

Reference number
1539-D

SPECIALTY GENERICS FIRST CRITERIA

POLICY

I. PROGRAM SUMMARY

The intent of the criteria is to require that members try and fail an A-rated generic equivalent prior to receiving a brand specialty medication. If the member has experienced treatment failure with an A-rated (i.e., AA, AB, AN, AO, AP, AT) generic equivalent medication due to an intolerable adverse reaction attributed to an inactive ingredient of the generic medication, the requested brand medication will be approved upon submission of supporting documentation.

Prior to dispensing, each referral is reviewed based on all programs implemented for the client.

II. CRITERIA FOR APPROVAL

Authorization may be granted for a requested medication when all of the following criteria is met:

1. The patient has failed treatment with the generic medication due to an intolerable adverse event (e.g., rash, nausea, vomiting)
2. The adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and generic medication)
3. The adverse event is documented in member's chart. Submission of one of the following is required for approval:
 - a. Specific and detailed chart documentation including description, date/time, and severity of the adverse event, dosage and duration of generic medication treatment, required intervention (if any), and relevant tests or laboratory data (if any)
 - b. MedWatch form of this trial and failure including the adverse reaction

III. NOTE

Due to brand and generic products containing identical active ingredients and having proven bioequivalent pharmacokinetics, differences in the FDA labeled indications between brand and generic products are not, by themselves, sufficient reason to allow access to the brand over the generic.