POLICY AND PROCEDURE

DEPARTMENT: Pharmacy Operations	**REFERENCE NUMBER:** CC.PHAR.10
EFFECTIVE DATE: 04/07	**POLICY NAME:** Preferred Drug List
REVIEWED/REVISED DATE: 02/08, 02/09, 02/10, 02/11, 02/12, 02/13, 11/13, 08/14, 08/15, 08/16, 11/16, 11/17, 11/18, 11/19, 11/20, 05/21, 11/21, 05/22, 11/22, 05/23	**RETIRED DATE:** N/A
PRODUCT TYPE: Medicaid	**PAGE:** Page 1 of 8

SCOPE:
Health Plan Pharmacy Departments, Centene Corporate Pharmacy and Therapeutics Committee, and Centene Pharmacy Services.

PURPOSE:
To maintain a comprehensive Preferred Drug List (PDL) to serve Centene health plan members while also identifying pharmaceutical management controls that assure appropriate use of drugs and a high quality pharmacy benefit. The Centene health plan PDLs include:

- A listing of drugs, including restrictions and preferences
- How to use the pharmacy management procedures
- An explanation of limits or quotas
- A description of how prescribers must provide information to support an exception request, and
- The health plans' process for generic substitution, therapeutic interchange, and step-therapy protocols

POLICY:
The Centene Corporate Pharmacy and Therapeutics (P&T) Committee is responsible for approving all changes to the Centene PDL, which consists of a core set of covered pharmaceuticals which is then adapted for each individual health plan. In addition, the Centene P&T Committee determines which drugs included in the PDL require pharmaceutical management edits including prior authorization, quantity limits, age and gender edits, and step therapy. Each health plan PDL is reviewed to verify compliance with state regulations and allows for variances based on specific state requirements.

Centene or 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:
The Clinical Pharmacy Advisory Committee (CPAC) monitors the drug approval pipeline and provides information to the Centene P&T Committee for evaluation including:

- Annual reviews, quarterly by therapeutic class, of the current drugs on the PDL to determine the appropriateness of PDL positioning
- Any pharmaceutical management protocols that may need to be implemented.

1. The criteria used to adopt pharmaceutical management procedures, in particular, criteria used when constructing the preferred drug list includes:

a. Pharmaceutical classes
   i. Classes preferred or covered at any level
   ii. Lists of preferred pharmaceuticals or formularies
   iii. Considerations for limiting access to drugs in certain classes
   iv. Prior Authorization criteria
   v. Generic substitution, therapeutic interchange, step therapy or other management methods to which the practitioner's prescribing decisions are subject

b. Within each class of pharmaceuticals
   i. Pharmaceuticals preferred or covered at any level
   ii. An exceptions process available to members
   iii. Substitutions made automatically or with permission of the prescribing practitioner
   iv. Evidence that preferred-status pharmaceuticals can produce similar or better results for a majority of the population than other pharmaceuticals in the same class
   v. Other requirements, restrictions, limitations or incentives that apply to the use of certain pharmaceuticals

2. <u>CPAC</u>

The Clinical Pharmacy Advisory Committee (CPAC) reviews new drugs that are released onto the market, and makes one of the following clinical recommendations:

a. There is significant potential for inappropriate use and utilization management should be considered.
   i. The CPAC rationale for prior authorization will be provided, along with a draft of the prior authorization criteria.

b. There is no significant potential for inappropriate use.

3. <u>P&T</u>

The Centene Corporate P&T Committee members are responsible for staying informed on the latest medications available on the market including newly arrived generic and brand-name products and changes in drug labeling. The following work

flow promotes an environment that allows all P&T Committee members input and recognizes regional differences in practice standards.

a. CPAC presents the clinical recommendations to the Centene Corporate P&T Committee.
b. The Centene Corporate P&T Committee reviews all clinical recommendations from CPAC on a quarterly basis.

4. SDC

The Strategy Development Committee (SDC) manages drug cost using a multi-disciplinary standardized approach to identify, develop and implement long and short-term strategies in support of health plan financial and other business objectives. Data and analytics optimize decision-making.

a. SDC performs data and financial analyses that originate from rebate modeling, new generic launches, and other changes in drug market dynamics (i.e. drug recalls/withdrawals, new clinical trial results, guideline changes, etc).
b. SDC formulary recommendations are created and provided to the health plan pharmacy leads via SDC recommendation packets.

5. PDL Update

a. The health plan pharmacy leads review SDC recommendation packets and communicate their acceptance or rejection of the formulary changes via Qualtrics survey.
b. If the health plan accepts the formulary changes, Formulary Management submits the changes for coding into the claims processing system.
c. Health plan web sites are updated and synchronized with published PDLs.
d. The health plan communicates changes to the PDL to members and providers on an annual basis. The health plan communicates the availability of the most current PDL on the website to members and providers via member and provider newsletters or other materials on an annual basis. If significant changes to the PDL are made, the health plan communicates the specific changes to providers via email blast, fax blast and/or newsletter. In addition, members receive notification via newsletter or mail.
e. Negative PDL changes (i.e. changes that result in restrictions or replacements) will be communicated only to affected members and their prescribing practitioners.

6. Requests for changes to the PDL from Providers

It is Centene's objective to offer uniform coverage across all Medicaid health plans for the membership that each plan serves. However, providers and health plans may request variances to the PDL.

a. Provider requests for changes to the PDL must be submitted in writing to the health plan pharmacist and substantiated with appropriate clinical rationale in order to be considered.
b. Recommendations for changes are forwarded to CPAC. The CPAC reviews the request and presents for consideration to the Centene Corporate P&T Committee.
c. For provider requests not agreed to by the P&T Committee, the health plan Pharmacist communicates the decision to the requesting provider.

7. Requests for changes to the PDL from Health Plans

a. Health plans may request variances to the PDL via submission of written request with clinical rationale to support the recommendation. Clinical rationale may include:
   i. Peer reviewed articles
   ii. Published double-blind, randomized studies (of sufficient size, normally N ≥100) that demonstrate a clearly superior benefit
   iii. Guidelines that are supported by evidence-based professional medical organizations
   iv. Pharmacoeconomic drug comparison studies, and/or
   v. State required mandates for coverage or coverage exclusions.

b. Requests for reconsideration should be forwarded to CPAC for presentation to and review by the Centene Corporate Pharmacy P&T Committee.
c. Any changes to the PDL consider applicable state regulations, and changes may require submission to the State for approval (where applicable).

REFERENCES:

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

ATTACHMENTS:

Attachment A: South Carolina Addendum

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Attachment B: New Hampshire Addendum
Attachment C: Arizona Addendum
Attachment D: Georgia Addendum
Attachment E: North Carolina Addendum

DEFINITIONS:
N/A

REVISION LOG

REVISION	DATE
Replace the "formulary" with "Preferred Drug List (PDL)" throughout the document.	02/08
Replace the "PBM" with "US Script" throughout the document.	02/08
Replace "pharmaceuticals for inclusion on the Centene Corporation and Health Plan Preferred Drug List (PDL)." With "pharmaceutical management controls that assure appropriate use of drugs and a high quality pharmacy benefit" under "PURPOSE".	02/08
Under "POLICY" replace "The State's Medicaid Drug Lists" with "The Centene Plan Medicaid Drug Lists".	02/08
Under "PROCEDURE" item "1" specify that the annual PDL review will be conducted quarterly by therapeutic class and add the note that "pharmaceutical management protocols that need to be implemented" will also be reviewed.	02/08
Under "PROCEDURE" item "2" replace "by the State" with "Centene Plan state regulations".	02/08
Under "PROCEDURE" item "3" change annual to quarterly.	02/08
Under "PROCEDURE" item "3" replace "a copy of the Health Plan's PDL will be provided to all Health Plan Primary Care Providers (PCPs) and Pharmacies by the Health Plan's Provider Relations staff and via the Plan's website." With "agreed to by the Centene Plan P&T committees and State approval is granted (where applicable), the Health Plan Web sites are updated and major changes are communicated via mail to Health Plan providers. The responsibility of communicating changes to Health Plan providers resides at the plan level."	02/08
Revise "PROCEDURE" item "6" to specify that physicians requesting	02/08

reconsideration must submit additional supporting information.	
Revised the SCOPE to include Corporate Centene Pharmacy Department, Centene Pharmacy and Therapeutic Committee, Health Plan Pharmacy and Therapeutic Committees.	02/09
Enhanced the POLICY to define responsibilities for PDL drug reviews, and highlight the collaborative process between Corporate and Plan P&T Committees for final determination of PDL drug positioning and associated pharmacy management edits.	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
Inclusion of language clarifying requirements for Health Plan requests for coverage variances from a standardized PDL. Language is as follows: It is the objective of Centene to offer uniform coverage across all Medicaid and Medicare Plans for the membership that it serves. The Health Plan may request variances from the Corporate P&T Committee recommended additions to, deletions from, or limitations of PDL coverage with submission of clinical rationale (peer reviewed articles or published studies or guidelines that are supported by professional medical organizations), pharmacoeconomic drug comparison studies, or State required mandates for coverage or coverage exclusions. Requests must include Health Plan P&T Committee agreement by a quorum approval vote. Requests for reconsideration should be forwarded to the Corporate Pharmacy team for presentation to and review by the Corporate Pharmacy P&T Committee. Final disposition will be decided by the Corporate P&T Committee.	02/11
Updated Health Plan Recommendation to Corporate Pharmacy & Therapeutics Committee form to specify the email address where the form should be sent.	02/11
No changes other than clarifying language.	02/12
Under clinical rationale to support a Health Plan P&T recommendation, language was expanded from "published studies" to "published double-blind, randomized, studies (of sufficient size, normally N ≥100) that demonstrate a clearly superior benefit".	02/13
Added the following to the procedure to address NCQA guidelines:	11/13

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The Health Plan communicates via Member and Provider newsletter on an annual basis the availability of the most current PDL on the website. If significant changes to the PDL are made, the Health Plan will communicate with the providers via Eblast, Faxblast and/or newsletter. In addition, members will receive notification via newsletter or mail.	
No changes deemed necessary.	08/14
Changed Scope to remove "Corporate Pharmacy Department" to "Pharmacy Solutions Group". Under Procedure item number 3, 6 and 8 changed "Corporate Pharmacy" to "Pharmacy Solutions Group". Added definition of "Add", and "Do not Add" to Procedure item 5. Under number 3 remove Medicare as this policy does not apply to Medicare Line of Business.	08/15
Annual Review	08/16
Updated "Procedure" section to incorporate new P&T process; removed reference to "pharmacy solutions group lead" and replaced with Envolve Pharmacy Solutions	11/16
Retiring Attachments A and B: PDL Change Request and HP PT Recommendation forms; other avenues of communicating these requests and recommendations are being used; Added discrimination statement; Updated references.	11/17
Annual Review.	11/18
Reviewed against current NCQA standards and guidelines; formatting and grammatical changes; changed "the PBM claims system" to "the claims processing system" in Procedure section 9.	11/19
South Carolina ATC Addendum added as Attachment A.	04/20
Annual Review. Reformatted entire policy, making it easier to follow the process. Added criteria used to adopt pharmaceutical management procedures in Step 1. Added Step 5.b. to describe the process where health plan pharmacy directors have the ability to accept or reject PDL changes that are recommended by SDC. Added "on a quarterly basis" to clinical recommendations presented by CPAC to the Centene Corporate P&T Committee. SC ATC Addendum (Attachment A) was revised by the health plan.	11/20

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SC ATC Addendum (Attachment A) was revised by the health plan, in addition to a new Addendum template.	05/21
Annual Review- Updated the SDC and PDL Update sections to reflect the new integrated SDC process.	11/21
Removed Centene Corporate Pharmacy Solutions. Changed Envolve Pharmacy Solutions to Centene Pharmacy Services. South Carolina Addendum was updated.	05/22
Annual Review- No changes deemed necessary.	11/22
Addendum added for New Hampshire. Addendum added for Arizona.	02/23
Removed Health Plan P&T Committee references. Updates made to reflect the new SDC process. Addendums added for Georgia and North Carolina.	05/23

POLICY AND PROCEDURE APPROVAL

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