POLICY AND PROCEDURE

DEPARTMENT: Pharmacy Operations	**DOCUMENT NAME:** Approval of Brand-Name Override
PAGE: 1 of 3	**REPLACES DOCUMENT:**
APPROVED DATE: 04/07	**RETIRED:**
EFFECTIVE DATE: 04/07	**REVIEWED/REVISED:** 02/08, 02/09, 02/10, 02/11, 02/12, 02/13, 08/14, 08/15, 08/16, 11/16, 05/17, 04/18
PRODUCT TYPE: Medicaid	**REFERENCE NUMBER:** OH.PHAR.02

SCOPE:
Centene Corporate Pharmacy Solutions, Health Plan Pharmacy Departments, Pharmacy Benefit Manager

PURPOSE:
The purpose of this policy is to ensure all requests for Brand Medically Necessary (BMN) or Dispense as Written (DAW) prescriptions are evaluated consistently.

POLICY:
The pharmacy benefit mandates use of the generic formulations of multi-source, AB-rated drugs. To obtain coverage for a brand name medication when a generic is available, criteria must be met for brand name overrides (see *Attachment A: CP.PMN.22 Brand Name Override*).

PROCEDURE:
1. The prescriber may request coverage for a specific, multi-source, brand name product by submitting a written or faxed request to the Pharmacy Benefit Manager (PBM).
2. A registered clinical pharmacist at the PBM will review the request and respond to the prescriber within 24 hours, during normal PBM business hours.
   NOTE: If necessary, a temporary override may be entered in the claims processing system to allow the patient to obtain the brand name drug therapy while the request is being reviewed.
3. Coverage of brand name medications will be granted for:
   a. Requests that are accompanied by recent, objective, measurable information demonstrating that a patient is unable to take the generic version of a product consistent with detailed criteria and information as defined in *Attachment A: CP.PMN.22 Brand Name Override*; or
   b. As dictated in accordance with health plan requirements.
4. Appeals of denials will be forwarded to the health plan for review and final determination by an appropriate clinician according to state regulations and plan requirements.

REFERENCES: N/A

ATTACHMENTS:
Attachment A: CP.PMN.22 Brand Name Override

DEFINITIONS:
- **Appropriate Clinician**: A clinician deemed responsible for making decisions of

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utilization management in accordance with NCQA UM 4, Element B, or as determined by health plan contractual obligations and state regulatory requirements.

- **AB-rated**: The Food and Drug Administration (FDA) defines AB-rated as multisource drug products, with generic availability, where actual or potential bioequivalence problems have been resolved with adequate *in vivo* and/or *in vitro* evidence supporting bioequivalence. Note: If there are no known or suspected bioequivalence problems, these are designated AA, AN, AO, AP, or AT depending on the dosage form.

REVISION LOG

REVISION	DATE
Remove from "Practitioners and Network Pharmacies" from "SCOPE" as those are external parties and are not to be included per template definition of "SCOPE".	05/07
Change Attachment A from "Prior Authorization Guideline" to "Medical Necessity Guideline".	02/08
Revised the SCOPE to include Corporate Centene Pharmacy Department.	02/09
Changed the criteria for brand name approval (Attachment A) to align with appropriate trials based on generic availability and USS P&P requirements.	02/09
Detailed the final reviews in the denial process to align with NCQA standards requiring a medical director review.	02/09
Revisions completed at this time were made to address clerical errors, align with NCQA standards and language, and represent the work processes in place at both the Plan level and at US Script.	02/10
No changes.	02/11
Updated FDA definition of AB-rated drugs.	02/12
Updated CP.PMN.22 Brand Name Override attachment.	02/12
No changes were deemed necessary.	02/13
Removed language regarding existing therapy on branded product as exclusion from policy. These users should also have trial of generic product unless medically contraindicated.	02/14
No changes.	08/14
No changes.	08/15
Annual Review	08/16
Changed US Script to Envolve Pharmacy Solutions	11/16
EPS Compliance: Removed the name Envolve Pharmacy Solutions where listed	05/17

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in the policy and replaced with Pharmacy Benefit Manager, Removed NurseWise from procedure, Under #3-Added "As dictated in accordance with health plan requirements", Under #4-changed that the final determination of appeals of denials will be made "by an appropriate clinician according to state regulations and plan requirements", Added definition of Appropriate Clinician.	
Annual Review – no changes.	04/18

POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

V.P., Pharmacy Operations: Approval on file

SR. V.P. Medical Affairs or Chief Medical Officer: Approval on file

NOTE: The electronic approval is retained in Compliance 360.