MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**202**	
Subject:	**Pharmacy & Therapeutics Committee**	
Section:	**Pharmacy**	
Initial Effective Date:	**06/06/2000**	
Revision Effective Date(s):	**07/18, 07/19, 07/20, 7/21, 11/21, 07/22, 7/23, 7/24, 7/25**	
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Review Effective Date(s):		
Historical Review Date(s):		
Responsible Parties:	**Health Plan Pharmacist, P&T Committee**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**MDH Standards and Reporting Requirements of Drug Use Management Programs for MCOs March 2025 edition Sections 1.0, 2.0. COMAR 10.67.06.04, NCQA 2025: UM 11A, 11B, 11D(2, 4) MD Medical Assistance Program MCO Transmittal No. 176, June 23, 2023**	
Approved:	**AVP Clinical Operations**	**Chief Medical Officer**

Purpose: **To standardize the structure and drug use management functions of the Pharmacy and Therapeutics (P&T) Committee to ensure compliance with regulatory requirements and NCQA standards.**

Scope: **MedStar Family Choice Maryland**

Policy: **The MedStar Family Choice P&T Committee oversees the management of the Pharmacy Benefit and medication formulary for Managed Care Organizations (MCO).**

Definition: **Medical Reviewer: Medical Director or Health Plan Pharmacist**

Procedure:

1. The P&T Committee manages the complete formulary.
    1.1. The Chairperson of the P&T Committee will be the Maryland Health Plan Pharmacist or other clinician appointed by the Chief Medical Officer.
    1.2. The P&T Committee meets five times per year.
        1.2.1. Quarterly in February, May, August, and November.
            1.2.1.1. Annual Policy Review is presented at the May P&T to approve policy updates that become effective July 1st.
        1.2.2. Annually in October for the full formulary review.
            1.2.2.1. Contents of the formulary preface are reviewed annually as part of the full formulary review.
    1.3. The P&T Committee has final authority to approve or deny all proposed changes to the MedStar Family Choice Formulary, including all utilization management (UM):
        1.3.1. Managed Drug Limitations (MDL) and/or Quantity Limits (QL)
            1.3.1.1. Age-limitations
            1.3.1.2. Gender-limitations
        1.3.2. Prior Authorization (PA) criteria,
        1.3.3. Step Therapy (ST) protocols,
        1.3.4. Copay tier designations for Brand drugs not otherwise defined by MDH,
        1.3.5. Any other clinical protocols that will impact MedStar Family Choice members.
    1.4. Evaluation for inclusion on the Formulary will include, but is not limited to:
        1.4.1. Pharmaceutical drug class,
        1.4.2. Clinical guidelines,
        1.4.3. Drug cost,
        1.4.4. Drug safety,
        1.4.5. Drug efficacy,
        1.4.6. Drug availability,
        1.4.7. Volume of member utilization; and
        1.4.8. Comparison of therapeutically equivalent treatments.
    1.5. The MedStar Family Choice formulary has a three-tiered copay structure outlined by MDH:
        1.5.1. Tier descriptions are maintained in the Preface of the Formulary document.
        1.5.2. Tier designations appear next to individual products on the Formulary document.
        1.5.3. Tier 0 products have no copay/cost to the member.
            1.5.3.1. Tier 0 products include:
                1.5.3.1.1. Family planning medications and devices
                1.5.3.1.2. Vaccines
        1.5.4. Tier 1 products have a $1.00 copayment per prescription.
            1.5.4.1. Tier 1 products include:
                1.5.4.1.1. All generic medications regardless of formulary status.
                1.5.4.1.2. All new and refill HIV/AIDS drugs.

1.5.4.1.3. Formulary preferred brand drugs. This is the default designation for formulary brand medications.

1.5.5. Tier 2 products have a $3.00 copayment per prescription.

1.5.5.1. Tier 2 products include:

1.5.5.1.1. Brand, formulary products when therapeutic equivalents are available on the formulary to promote lower-cost, formulary alternatives.

1.5.5.1.2. Brand, formulary products that are first-in-class medications where clinical guidelines establishing place in therapy are not yet available.

1.5.5.2. Assignment of a Tier 2 designation for a brand, formulary product shall be approved by the P&T Committee.

1.5.6. Non-formulary medications

1.5.6.1. Non-formulary medications that are brand-name, single-source products have a $3 copay requirement.

1.5.6.2. Non-formulary, generic products have a $1.00 copay requirement.

1.5.7. As defined by MDH, the following classes of individuals shall be exempt from any copay requirements described above:

1.5.7.1. Individuals under age 21.

1.5.7.2. Pregnant persons.

1.5.7.3. Individuals in hospice care or long-term care facilities.

1.5.7.4. Native American individuals.

1.5.7.5. Any individual who self-reports that they are unable to pay the copayment.

2. The P&T Committee will have representation from the network physicians, pharmacists, utilization management, nursing, pharmacy vendors and others as selected by MedStar Family Choice.

2.1. At least half of the voting members of the Committee shall be composed of healthcare practitioners with direct patient care responsibilities for MedStar Family Choice members including prescribing, dispensing, or administering medications.

2.1.1. This shall be recorded in the attendance section of the minutes.

2.2. Specialist practitioners will be consulted, as appropriate, for advice concerning medications being evaluated.

2.2.1. The content of such advice shall be reported into the minutes.

3. Voting will be by simple voice consensus unless there is a dissenting voice, in which case a formal vote shall take place with a simple majority to carry the vote.

4. Members of the P&T Committee will be expected to abide by MedStar Family Choice Policy 711: Conflict of Interest as it pertains to their role on the Committee.

4.1. When the P&T Meeting Agenda is distributed, the manufacturer of any drug or product to be reviewed will be published.

4.2. Any member of the P&T Committee with an interest or relationship to a manufacturer of a reviewed drug or product shall abstain from participating in any action or vote related to the proposed drug or product.

5. The Chairperson is responsible for overseeing MedStar Family Choice P&T Committee activities as described below:
   5.1. Prepare and disseminate the consent and meeting agendas at least one week prior to the scheduled P&T meetings.
   5.2. Develop meeting content, including DUE, drug utilization information, drug safety information, and recommendations for MDL, PA criteria, ST protocols, Copay Tier designation, and any other clinical updates that will impact members of MedStar Family Choice.
   5.3. Update and maintain the Prior Authorization and Step Therapy table.
      5.3.1. The P&T Committee shall review and approve the criteria.
      5.3.2. PA and ST criteria and protocols shall be reviewed at least annually.
   5.4. Create and maintain minutes for each meeting.
      5.4.1. Provide Minutes, along with Policies and Procedures, at the request of the Maryland Department of Health (MDH).
      5.4.2. Submit minutes for review and approval by Committee members via email within 45 days of the meeting date.
   5.5. Submit all Formulary changes monthly to MDH via the Formulary Navigator.
   5.6. Prepare for MDH approval all member and/or provider formulary change notification letters.
      5.6.1. Negative formulary change notification will occur not less than 30 calendar days prior to the effective date of the change.
         5.6.1.1. Communications may occur via secure email for network providers or via USPS for out-of-network providers.
   5.7. Collaborate with the MedStar Family Choice contracted pharmacy benefits manager (PBM) to:
      5.7.1. Update the MedStar Family Choice formulary coding.
      5.7.2. Obtain quarterly documents that capture all formulary information in JSON and PDF formats as required for MedStar Family Choice to post on its website.
         5.7.2.1. Interim formulary changes may not be reflected online until the next quarterly document update.
         5.7.2.2. The PBM will provide at least annually an opportunity to update the Formulary Preface statement. The updates may include, may not limited to:
            5.7.2.2.1. Copayment/coinsurance requirements and the products to which they apply.
            5.7.2.2.2. Definitions of UM requirements.
            5.7.2.2.3. List of preferred formulary products.
            5.7.2.2.4. Medications covered under the medical benefit but have PA requirements established by the P&T Committee.

5.7.3. Update all Specialty medication lists and associated MDL to post on the website.

5.8. May make urgent formulary change decisions e.g., additions, removals, changes to PA, ST or utilization management criteria without prior approval from the P&T Committee.

5.8.1. Interim decisions will be reviewed by the Committee at the next scheduled P&T Committee meeting.

5.8.2. The Committee has final authority to approve or modify the decision(s).

5.9. Ensure all current formulary information is posted publicly.

5.9.1. All pharmacy benefit UM requirements are indicated within the formulary document.

5.9.2. Criteria for all ST protocols and PA requirements are included on the MedStar Family Choice Prior Authorization and Step Therapy Tables.

5.9.3. A summary of upcoming formulary changes will be posted to the MedStar Family Choice website at least 30-days prior to the effective date of the change.

5.9.4. A summary of upcoming formulary changes will be included in the Quarterly Provider Newsletter.

5.10. Coordinate the annual review of policies and procedures in accordance with Policy 208: P&T Policy and Procedure Review.

Summary of Changes:	**07/25:** • Updated all NCQA, MCO Standards, and COMAR to current references. • Added section 1.2.2 to acknowledge annual policy updates. • Added subsections 1.3.1.1 and 1.3.1.2 to capture all UM features. • Section 1.4: removed the word “continued” for clarity. • Added “Pharmaceutical Drug class” as Section 1.4.1. • Section 2: Corrected “quality management” to “utilization management”. • Added sections 5.6.1 and 5.6.1.1 for clarity and completeness. • Added the clause “but are not limited to…” to section 5.7.2.2. • Added section 5.7.3 to capture publication of Specialty Drug quantity limits. • Added section 5.9.4 to capture required provider communications. **07/24:** • Moved P&T Committee listing from “Responsible Department” to “Responsible Parties” section. • Reformatted font and procedure to improve readability. • Updated all NCQA, MCO Standards, and COMAR to current year references. • Updated policy Approver titles and removed individual names. • Clarified Purpose statement. • Removed “Review and Approve Drug Safety programs”. (6) • Replaced MFC abbreviations for standardized referencing.

	• Added references to annual update of formulary Preface. • Added time frames for P&T Communications. • Added Section 1.5 all references to Copays and Tier assignments due to new copay regulations eff. 5/1/2024. • Added Policy 711 reference for Conflicts of Interest. • Expanded listing of PBM related tasks for completeness. • Added references to maintaining Specialty medication info. • Added Formulary change letters to responsibilities of P&T Chairperson. • Added information regarding review and approval of PA/ST criteria. • Transferred procedures for communicating negative formulary changes to members to Pharmacy Policy 209, Section 5.3 • Transferred policy describing timing of formulary changes to Pharmacy Policy 209: Section 6. **07/23:** • Responsible Parties changed to Health Plan Pharmacist • Updated regulatory reference to March 2023 MDH Standards • Updated NCQA Reference to 2023 Standards • Updated Approved by to: Dr Wills and C. Attia • Updated Statement 6.f. to updated web location: https://dsd.maryland.gov/regulations/Pages/10.67.06.04.aspx • Reorganized Procedure section to align with current P&T Committee processes, including creating a section describing the role and responsibilities of the P&T Committee Chairperson. • Removed details about communication of Formulary information to providers and members, and added a reference to the policy that describes this process. **07/22:** • Removed reference to jurisdictions. • Removed Dr. Toye and Dr. Gerry as Responsible parties. Added Dr. Gregory Dohmeier as Responsible party. • Updated regulatory reference to April 2022 MDH Standards Updated NCQA Reference to 2022 Standards • Add Statement to 6f **-** Unless approved by the Department, an MFC will not require or utilize prior authorization or step therapy criteria for coverage of formulary drugs if such prior authorization or step therapy requires a participant to use a drug that is included in the pharmacy carve out program as stated in COMAR 10.67.06.04(E)(6) (http://www.dsd.state.md.us/comar/comarhtml/10/10.67.06.04.htm) . **11/21:**

	• Changed meeting schedule from every other month/no less than 5X per year to meeting quarterly and October for a total of 5 meetings per year. **07/21:** • Added Maryland to scope. • Changed Case Management to Clinical Operations in Responsible Departments. **07/20:** • Updated Regulatory References to reflect 2020 NCQA Standards. • Added that the P&T Committee does an annual review of the formulary. • Removed references to paper formulary booklets. **07/19:** • Updated NCQA Reference to reflect 2019 Standards. • Removed “Maryland” from scope. **07/18:** • Updated NCQA regulatory references to reflect 2018. • Modified Effective Date to Initial Effective Dates; added Historical Revision Dates and Revision Effective Dates; and added Historical Review Dates and Review Effective Dates. **11/17:** • Removed District references, changed DHMH to MDH. **07/17:** • Updated titles and regulatory references. Removed DC CAB as there is no group that is meeting, removed posting to DHCF website as that is not done. **10/16:** • Removed reference to ePocrates. **10/15:** • Under #5, added h. – regarding monthly report to DH.