POLICY AND PROCEDURE

DEPARTMENT: Pharmacy Operations	REFERENCE NUMBER: CC.PHAR.07
EFFECTIVE DATE: 02/03	POLICY NAME: Pharmaceutical Management
REVIEWED/REVISED DATE: 10/04, 11/06, 04/07, 02/08, 02/09, 02/10, 02/11, 02/12, 02/13, 02/14, 08/14, 08/15, 08/16, 11/16, 11/17, 11/18, 02/19, 05/19, 02/20, 05/20	RETIRED DATE: N/A
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SCOPE:
Centene Corporate Pharmacy Solutions, Envolve Pharmacy Solutions and Health Plan Pharmacy Departments.

PURPOSE:
To ensure that Centene Corporate Pharmacy Solutions and Envolve Pharmacy Solutions, to whom pharmaceutical management has been delegated, develop and annually review and update policies and procedures for pharmaceutical management, using sound clinical evidence and provide these policies to Centene health plans in which a pharmacy benefit is provided.

POLICY:
All policies and procedures utilized by Centene health plans or Envolve Pharmacy Solutions, related to pharmaceutical management (including drugs covered under the medical benefit), consider guidance recommended by the Pharmacy Solutions Group, Clinical Pharmacy Advisory Committee (CPAC) and adopted by the Centene Pharmacy and Therapeutics Committee. Pharmacy decisions are made using input from National Pharmacy Standards Organizations including, but not limited to, the Academy of Managed Care Pharmacy, Center for Drug Evaluation and Research, Food and Drug Administration, Facts and Comparisons, Clinical Pharmacology, and the governing bodies of medical specialties. Current medical and pharmaceutical literature is researched for relevant clinical studies and nationally recognized clinical guidelines (e.g. JNC VII, ATP III, TMAP, NHLBI, NIH, NCEP, AAP, peer reviewed journals etc.) are utilized. Centene health plans adjust these policies and procedures to comply with state regulations as needed, reporting these changes to the Corporate Pharmacy Department. Policies and procedures are reviewed and approved by both the Corporate and health plan Pharmacy and Therapeutics (P&T) committees. The members of these committees include community practitioners, medical specialists, and pharmacists.

When pharmaceutical management is delegated to Envolve Pharmacy Solutions, Centene health plans maintain responsibility for ensuring the functions are being performed according to the expectations outlined in this policy. In the event that the responsibility for pharmacy management has been retained by the State or other external entity, this policy does not apply.

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Centene and its subsidiaries does not discriminate on the basis of race, color, national origin, sex, age or disability, nor exclude from participation in, deny the benefits of, or otherwise subject to discrimination under any applicable Company health program or activity.

PROCEDURE:
I. Pharmaceutical management policies include the following:
   A. The criteria used to adopt pharmaceutical management procedures. In particular, criteria used when constructing the preferred drug list, including those covered under the medical benefit,or preferred status, shows how decisions are made about:
      1. Classes of pharmaceuticals
         a. Classes preferred or covered at any level
         b. Any exception processes available to members for obtaining non-covered pharmaceuticals
         c. Considerations regarding limiting access to drugs in certain classes
      2. Within each class of pharmaceuticals
         a. The pharmaceuticals preferred or covered at any level
         b. The criteria for prior authorization of any pharmaceutical
         c. Any exceptions process available to members
         d. Substitutions made automatically or with physician permission
         e. Evidence showing how preferred-status pharmaceuticals can produce similar or better results for a majority of the population as compared to other pharmaceuticals in the same class
   B. A process that uses clinical evidence from appropriate external organizations. This evidence includes relevant findings of the Food and Drug Administration, Centers for Drug Evaluation and Research, drug manufacturer dossiers, the Academy of Managed Care Pharmacy, and others. In addition, clinical review using peer-reviewed journals, medical specialty guidelines, and authoritative compendia is performed for determination of pharmaceutical coverage positioning.
   C. Adoption or creation of a system for point of dispensing communications to identify and classify by severity, drug-drug interactions. Envolve Pharmacy Solutions, as the delegated PBM, uses a Medispan database as the source of drug interactions, which are classified by severity. Envolve Pharmacy Solutions uses a passive point-of-service (POS) communication to dispensing pharmacies designed to avoid

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interference with prescribed drug therapy and to complement network pharmacy applications.

D. Notification to dispensing providers at the point of dispensing of specific interactions when such interactions meet the severity threshold. Envolve Pharmacy Solutions uses Medispan resources to send electronic alerts to dispensing pharmacies via standard POS messaging when potential drug interactions are detected.

E. Identification and notification of members affected by a Class I recall are notified in 14 business days. Class II recalls, Class III recalls, or other equivalent severity safety alerts must be completed within 30 days of receiving the FDA notice.
    1. Exceptions include:
        a. Withdrawls unrelated to safety issues
        b. Recalls that do not pose serious health hazards
        c. Recalled or withdrawn pharmaceuticals for which the Plan or PBM is unable to identify affected members from the batch or lot numbers
        d. Wholesale-only drug recalls and withdrawals

F. Exception policies and procedures that describe the process for:
    1. Making an exception request based on medical necessity
    2. Obtaining medical necessity information from prescribing practitioners, including notifying prescribers for a request for additional information to support medical necessity.
    3. Using appropriate pharmacists and practitioners to consider exception requests
    4. Timely request handling
    5. Communicating the reason for a denial and an explanation of the appeal process when it does not approve an exception request.

II. The preferred drug list (PDL) and pharmaceutical management edits are posted on health plan websites. Envolve Pharmacy Solutions is responsible for communicating the availability of the current PDL to members and providers. The health plan is responsible for communicating information for drugs covered under the medical benefit. All communication of pharmacy information and pharmacy management procedures is done at least annually and upon updates, through the member and provider newsletter or other materials such as a postcard. Major changes in drug coverage and pharmaceutical management edits are communicated to providers and members by direct mail (e.g. fax, email, mail) as needed. All

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pharmaceutical management edits and coverage limitations meet state-specific requirements and any variances are preapproved by the individual state Medicaid programs, where required.

The PDL or similar health plan materials includes restrictions and preferences, and addresses:
A. How to use the pharmaceutical management procedures
B. An explanation of any limits or quotas
C. An explanation of how prescribing practitioners must provide information to support an exception request
D. The process for generic substitution, therapeutic interchange, and step-therapy protocols

III. In the event that Centene health plan staff is involved in the pharmaceutical prior authorization process, decisions are made by licensed health care professionals utilizing clinical judgment in consultation with the health plan Vice President of Medical Affairs or designated Medical Director and/or Plan Pharmacist, as appropriate, and Envolve Pharmacy Solutions. Envolve Pharmacy Solutions may be delegated the responsibility for reviewing daily prior authorization and medical necessity requests for drugs not listed on the PDL. For drugs not designated as pharmacy benefits, procedures are outlined via Policy CC.UM.02. All reviews are performed within 24 hours, upon receipt of all necessary and requested information. All denials or adverse determinations are made by an Envolve Pharmacy Solutions clinical pharmacist or physician, if required by state regulations.

IV. Centene Corporation has delegated pharmacy benefit management to Envolve Pharmacy Solutions. The health plan maintains accountability for delegated services and monitors performance of these services. Initial monitoring occurs through the approval of the delegate's applicable policies and procedures for the delegated portions of the program. Subsequent performance reviews are achieved through routine reporting and at least annual evaluation. Performance evaluation criteria include accreditation and state/federal requirements and health plan standards. The health plan also retains the right to reclaim the responsibility for performance of this function should standards not be maintained.

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REFERENCES: NCQA Standards and Guidelines CC.COMP.42_ACA 1557 Nondiscrimination in Health Programs Activities

ATTACHMENTS: N/A

DEFINITIONS: N/A

REVISION LOG	DATE
Insert applicable references to NCQA standard and elements. Updated E to reflect Class II recalls and associated exceptions. Added section IV regarding delegation of pharmacy management. Added policy approval section with appropriate signature lines.	05/07
Add "US Script, Inc." to the "SCOPE".	02/08
Add "peer reviewed journals" to the list of "Current medical and pharmaceutical" under "POLICY".	02/08
Remove the following from "POLICY": "In the absence of a PBM, the development of and adherence to the policies described within this policy will be the responsibility of the Corporate Pharmacy Department."	02/08
Add the following to item "C" under "PROCEDURE" part "I": "US Script, as the delegated PBM, uses a Medispan database as the source of drug interactions. These are classified by severity."	02/08
Add the following to item "D" under "PROCEDURE" part "I": "US Script, the delegated PBM, uses Medispan resources to send electronic alerts to dispensing pharmacies via standard point of service (POS) messaging when potential drug interactions are detected."	02/08
Add "Class I or" to item "E" under "PROCEDURE" part "I".	02/08
Move MHS-WI to the carve out section in "PROCEDURE" part "IV".	02/08
Adjust the POLICY to reflect the references used for development of clinical criteria and policies and procedures.	02/09
Clarified the PROCEDURE to incorporate the PBM's role in POS messaging, identification and notification to the Plan of members affected by drug recalls, and outline the PBM's responsibilities for the delegated task of reviewing a	02/09

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Prior Authorization requests and timeliness of same.	
Revisions completed at this time were made align with NCQA standards and language.	02/10
Clarified that Centene Corporation has currently delegated pharmacy benefit management to US Script for all Health Plans for which it provides a pharmacy benefit in section IV. of the PROCEDURE.	02/11
Reviewed 2012 NCQA standards and no substantive changes were made.	02/12
Reviewed 2013 NCQA standards and added or changed the following language accordingly. In element "F", added language for requesting additional information supporting "medical necessity". Added language to element II to expand the definition of the Preferred Drug List and how drug coverage changes are communicated to providers. In element "IV", added URAC as a governing body for certifying quality performance measures.	02/13
No changes deemed necessary.	02/14
No changes deemed necessary.	08/14
Removed from Scope: "Corporate Pharmacy Department and US Script" and replaced with "Pharmacy Solutions Group". Removed from initial paragraph: "incorporate the criteria instituted by the Corporate Pharmacy Department" and replaced with "shall consider guidance recommended by the pharmacy solutions group and adopted by the Centene Pharmacy and Therapeutics Committee". Removed from I.E. "Corporate Pharmacy Department and US Script" and replaced with "Pharmacy Solutions Group". In the first paragraph of item III, "Corporate Pharmacy Department" was replaced by "Pharmacy Solutions Group". Deleted from item IV. "for all Health Plans for which it provides a pharmacy benefit" from first sentence.	08/15
Annual Review; changed reference to "NCQA Standards and Guidelines".	08/16
Under section II, added "members" that changes are sent to as well as providers; changed US Script to Envolve Pharmacy Solutions	11/16
Added discrimination statement; Updated references.	11/17
Updated template. Annual review no changes.	11/18
Updated prior authorization review time from one business day to 24 hours in section III. NCQA Review: Updated section 1e to reflect the requirement that Class II recalls must have notification within 30 days.	02/19
Minor edit to Procedure Section II, adding "pharmacy management	05/19

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procedures". Added Addendum for Peach State Health Plan to Attachments section.	
Updated to include drugs covered under the medical benefit and Clinical Pharmacy Advisory Committee (CPAC)	02/20
Peach State Health Plan Addendum was retired by the plan and has been removed from Attachments. Minor grammatical update in Procedure F.5.	05/20

POLICY AND PROCEDURE APPROVAL

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