POLICY AND PROCEDURE

DEPARTMENT: Pharmacy Operations	**REFERENCE NUMBER:** CC.PHAR.13
EFFECTIVE DATE: 02/10	**POLICY NAME:** Pharmacy & Therapeutics Committee
REVIEWED/REVISED DATE: 08/10, 07/11, 02/12, 02/13, 02/14, 08/14, 08/15, 08/16, 11/16, 02/17, 02/18, 02/19, 02/20, 02/08/21	**RETIRED DATE: N/A**
PRODUCT TYPE: Medicaid	**PAGE: Page 1 of 5**

SCOPE: Centene Health Plan Pharmacy Department, Centene Corporate Pharmacy Solutions, Centene Corporate Pharmacy and Therapeutics Committee, and Envolve Pharmacy Solutions.

PHARMACY & THERAPEUTICS COMMITTEE CHARTER

1. **PURPOSE.** The purpose of the Centene Pharmacy & Therapeutics (P&T) Committee is to review and make decisions for changes to the drugs listed for coverage, the edits related to controls or limitations of drug coverage, and the policies and procedures governing provision of drug coverage under the Medicaid Preferred Drug List (PDL) to promote access to safe, effective and quality drug therapy. Centene and its subsidiaries do 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. The Centene P&T Committee:

    a. Objectively appraises, evaluates, and selects drugs for coverage on the Medicaid PDL.
    b. Meets quarterly, and if necessary more frequently, to review and update the PDL to consider adding newly approved drugs and recommending changes to existing drug coverage in consideration of changes in FDA approved labeling, safety concerns, or current market conditions.
    c. Reviews and approves Drug Utilization Review (DUR) initiatives delegated to the Clinical Pharmacy Advisory Committee (CPAC) and Envolve Pharmacy Solutions that are sent to health plans for provider or member intervention.
    d. Reviews, updates, and approves policies and procedures governing provision of the Medicaid pharmacy benefits.
    e. Reviews, updates, and approves criteria guidelines for the use of restricted access drugs and non-PDL covered drug therapy.
    f. Reviews newly FDA approved drug products within 90 days, and reach a coverage decision for each newly FDA approved drug within 180 days of market availability.
    g. Reviews and evaluates the clinical appropriateness protocols and procedures for formulary exceptions and other utilization management activities such as prior authorizations, step therapies, quantity limits, generic substitutions, drug utilization, drug compliance and related activities that impact consumer access to drugs. The P&T Committee set protocols and procedures which insure that drug utilization management decisions are evidence-based clinical decisions.
    h. Interface with Pharmacy Benefit Management (PBM) quality improvement programs and drug utilization management programs to coordinate efforts and allow verification of P&T Committee processes. The Quality Improvement Committee

reviews the Drug Utilization Program and Quality Improvement Program and makes recommendations to the P&T Committee. The P&T Committee reviews these recommendations and considers quality improvement factors when making decisions regarding formulary, step therapy and drug utilization management criteria.

2. **MEMBERSHIP & ORGANIZATION.** The Centene P&T Committee is chaired by the Centene Vice President (VP) of Medical Affairs, or the Centene Chief Medical Officer or his/her designee. The Secretary of the Committee is Centene's VP of Pharmacy Solutions Group or his/her designee. Voting members of the Committee include appropriately credentialed community-based practitioners and pharmacists representing various clinical specialties that adequately represent the needs of Centene health plan members. The Committee includes at least one practicing physician and one practicing pharmacist who are experts regarding the care of elderly or disabled individuals. Outside specialty consultants, independent and free of conflict with respect to Centene health plans and pharmaceutical manufactures, may be recruited as deemed necessary, to provide input related to their areas of expertise and to provide advice on specialty practice standards. All members will be required to participate in the annual conflict of interest training along with signed documentation. All members have an ongoing responsibility to disclose conflicts of interest if they arise. A quorum is required to transact business and make decisions, which is at minimum 50% of Centene P&T Committee members, three (3) of whom must be community based practitioners.

   All members shall serve a two-year term. Every two years members will be contacted to confirm their willingness to continue participation in the P&T Committee. Once a member confirms willingness to continue, the member will fill a subsequent two year appointment unless resignation or less than 50% attendance applies. Employees of pharmaceutical manufacturers and other product sponsor representatives may not serve as members of the P&T Committee or attend meetings.

3. **ATTENDANCE AND PARTICIPATION.** It is the responsibility of all members to ensure optimal discussion of agenda items. Membership of the P&T Committee reflects a multi-disciplinary approach to drug evaluation.

   Attendance of greater than 50% of P&T Committee meetings in a rolling 12 months is required to maintain the rights of a voting member.

4. **RESPONSIBILITIES.** The Centene P&T Committee carries out its mission and performs its duties by applying the following principles:

    a. Clinical decisions are based on the strength of scientific evidence and standards of practice that include, but are not limited to, the following:
        i. Assessing peer reviewed medical literature, randomized clinical trials, and outcomes research data.
        ii. Employing well established clinical practice guidelines developed by means of an evidence-based process and make use of other sources of appropriate information.
        iii. Comparing the safety, efficacy, the frequency of side effects and potential drug interactions among alternative drug products.
        iv. Assessing the likely impact of a drug product on patient compliance when compared to alternative products.
        v. Basing PDL coverage decisions on a thorough evaluation of the benefits, risks, and potential outcomes for patients.
        vi. Reviewing and monitoring medication utilization trends and comparing data to recognize and established professional practice standards or protocols to facilitate the development or revision of coverage criteria, to assess appropriate use, to make recommendations for changes in PDL positioning, and to provide feedback to prescribers.
        vii. Review, at least annually, the prior authorization and medical necessity criteria guidelines for drug coverage to ensure they reflect current market conditions and standards of care.
    b. The decisions from the Centene P&T Committee proceed to the Strategy Development Committee (SDC) who make PDL decisions through financial analyses that are consistent with Centene P&T Committee decisions. The 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.
    c. Ad hoc meetings, if necessary, may be in the form of an in-person meeting, via phone or an online meeting with online vote. Decisions rendered through ad hoc meetings are considered effective as of the date of the final vote and will be brought to quarterly meeting for review and notation in meeting minutes. This section does not absolve the CPTC from all requirements provided for under the Membership and Organization section.
    d. Administrative considerations include, but are not limited to, the following:
        i. Notifying Centene health plans regarding any suggestions for additions, deletions, or changes to the PDL, clinical guidelines, or utilization edits.

ii. Notifying Centene health plans, via committee meeting minutes, of the proceedings and decisions made by the Committee.
iii. Notifying Centene health plans of the Committee's meeting schedule on an annual basis.

5. **DELEGATED FUNCTIONS**. The Centene P&T Committee delegates the creation of oncology product(s) clinical criteria to an external vendor, New Century Health, for those health plans that have signed a delegation agreements, unless there is state mandated criteria. Such agreements are subject to vendor oversight and annual review of the delegate's clinical policies.

6. **REVIEW OF CHARTER.** The Centene P&T Committee reviews this charter annually from the date of original approval or revision date, whichever is more current.

REFERENCES: N/A
ATTACHMENTS: N/A
DEFINITIONS: N/A

REVISION LOG

REVISION	DATE
Addition of language requiring annual review of PA and MN criteria by Corporate and Health Plan Pharmacy and Therapeutics Committees.	08/10
Addition of quorum requirements.	08/10
Clerical changes.	07/11
No changes.	02/12
Clerical grammatical changes.	02/13
No changes deemed necessary.	02/14
No changes deemed necessary.	08/14
Changed VP of Pharmacy to VP of Pharmacy Solutions Group. Clarified section 3b to reflect a change from Cost to Health Outcomes.	08/15
No changes deemed necessary.	8/16
Updated responsibilities to include SDC responsibility of financial analyses; changed US Script to Envolve Pharmacy Solutions.	11/16
Added the need for ad-hoc voting on occasion under Responsibilities.	02/17
Annual Review; Added discrimination statement.	02/18
Created new section #4 Delegated Functions. NCQA review:	02/19

Grammatical updates; removed abbreviations; replaced P&T with Centene P&T Committee.	
Updated section on Ad Hoc meetings to provide more detail.	02/20
Added to the Membership & Organization section: Length of term information, appropriate credentialing of voting members, required annual Conflict of Interest training and signed documentation, and employees of pharmaceutical manufacturers or product sponsor representatives may not serve as members or attend meetings. Added a new section 3 for Attendance & Participation. Added information to 1 g. that describes a process for the P&T Committee to review for clinical appropriateness, protocols and procedures for formulary management activities. Added information to 1 h. that defines how the P&T Committee interfaces with the quality improvement and drug utilization management programs. Removed Medicare references from the Purpose section.	02/08/21

POLICY AND PROCEDURE APPROVAL

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