POLICY AND PROCEDURE

POLICY NAME: Approval of Brand Name Override	**POLICY ID:** CC.PHAR.02
BUSINESS UNIT: Corporate	**FUNCTIONAL AREA:** Utilization Management
EFFECTIVE DATE: 04/2007	**PRODUCT(S):** Medicaid
REVIEWED/REVISED DATE: 02/08, 02/09, 02/10, 02/11, 02/12, 02/13, 08/14, 08/15, 08/16, 11/16, 05/17, 05/18, 05/19, 05/20, 05/21, 05/22, 05/23, 02/24, 05/24, 05/25, 08/25	
REGULATOR MOST RECENT APPROVAL DATE(S):	

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.

SCOPE:
This policy applies to Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
- **Appropriate Clinician**: A clinician deemed responsible for making decisions of utilization management in accordance with NCQA 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.

POLICY:
The pharmacy benefit requires generic substitution when AB-rated generic equivalents are available. To obtain coverage for a brand name medication when a generic is available, criteria must be met for brand name overrides. Brand name drugs may be approved in certain circumstances where there are adverse reactions or due to therapeutic failure of generic drugs (Reference CP.PMN.22 Brand Name Override).

PROCEDURE:
1. Prescribers, pharmacies, members and/or member representatives may request coverage for a brand name product by submitting a request to Pharmacy Services by mail, telephone, fax, or automated process (if implemented).
2. A registered clinical pharmacist or pharmacy technician in Pharmacy Services will review the request and notify the prescriber of the decision by telephone, fax, or other electronic telecommunication device within 24 hours. For members, a letter is sent via mail for denial decisions. Approval notifications are mailed to members where required by the state.
   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 *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:
- CC.PHARM.03A Medicaid Prior Authorization Review
- CP.PMN.22 Brand Name Override

ATTACHMENTS:
A. Texas Addendum
B. Arizona Addendum

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Ad hoc	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
Annual Review	Change Attachment A from “Prior Authorization Guideline” to “Medical Necessity Guideline”.	02/08
Annual Review	Revised the SCOPE to include Corporate Centene Pharmacy Department.	02/09
Ad hoc	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
Ad hoc	Detailed the final reviews in the denial process to align with NCQA standards requiring a medical director review.	02/09
Annual Review	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
Annual Review	No changes.	02/11
Annual Review	Updated FDA definition of AB-rated drugs.	02/12
Ad hoc	Updated CP.PMN.22 Brand Name Override attachment.	02/12
Annual Review	No changes were deemed necessary.	02/13
Annual Review	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
Annual Review	No changes.	08/14
Annual Review	No changes.	08/15
Annual Review	Annual Review	08/16
Ad hoc	Changed US Script to Envolve Pharmacy Solutions	11/16
Annual Review	EPS Compliance: Removed the name Envolve Pharmacy Solutions where listed 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.	05/17
Annual Review	Annual review	05/18
Annual Review	Added EPS.PHARM.03A Medicaid Prior Authorization Review policy to References section.	05/19
Annual Review	Moved CP.PMN.22 Brand Name Override policy from Attachments to References section.	05/20
Annual Review	Added pharmacies, members and/or member representatives as people who may request a brand name override. Added pharmacy technician as a reviewer of the request. Added telephone, fax, or other electronic telecommunication device to how prescribers are notified. Added that a letter is mailed to members for denial decisions, and approval notifications are mailed to members where required by the state.	05/21
Annual Review	References to PBM changed to Centene Pharmacy Services. EPS.PHARM.03A changed to CC.PHARM.03A in the References section. Removed Centene Corporate Pharmacy Solutions.	05/22
Annual Review	No changes deemed necessary. Addendum added for Texas.	05/23
Ad hoc	Addendum added for Arizona.	02/24
Annual Review	Updated Policy section with verbiage from CP.PMN.22 Brand Name Override criteria.	05/24
Annual Review	Updated Scope of policy, and Procedure section to include all methods for receiving requests.	05/25

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Ad hoc	Addendum for Arizona was updated.	08/25

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.