

Excerpts from Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance

The following criteria for Part D plan coverage exceptions are a portion of the guidance provided by the Centers for Medicare & Medicaid Services regarding the Part D grievances, coverage/organization determinations, and appeals process. Complete information regarding the process is available at <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev>. Healthcare providers should always confirm coverage for individual patients with their insurance providers.

40.5.3 – Supporting Statements for Exception Requests

Criteria for Tiering Exceptions

The prescriber's supporting statement must indicate that the drug(s) in the applicable lower cost-sharing tier(s) for the treatment of the enrollee's condition would:

- (1) Not be as effective as the requested drug; and/or
- (2) Have adverse effects.

If the physician provides a supporting statement indicating factors (1) and/or (2), but the plan sponsor believes it needs additional information to support one of those factors, the plan sponsor must obtain the additional information.

Criteria for Formulary Exceptions

The prescriber's supporting statement must indicate that the requested drug is medically necessary for one of the following reasons:

- (1) All covered Part D drugs on any tier of the plan's formulary would not be as effective for the enrollee as the requested non-formulary drug, and/or would have adverse effects;
- (2) The number of doses available under a dose restriction for the requested 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 the physician provides a supporting statement indicating factors (1), (2), and/or (3), but the plan sponsor believes it needs additional information to support one of those factors, the plan sponsor must obtain the additional information.