

POLICY AND PROCEDURE

POLICY NAME: Pharmacy & Therapeutics Committee	POLICY ID: CC.PHAR.13
BUSINESS UNIT: Corporate	FUNCTIONAL AREA: Quality Improvement
EFFECTIVE DATE: 02/2010	PRODUCT(S): Medicaid, Commercial, Marketplace (On Exchange and Off Exchange)
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, 02/21, 05/21, 08/21, 11/21, 02/22, 05/22, 6/22, 02/23, 05/23, 08/23, 12/23, 02/24, 08/24, 02/25, 05/25, 08/25	
REGULATOR MOST RECENT APPROVAL DATE(S):	

SCOPE:

This policy covers Centene Health Plan Pharmacy Department, Centene Corporate Pharmacy and Therapeutics Committee, and Centene Pharmacy Services (CPS). Where Marketplace is indicated as Product applicable to this policy, this includes both On Exchange and Off Exchange plans.

1. PURPOSE:

The purpose of the Centene Pharmacy & Therapeutics (P&T) Committee is to review and make decisions for clinical appropriateness of drug criteria, the edits related to controls or limitations of drug coverage, and the policies and procedures governing provision of drug coverage 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 formulary.
- b. Meets quarterly, and if necessary more frequently, to review newly approved drugs or recommend 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 Pharmacy Services that are sent to health plans for provider or member intervention.
- d. Reviews, updates, and approves policies and procedures governing the provision of pharmacy benefits.
- e. Reviews, updates, and approves criteria guidelines for the use of restricted access drugs and non-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 ensure that drug utilization management decisions are evidence-based clinical decisions.

2. MEMBERSHIP & ORGANIZATION

The Centene P&T Committee is comprised of voting and non-voting guests and is co-chaired by a Medical Director and the Director of Drug Information or their designee. One of the chairs of the Committee must be a board-certified licensed physician. The Secretary of the Committee is Centene's Pharmacy Services Director of Pharmacy Operations 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 in the care of elderly or disabled individuals, and a mental health specialist. All membership (voting and non-voting) is comprised of individuals in a state in which health plan membership is established. 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 external professional members shall be licensed in the respective state that they represent. 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, which is more than 50 percent of Centene P&T Committee members, is required to transact business and make decisions. The majority of committee members must be community-based practitioners.

- a. More than 50 percent of the P&T Committee members will have no conflict of interest with respect to Centene Health Plans and pharmaceutical manufacturers.
- b. No P&T Committee member with a conflict of interest with respect to Centene Health plans or a pharmaceutical manufacturer will vote on any matters for which the conflict exists.
- c. All members of the P&T committee shall be required to disclose any conflict of interest, including but not limited to compensation or funding from a pharmaceutical manufacturer, developer, labeler, wholesaler, or distributor.
- d. The Committee Chair(s) are the determining vote in the case of a tie vote.

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 percent attendance applies. Employees of pharmaceutical manufacturers and other product sponsor representatives may not serve as members of the P&T Committee or attend meetings.

- e. Other subject matter experts may be invited to Committee meetings as non-voting guests on an ad hoc basis for additional advice and input, and can include:
 - i. Medical Directors aside from those listed as voting members;
 - ii. Pharmacy Market leadership;
 - iii. Strategy Development Committee leadership;
 - iv. CPS Fraud Waste and Abuse leadership;
 - v. Drug Utilization Review and Oversight Committee leadership;
 - vi. CPS Trade leadership;
 - vii. CPS Pharmacy Program leadership.

3. MEETINGS

The Centene P&T Committee meets on a regular basis, but no less than once quarterly. Meetings are held via audio teleconference. Electronic surveys are completed prior to the live meeting. 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 the next quarterly meeting for review and notation in meeting minutes. An agenda, supplemental materials, and minutes from the previous meeting will be submitted to the P&T members at least seven (7) days before the next scheduled meeting for members to review. Comments for discussion at the next scheduled meeting must be submitted at least two (2) days prior to the scheduled meeting. The P&T Committee Chair reserves the right to reschedule informational agenda items, if necessary, due to time constraints of the meeting as long as it does not interfere with a CMS schedule for drug/criteria review or an agenda item that is up for annual review. Minutes of the P&T meetings shall be prepared in writing by the recording secretary within five (5) calendar days and maintained as permanent electronic records.

4. 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 percent of P&T Committee meetings in a rolling 12 months is required to maintain the rights of a voting member.

5. 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 formulary 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 formulary positioning, and to provide feedback to prescribers.

- vii. Reviewing, 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 Centene P&T Committee works in coordination with the Strategy Development Committee (SDC) who make formulary decisions through financial analyses that are consistent with Centene P&T clinical decisions and state-specific regulatory requirements. 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. 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 formulary, 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.

6. DELEGATED FUNCTIONS

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

7. 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.

DEFINITIONS:

Expert in the care of the elderly- A health care provider who meets any of the following:

- Diplomate certification in geriatric medicine
- Certified geriatric pharmacist
- Practice includes consultation on patients residing in long-term care facilities
- Majority of patients in the health care provider's practice are elderly individuals

REFERENCES:

CC.PHAR.16 Pharmacy and Therapeutics Committee Member Documentation and Tracking
 CC.PHAR.17 Conflict of Interest and Confidentiality Agreement for Pharmacy and Therapeutics Committee Membership

ATTACHMENTS:

Attachment A: Iowa Addendum
 Attachment B: Arizona Addendum
 Attachment C: New Hampshire Addendum
 Attachment D: Texas Addendum
 Attachment E: Nebraska Addendum

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Ad hoc	Addition of language requiring annual review of PA and MN criteria by Corporate and Health Plan Pharmacy and Therapeutics Committees.	08/10
Ad hoc	Addition of quorum requirements.	08/10
Ad hoc	Clerical changes.	07/11
Annual Review	No changes.	02/12
Annual Review	Clerical grammatical changes.	02/13

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Annual Review	No changes deemed necessary.	02/14
Annual Review	No changes deemed necessary.	08/14
Annual Review	Changed VP of Pharmacy to VP of Pharmacy Solutions Group. Clarified section 3b to reflect a change from Cost to Health Outcomes.	08/15
Annual Review	No changes deemed necessary.	8/16
Ad hoc	Updated responsibilities to include SDC responsibility of financial analyses; changed US Script to Envolve Pharmacy Solutions.	11/16
Annual Review	Added the need for ad-hoc voting on occasion under Responsibilities.	02/17
Annual Review	Added discrimination statement.	02/18
Annual Review	Created new section #4 Delegated Functions. NCQA review: Grammatical updates; removed abbreviations; replaced P&T with Centene P&T Committee.	02/19
Annual Review	Updated section on Ad Hoc meetings to provide more detail.	02/20
Annual Review	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
Ad hoc	Membership & Organization: Changed the Secretary of the Committee is Centene's VP of Pharmacy Solutions Group to Centene's Director of Medical Affairs Pharmacy Operations. Updated the Strategy Development Committee (SDC) section to say that P&T works in coordination with SDC, instead of P&T decisions proceeding to SDC. Also added clarification that SDC decisions are consistent with P&T clinical decisions and state-specific regulatory requirements. Removed section that described how Centene P&T interfaces with PBM Quality Improvement (QI) and DUR programs. The PBM QI and DUR programs interface with the PBM P&T committee. Updated delegated functions to remove New Century Health as the vendor for oncology product(s) clinical criteria.	05/21
Ad hoc	Added Addendums for Iowa and South Carolina.	08/21
Ad hoc	Wellcare P&T Committee policy integrated into Centene policy. Added CC.PHAR.16 P&T Committee Member Documentation and Tracking policy to the References section. Added CC.PHAR.17 Conflict of Interest and Confidentiality Agreement for P&T Committee membership policy to the References section.	11/21
Annual Review	Annual Review- Changed insure to ensure in section 1.g.	02/22
Ad hoc	South Carolina Addendum was updated. Changed Envolve Pharmacy Solutions to Centene Pharmacy Services. Changed Medical Affairs to Centene Pharmacy Services. Updated the Chairman to the Centene Chief Medical Officer or his/her designee by removing the Vice President of Medical Affairs.	05/22
Ad hoc	Updated the Chair from the Centene Chief Medical Officer to the Centene Pharmacy Services Chief Medical Officer.	06/22
Annual Review	Added Commercial line of business to scope. Removed Medicaid-specific language. Added definition for Expert in the care of the elderly. Clarified a quorum is more than 50% of members.	02/23

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
	Addendum added for New Hampshire.	
Ad hoc	Addendum added for Texas.	05/23
Ad hoc	Addendum added for Nebraska.	08/23
Ad hoc	Under Membership and Organization changed the Chair from the Centene Pharmacy Services Chief Medical Officer to co-chaired by a Medical Director and the Director of Drug Information or their designee. Clarified one of the chairs of the Committee must be a board-certified licensed physician. Added d. The Committee Chair(s) are the determining vote in the case of a tie vote.	12/23
Annual Review	South Carolina Addendum retired and removed.	02/24
Ad hoc	Addendum added for Arizona.	08/24
Annual Review	Revised the purpose to “decisions for clinical appropriateness of drug criteria” and removed changes to the drugs listed for coverage.	02/25
Ad hoc	Updated Individual Family Plans to Marketplace (On Exchange and Off Exchange) for PRODUCT(S). Added Where Marketplace is indicated as Product applicable to this policy, this includes both On Exchange and Off Exchange plans to SCOPE. Changed Functional Area from Business Operations to Quality Improvement. Addendums for New Hampshire and Nebraska were updated.	05/25
Ad hoc	Updated scope to include the acronym (CPS) and updated the membership to identify non-voting guests serving as ad hoc advisors.	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.