

POLICY AND PROCEDURE

DEPARTMENT: Ambetter Health Plans	REFERENCE NUMBER: HIM.PHAR.03
EFFECTIVE DATE: 02/14	POLICY NAME: Pharmacy & Therapeutics Committee
REVIEWED/REVISED DATE: 02/15, 02/16, 11/16, 02/17, 02/18, 02/19, 02/20, 02/21	RETIRED DATE: N/A

SCOPE:

Health Insurance Marketplace (Ambetter) Plans, Envolve Pharmacy Solutions, Centene Corporate Pharmacy and Therapeutics Committee.

PURPOSE: To establish a Pharmacy & Therapeutics Committee Charter

PHARMACY & THERAPEUTICS COMMITTEE CHARTER

1. THE CPTC SHALL:

- a. Objectively appraise, evaluate, and select drugs for coverage on the HIM formulary and/or medical benefit and review the coverage requirements as directed by the Centers for Medicare and Medicaid Services (CMS) with at least 1 drug in every USP class and/or State specific benchmark requirements.
- b. Meet quarterly, and if necessary more frequently, to review and update the formulary 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. 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.
- c. Review and approve Drug Utilization Review (DUR) initiatives delegated to Envolve Pharmacy Solutions that are sent to the Ambetter Plans for provider or member intervention.
- d. Review and approve policies and procedures governing provisions of the Ambetter pharmacy benefits.
- e. Review and approve criteria guidelines for the use of restricted access drugs and non-formulary covered drug therapy.
- f. Review newly FDA-approved drug products within 90 days, and reach a coverage decision for each newly FDA-approved drug within 180 days of its market availability.

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2. **MEMBERSHIP & ORGANIZATION:**

The CPTC will be chaired by the Centene VP of Medical Affairs, or the Centene Chief Medical Officer or his/her designee. Voting members of the Committee will include practicing community-based practitioners and pharmacists representing various clinical specialties that adequately represent the needs of Ambetter 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 manufacturers, may be recruited, as deemed necessary, to provide input related to their areas of expertise and to provide advice on specialty practice standards. A quorum is required to transact business and make decisions. A quorum shall consist of more than 50% of members, 3 of whom must be community-based practitioners.

- a. At least 20 percent of the CPTC members will have no conflict of interest with respect to Centene Health Plans and pharmaceutical manufacturers.
- b. No CPTC 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.

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.

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. Once a member confirms willingness to continue a member will fill a subsequent two year appointment unless member resigns or attends less than 50% of P&T Committee meetings in a rolling 12 months.

3. **RESPONSIBILITIES:**

The CPTC will carry out its mission and perform 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:

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- i. Assessing peer reviewed medical literature, randomized clinical trials, pharmacoeconomic studies, and outcomes research data;
 - ii. Employing well established clinical practice guidelines developed by means of an evidenced-based process and making 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 and/or medical benefit 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 recognized 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 criteria guidelines for drug coverage to ensure that they reflect current market conditions and standards of care.
- b. Economic considerations that include, but are not limited to the following will be delegated to Strategy Development Committee:
- i. Basing formulary coverage decisions on cost factors only after the safety, efficacy and therapeutic need have been established by the CPTC
 - ii. Evaluating drug products and therapies in terms of their impact on total health care costs.
- c. Administrative considerations include, but are not limited to, the following:
- i. Notifying Ambetter Health Plans regarding any suggestions for additions, deletions or changes to the formulary, clinical guidelines, or utilization edits.
 - ii. Notifying Ambetter Health Plans, via committee meeting minutes, of the proceedings and decisions made by the Committee.

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- iii. Notifying Ambetter Health Plans of the Committee’s meeting schedule on an annual basis.

4. VOTING

- a. Attendance at the meeting is required for a vote to be counted.
- b. Permanent voting members not in attendance will not vote by proxy.
- c. All voting members have equal voting privileges.
- d. Decisions are documented by counting Yea, Nay, and Abstain options.

5. DELEGATED FUNCTIONS:

P&T delegates creation of oncology product(s) clinical criteria to an external vendor, for those plans that have signed delegation agreement(s). Such agreement(s) are subject to vendor oversight and annual review of external vendor clinical policies.

6. REVIEW OF CHARTER:

The CPTC will review this charter annually from the date of original approval or revision date, whichever is more current.

REFERENCES: 45 CFR 156.122(a)(3)

ATTACHMENTS: N/A

DEFINITIONS: N/A

REVISION LOG

REVISION	DATE
Changed reference from Corporate Pharmacy Department to US Script Utilization Management Pharmacy Department.	02/16
Changed reference from US Script Utilization Management Pharmacy Department to Envolve Pharmacy Solutions to reflect change in branding. Removed: “The secretary of the Committee will be Centene’s VP of Pharmacy or his/her designee” as there is no longer Corporate Pharmacy department. Under section b. added that the economic considerations will be delegated to Strategy Development	11/16

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Committee (SDC). Under section b. i. added “by the P&T Committee at the end of the sentence. Minor grammatical changes.	
Expanded section b. to include information on ad hoc meeting.	02/17
Reviewed Policy. No changes.	02/18
Reviewed Policy. Created new section #4 Delegated Functions.	02/19
Revised section 1. to add “and/or provided under the Ambetter Health Insurance Marketplace (HIM) medical benefit.” Revised section 2. a. and 4. v. to add “and/or medical benefit’. Under section 2. subsection b. added “via phone” to indicate that ad-hoc meetings can take place via phone as well.	02/20
Under Membership and Organization added: ”The Committee includes at least one practicing physician and one practicing pharmacist who are experts regarding the care of elderly or disabled individuals.” Edited Membership section to add: 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. AND 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. Once a member confirms willingness to continue a member will fill a subsequent two year appointment unless member resigns or attends less than 50% of P&T Committee meetings in a rolling 12 months. Added new section #4 VOTING Deleted: The Centene Pharmacy & Therapeutics Committee (CPTC) is responsible for reviewing, evaluating and deciding on changes to drugs listed for coverage and associated edits related to controls or limitations of drug coverage, and the policies and procedures governing provision of drug coverage under the	02/5/21

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Ambetter Health Insurance Marketplace (HIM) formularies and/or provided under the Ambetter Health Insurance Marketplace (HIM) medical benefit due to redundancy.	
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POLICY AND PROCEDURE APPROVAL

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