

Title: Mid Rogue Community Health Plan CareSource Part D – Exceptions Process		Policy Number: PD003	
Department: Medical Affairs/Appeals & Grievance		Effective: 01/01/2006	Date(s) Last Revised:
Approved By: (name/title)			
Written By:			
Reference: 42 CFR §423.562, 423.564			

Description:

This document outlines the basic exceptions process to be followed when processing coverage and redetermination requests for Part D drug coverage.

Policy:

1. CareSource will grant an exception whenever it determines that the non-preferred drug for treatment of the member’s conditions is medically necessary, consistent with the physician’s statement.
2. CareSource will establish and maintain an exceptions process that addresses the following circumstances:

The exception criteria must include, but are not limited to:

- A. A description of the criteria a plan uses to evaluate a determination made by the member’s prescribing physician.
- B. Consideration of whether the requested drug that is the subject of the exceptions request is the therapeutic equivalent of any other drug on the formulary. Drug products evaluated as “therapeutically equivalent” can be expected to have an equal effect and no difference when substituted for the requested drug.
- C. Consideration of the number of drugs on the formulary that are in the same class and category as the requested prescription drug.

3. A member or the member’s prescribing physician (on behalf of the member) may file a request for an exception. A prescribing physician must provide an oral or written supporting statement that the preferred drug on the sponsor’s formulary may have adverse effects for the enrollee, or both. If the physician provides an oral statement, the plan will usually require a written supporting statement. The plan may also require the physician to provide additional supporting medical documentation.

4. CareSource will not be required to cover a non-preferred drug at the generic drug cost-sharing level since the plan maintains a separate tier dedicated to generic drugs.
5. Formulary use includes the application of cost utilization tools such as a dose restriction that causes a particular drug not to be covered for the number of doses prescribed or a step therapy requirement that causes a particular drug not to be covered until the requirements of the plan's coverage policy are met, or a therapeutic substitution requirement.
6. The exceptions process will also address the following circumstances:
 - A. Situations where a formulary changes during the year and situations where a member is already using a given drug;
 - B. Continued coverage of a particular drug that the plan is discontinuing coverage on the formulary for reasons other than safety or because the drug cannot be supplied by or was withdrawn from the market by the drug's manufacturer; or
 - C. An exception to a plan's coverage policy because of cost utilization tools, such as a requirement for step therapy, dosage limitations or therapeutic substitution.
7. If CareSource covers a non-formulary drug, the cost(s) incurred by the member for that drug are treated as being included for purposes of calculating and meeting the annual out-of-pocket threshold (TrOOP).
8. A member, the member's appointed representative, or the prescribing physician (on behalf of the member) may file a request for an exception.
9. CareSource will require the prescribing physician to provide an oral or written supporting statement that the requested drug is medically necessary to treat the member's disease or medical condition because:
 - A. All of the covered Part D drugs on any tier of a plan's formulary for treatment for the same condition would not be as effective for the member as the non formulary drug, or the formulary drug would have adverse effects for the member, or both.
 - B. The drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements:
 - Has been ineffective in the treatment of the member's disease or medical condition, or, based on both sound clinical evidence and medical and scientific evidence and 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;
 - 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 member;

- The number of doses that is available under a dose restriction for the drug has been ineffective in the treatment of the member's disease or medical condition, or, based on both sound clinical evidence and medical and scientific evidence and 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.

10. When a **tiering or non-formulary** exceptions request is approved, the plan must provide coverage for the approved prescription drug at the cost-sharing level that applies for preferred drugs and may not:

- A. Require the member to request approval for a refill or a new prescription to continue using the prescription drug after the refills for the initial prescription are exhausted, as long as the member's physician continues to prescribe the drug, and the drug continues to be considered safe for treating the member's disease or medical condition and the enrollment period has not expired.
- B. If a member renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.