor must request the additional information, make its decision, and notify the enrollee and/or physician or other prescriber, within the normal 24 hours (expedited requests for benefits), 72 hours (standard requests for benefits), or 14 calendar days (reimbursement requests) after receiving the initial written statement (i.e., the time frame is not tolled if the plan asks for additional information after it has received a written supporting statement that includes the required information indicated above).

Example:
On June 1 at 12n an enrollee requests a drug that is not on formulary and the request does not need to be expedited. The provider submits a written supporting statement that includes the required information however, the plan sponsor needs copies of recent lab values to substantiate the beneficiaries condition. The normal coverage determination timeframes starts with the receipt of the exception request (in this case 72 hours).
On June 1 at 4pm, the plan sponsor sends a request to the enrollee and the provider for the required additional information.
June 2 at 11am the plan sponsor sends another request.
June 3 at 1pm, the plan sponsor receives the additional supporting information and the request is reviewed based on the exception criteria.
June 4 at 9am the plan sponsor approves the exception and notifies the enrollee and the provider using the normal standard coverage determination process.

If the physician or other prescriber provides an oral statement and the plan sponsor determines that the oral statement does not sufficiently demonstrate the medical necessity of the requested drug, the Part D plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement that includes the required factors from above. If the written supporting statement is needed, the plan sponsor must

immediately contact the enrollee and/or the enrollee's prescribing physician or other prescriber and request the supporting statement. For benefit requests (where the enrollee has not received the drug) the normal 24 hour (expedited request) or 72-hour (standard request) timeframes for resolving coverage determination requests does not begin until the enrollee's prescribing physician or other prescriber provides the required written supporting statement as indicated above. For requests for reimbursement the 14 calendar-day timeframe for processing a reimbursement request is not tolled pending receipt of a prescriber's written supporting statement so a decision must be made within the 14 days.

Sponsors can find regulatory requirements related to exceptions at 42 CFR § 423.578 and manual guidance in Chapter 18 of the Prescription Drug Benefit Manual at https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/index.html

Please submit general questions regarding this memorandum to PartD_Appeals@cms.hhs.gov.