MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**209**	
Subject:	**Pharmacy Benefits Management**	
Section:	**Pharmacy**	
Initial Effective Date:	**06/04/2000**	
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Historical Revision Date(s):	**09/01, 04/03, 04/04, 10/05, 10/06, 10/07, 10/08, 10/09, 10/10, 10/11, 09/12, 10/13, 10/14, 07/17, 11/17, 7/18**	
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 2.0, 3.0, 4.0 March 2024. 2021 MDH High-Cost, Low-Volume Drug Risk Mitigation Policy COMAR 10.34.10.01C (2), COMAR 10.67.06.04, COMAR 10.09.03.05(14) and C (3) NCQA 2024: UM 11A: 1, 2, 4, UM 11B 1, 2, 3, 5; UM 11D, ME 5D United States Code of Federal Regulations 1396r-8(d)(2)(h)**	
Approved:	**AVP Clinical Operations**	**Chief Medical Officer**

Purpose: To ensure that the MedStar Family Choice has standard processes in place for Pharmacy Benefits Management, as overseen by the Pharmacy & Therapeutic (P&T) Committee.

Scope: MedStar Family Choice Maryland

Policy: MedStar Family Choice P&T Committee oversees the Pharmacy Benefit; including management of the closed formulary, utilization management, and implementation of all approved changes. To ensure that all members and providers have the most current

Pharmacy Benefit information, MedStar Family Choice Maryland adheres to standard processes for communicating all formulary updates per NCQA and Maryland state requirements.

Definition: Medical Reviewer: Medical Director or Health Plan Pharmacist

Procedure:

1. FORMULARY MANAGEMENT

1.1. The MedStar Family Choice P&T Committee is responsible for managing the formulary.

1.2. Medications and Durable Medical Equipment and supplies that are administered in an outpatient setting or dispensed from a retail pharmacy may be considered for inclusion on the formulary.

1.2.1. Exceptions to the scope of the formulary may be made to apply utilization management (UM) criteria to medications administered through the medical benefit whereas criteria could not otherwise be applied but are clinically or fiscally prudent.

1.3. MedStar Family Choice may exclude from coverage any medication ordered for an excluded benefit, as limited in COMAR 10.09.03.05 or the United States Code of Federal Regulations 1396r-8(d)(2)(h).

1.3.1. Pharmacy benefit exclusions include but are not limited to:

1.3.1.1. Medications ordered for weight management.

1.3.1.2. Experimental or investigational drugs.

1.3.1.3. Medications ordered to treat sexual or erectile dysfunction.

1.3.1.4. Medications ordered for cosmetic purposes.

1.3.1.5. Medications ordered for off-label indications.

1.3.2. Medications that are only Food and Drug Administration (FDA)-approved for an excluded benefit will be excluded from the MedStar Family Choice formulary.

1.4. Medications carved out to the MDH.

1.4.1. MDH maintains a list of medications that are excluded from coverage by the MCO and are covered under the MDH with their own separate formulary and UM. These medications include:

1.4.1.1. Behavioral Health (Mental Health and Substance Abuse)

1.4.1.2. Anticonvulsants

1.4.1.3. Antiparkinson Agents

1.4.1.4. Attention Deficit Hyperactivity Disorder for members aged 6-17 years.

1.4.1.5. Fibromyalgia

1.4.1.6. Movement Disorders

1.4.1.7. Musculoskeletal Therapy Agents

1.4.1.8. Alcohol Deterrents

1.4.1.9. Opioid Antagonists

1.4.1.10. Partial Opioid Antagonists

1.4.1.11. Partial Opioid Agonist/Antagonist combinations

1.4.1.12. Smoking Deterrents

1.5. MedStar Family Choice prefers generic and biosimilar medications when available.
   1.5.1. Innovator products on the formulary will be automatically replaced when interchangeable generic or biosimilar products become available.
1.6. Medications may be identified to bring to a P&T committee meeting for formulary consideration based on:
   1.6.1. New FDA approval of a medication or new indication for use.
   1.6.2. Discussion with MedStar Family Choice staff members.
   1.6.3. Maryland State Department of Health (MDH) requirements.
   1.6.4. Recommendations from pharmacy vendors or vendors associated with MedStar Family Choice Maryland.
   1.6.5. Suggestions from MedStar Family Choice Staff.
   1.6.6. Recommendations from other MedStar Family Choice Committees.
   1.6.7. Non-formulary emergency override reports.
   1.6.8. Newly released generic medications if the brand is non-formulary.
1.7. Medications are selected for inclusion or exclusion on the closed Formulary based upon discussion within the MedStar Family Choice P&T Committee. Discussion may include the following types of information about a medication:
   1.7.1. Drug monograph information including generic name, brand name(s), manufacturer, dosage forms and strengths, FDA approved/labeled indication, mechanism of action, pharmacokinetics and pharmacodynamics, adverse effects, drug interactions, monitoring parameters, dosage, schedule, and administration.
   1.7.2. Evaluation of clinical trials
   1.7.3. Comparison of clinical therapeutics
   1.7.4. Evaluation of available pharmacoeconomic studies
   1.7.5. Comparative cost information to clinically equivalent formulary alternatives
   1.7.6. Current utilization if any
   1.7.7. Formulary recommendations, including any associated utilization management restrictions.
1.8. The P&T Committee will consider relevant findings from government agencies, medical literature and journals, national guidelines, MedStar Health practice guidelines, MedStar Health subject matter experts, and other sources such as large commercial insurance carriers, as applicable when considering a medication for formulary inclusion.
1.9. Formulary change requests should be submitted to the Chairperson of the P&T Committee.
   1.9.1. Criteria and rationale for additions or deletions must be supplied to the Committee by the requesting party.
   1.9.2. Requests can be made:
      1.9.2.1. Via email at MFC-FormularyFeedback@MedStar.net
      1.9.2.2. Via phone at 410-933-2200
      1.9.2.3. Via fax at 410-933-2274 or
      1.9.2.4. Via postal mail: Chairperson, P&T Committee, MedStar Family Choice, 5233 King Avenue, Suite 400, Baltimore, MD 21237.

1.9.3. All formulary requests will be brought to the P&T Committee within two meeting cycles from the initial submission to the Chairperson.

1.10. All medications included in the closed Formulary are reviewed annually by the P&T Committee, as described in Pharmacy Policy #202: Pharmacy & Therapeutics Committee.

1.10.1. Annual formulary review encompasses a complete review of all utilization management requirements as described in Sections 3 and 4 of this Policy.

2. PRESCRIPTION PLAN COVERAGE (DAY SUPPLY LIMITS)

2.1. A 30-day supply of medication is the standard covered benefit.

2.2. A 90-day supply of medication is the standard covered benefit for maintenance medications as defined in COMAR 10.09.03.01. "Maintenance medication" means medication in chronic therapeutic categories corresponding to the following American Hospital Formulary Service (AHFS) classification numbers:

2.2.1. Cardiac drugs (24:04)
2.2.2. Antilipemic agents (24:06)
2.2.3. Hypotensive agents (24:08)
2.2.4. Vasodilating agents (24:12)
2.2.5. Sclerosing agents (24:16)
2.2.6. Alpha-adrenergic blocking agents (24:20)
2.2.7. Beta-adrenergic blocking agents (24:24)
2.2.8. Calcium-channel blocking agents (24:28)
2.2.9. Renin-angiotensin-aldosterone system inhibitors (24:32)
2.2.10. Hydantoins (28:12:12), excluding carveout.
2.2.11. Oxazolidinediones (28:12:16)
2.2.12. Succinimides (28:12:20)
2.2.13. Anticonvulsants, miscellaneous (28:12:92); (excluding carveout)
2.2.14. Replacement solutions (40:12) (potassium supplements only)
2.2.15. Diuretics (40:28)
2.2.16. Lipotropic agents (56:24)
2.2.17. Contraceptives (68:12)
2.2.18. Estrogens and antiestrogens (68:16)
2.2.19. Antidiabetic agents (68:20)
2.2.20. Antihypoglycemic agents (68:22)
2.2.21. Parathyroid (68:24)
2.2.22. Progestins (68:32)
2.2.23. Thyroid and antithyroid agents (68:36)
2.2.24. Vitamins (88:00)
2.2.25. Sodium fluoride (92:00), and
2.2.26. Iron preparations, oral (20.04.04) (oral products in which ferrous sulfate is the only active ingredient and chewable tablets of any ferrous salt if combined with vitamin C, multivitamins, multivitamins and minerals, or other minerals in the formulation).

2.3. Members may obtain 90-day supplies of maintenance medication from any in-network retail pharmacy or through the Pharmacy Benefit Manager's (PBM) Mail Order Pharmacy.
  2.3.1. Members are not required to use Mail Order Pharmacy Services for any reason.
  2.3.2. If a non-formulary medication request is approved for a maintenance medication as defined in Section 2.2 of this policy, then the entered override will allow a 90-day supply to be dispensed.
2.4. Exceptions to standard 30- or 90-day supply limits:
  2.4.1. The P&T Committee may adjust the covered benefit day supply for certain medications to align with clinically appropriate use and/or product package sizes.
  2.4.2. Oral contraceptive medications may be dispensed for up to a 365-day supply.

3. HIGH-COST, LOW-VOLUME MEDICATIONS

3.1. High-cost, low-volume medications (HCLV) have an expected annual cost greater than $500,000 per member.
3.2. MedStar Family Choice is responsible for authorizing, managing, and paying all claims related to medications in this category.
  3.2.1. MedStar Family Choice shall invoice MDH for incurred expenses on a quarterly basis.
3.3. MedStar Family Choice is expected to develop and adhere to medical necessity criteria to ensure that all instances of utilization of HCLV medications follow clinical best practices.
  3.3.1. Clinical criteria for PA are maintained in a separate document titled "MedStar Family Choice High-Cost Medication PA Criteria" which is posted on the MedStar Family Choice Maryland website.
3.4. MedStar Family Choice may be asked to evaluate a request for a HCLV medication before such criteria are established.
  3.4.1. A PA is required regardless of formulary status to comply with MDH expectations.
  3.4.2. All requests for authorization of a HCLV medication must be reviewed by a Medical Reviewer.
  3.4.3. The duration of a PA for HCLV medications will be limited to a maximum of 3 months to facilitate the quarterly collection of updated clinical documentation required by MDH.
    3.4.3.1. The duration of authorization may be reduced based on clinical appropriateness.
  3.4.4. HCLV medications will be presented to P&T with a recommendation to add to formulary with PA requirements even if outside of the scope of the outpatient formulary, i.e., when covered under the Medical Benefit, to establish standardized criteria.

4. UTILIZATION MANAGEMENT

4.1. The P&T Committee will determine which formulary medications will have utilization management (UM) requirements, which may include but are not limited to:

- 4.1.1. Step Therapy (ST) protocols,
- 4.1.2. Prior Authorization (PA) criteria,
- 4.1.3. Managed Drug Limitations (MDL) and/or Quantity Limits (QL),
- 4.1.4. Age, gender
- 4.1.5. Copay tier designations for Brand drugs not otherwise defined by MDH,
- 4.1.6. Any other clinical protocols that will impact MedStar Family Choice members.

4.2. Step therapy is a process that requires members to trial one or more formulary medications prior to accessing the medication prescribed by the provider.

- 4.2.1. Specific ST criteria is included in the "Prior Authorization and Step Therapy Table" found on the MedStar Family Choice website.
  - 4.2.1.1. Application of ST requirements may be automated by the pharmacy benefits manager (PBM).
  - 4.2.1.2. If the claims history does not support an automatic approval of the medication, a manual PA request will be required.
    - 4.2.1.2.1. The request will be processed as described in pharmacy Policy 218: Prior Authorization Process.

4.3. Prior authorization is a prospective process that requires prescribers to obtain approval from MedStar Family Choice before a specific medication is dispensed to the member.

- 4.3.1. Specific PA criteria is maintained in the "Prior Authorization and Step Therapy Table" and posted on the MedStar Family Choice website.
- 4.3.2. The PA criteria is established and approved by the P&T Committee.
- 4.3.3. Criteria is reviewed at least annually to evaluate and update the content.
- 4.3.4. Aggregate PA data will be reviewed annually to determine the clinical utility of the requirements and may be brought to P&T for evaluation.
- 4.3.5. PA criteria includes, but is not limited to:
  - 4.3.5.1. Medication name (brand, generic, dosage form, and strengths)
  - 4.3.5.2. Any MedStar Family Choice specific requirements, including covered indications.
  - 4.3.5.3. Duration of authorization.
  - 4.3.5.4. Renewal Criteria – continuation of therapy beyond first approval.
- 4.3.6. MedStar Family Choice reserves the right to consult clinical resources in addition to the PA table to determine medical necessity for indications that are not directly addressed by the PA criteria.
- 4.3.7. When a formulary medication is FDA-approved for an indication that is an excluded benefit as described in Policy 205: Non-Formulary Medications, MedStar Family Choice will require PA to validate the ordered indication.

4.4. Managed drug limitations (MDL) and Quantity limits (QL) are limits that may be applied to formulary medications to promote appropriate utilization for reasons including, but not limited to:

- 4.4.1. FDA-labelled maximum daily doses.

4.4.2. FDA-labelled maximum therapy durations.
4.4.3. Clinical guidelines for use.
4.4.4. To identify and prevent clinical inertia.
4.4.5. Potential safety or utilization concerns.

4.5. Age, gender, or other limitations are UM features that may be applied to formulary medications to align with FDA-approved product labelling.

4.6. Specialty medications are defined by MDH based on cost, complexity of therapy, unusual storage requirements, and/or limitations on distribution channels.

4.6.1. Due to the complexity of Specialty medications, MedStar Family Choice reserves the right to delegate formulary and/or utilization management to the contracted PBM.

5. COMMUNICATION OF PHARMACEUTICAL UTILIZATION CHANGES

5.1. Formulary changes will:

5.1.1. Be posted quarterly to the MedStar Family Choice website.

5.1.1.1. Negative formulary changes (e.g., removal from the formulary or addition of PA or ST requirements) will be posted to the MedStar Family Choice website no less than 30 days prior to implementation of the change.

5.1.2. Be disseminated in the MedStar Family Choice Provider Newsletter.

5.1.3. Be disseminated in the MedStar Family Choice Member Newsletter, if applicable.

5.1.4. Be submitted monthly to MDH via email.

5.1.4.1. A copy of any formulary-change letters sent to providers and/or members will be included with the monthly submission.

5.2. Current PA and/or ST requirements will be posted quarterly to the MedStar Family Choice website.

5.3. Members impacted by negative formulary changes e.g., removals, addition of PA or ST criteria, MDL etc., shall be notified by U.S. postal mail no less than 30 days before the change becomes effective.

5.3.1. The content of the member notification letters shall be submitted to MDH, and approval received prior to mailing.

5.4. Prescribers of medications impacted by negative formulary changes e.g., removals, addition of PA or ST criteria, MDL, etc., shall be notified via electronic or postal mail no less than 30 days before the change becomes effective.

5.4.1. Prescribers will be provided with the names of individual patients affected by the formulary change.

5.5. The content of the provider notification letters shall be submitted to MDH, and approval received prior to distribution.

5.6. The Formulary Preface is maintained as part of the Formulary Document.

5.6.1. Is updated not less than annually.

5.6.2. The current formulary document is maintained on the MedStar Family Choice website and is updated quarterly, but no less than annually.

5.6.3. Includes information describing how to use the pharmaceutical management procedures and utilization requirements:

5.6.3.1. Generic substitution processes.

5.6.3.2. Process for initiating medical exception, prior authorization, and non-formulary requests.

5.7. A printed copy of any and all pharmaceutical management procedures, policies, protocols, etc., will be made available upon request.

5.8. Written notification of the availability of the updated information will be made at the time of member enrollment and at least annually.

5.9. "Frequently Asked Questions" resources for navigating the Pharmacy Benefits are available on the MedStar Family Choice website for both members and providers.

5.9.1. Topics addressed include, but are not limited to:

5.9.1.1. Explanation of medication limits,

5.9.1.2. How prescribers must provide information to support an exception request,

5.9.1.3. Process for generic substitution, therapeutic interchange, and step therapy protocols.

5.10. MedStar Family Choice updates member pharmacy benefit information on its website and in materials used by telephone staff, prior to the effective date of a formulary change.

5.10.1. Quarterly summaries of all formulary changes are posted on the website.

5.10.2. A representative of the P&T Committee will attend quarterly Member Service meetings to convey notice of changes and support member-facing staff whose responsibilities include communicating with members regarding formulary content.

6. TIMING OF FORMULARY CHANGE IMPLEMENTATION

6.1. Additions of medications may be implemented at any time.

6.1.1. Interim additions of medications will be reviewed at the next occurring P&T meeting.

6.1.2. The Committee has final authority to approve or change the addition.

6.2. Changes or additions to PA criteria, ST protocols, MDL, and copay tier designations are implemented following the regular schedule of P&T meetings.

6.2.1. Relaxation of PA criteria or ST protocols may be implemented at any time to respond to updates of Standards of Care or changes to the availability of formulary alternatives.

6.2.1.1. Interim adjustments to PA or ST requirements will be reviewed at the next occurring P&T meeting.

6.2.1.2. The Committee has final authority to approve or change the modifications.

6.3. Removals of medications from the formulary are implemented following the regular schedule of P&T meetings.

6.3.1. Removals become effective on the first day of the second full month following the meeting date.

6.3.2. Exceptions listed below may be removed on an interim basis:

6.3.2.1. Brand drugs when a generic equivalent becomes available.

6.3.2.2. Innovator biologics when a biosimilar therapeutic equivalent becomes available.
6.3.2.3. Upon FDA removal of a medication from the marketplace.
6.3.2.4. Upon manufacturer withdrawal of a drug product.
6.3.3. The P&T Committee may elect to permit continued coverage of medications removed from the formulary for current utilizers.
6.3.3.1. If current utilizers are permitted access to medication, no member-specific notification of the formulary change is required.

Summary of Changes:	**07/24:** • Changed title from "Review, Selection & Evaluation of Meds Included in the Closed Formulary" to "Pharmacy Benefit Management" to reflect all current content. • 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. • Aligned the Purpose statement and Policy statement with the updated content. • Incorporated the content of retired policies: 200: Additions and Deletions to the Formulary (1) 204: Section re: 90-day supplies (2.2, 2.3) 210: Step Therapy (2.5) 212: Prior Authorization (2.6) 214: P&T Website Update (3) 215: PA Table Review (1.10.1; 2.6; 3.1, 3.2) 222: Specialty Pharmacy (2.9) • Added description of benefit excluded medications (1.3) and medications carved out to FFS (1.4) • Established that brand product coverage converts to generic once available (1.5.1) • Added statement that all formulary requests will be brought to P&T within 2 meeting cycles (1.9.3). • Included description of MDL/QL as part of UM (3.4) • Added that provider notification may occur via electronic mail (4.4) • Consolidated redundant content. **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 **07/22:** • Responsible Parties changed to Dr. Gregory Dohmeier • Removed from Responsible Parties: Dr. Gerry and Dr. Toye • Updated Regulatory Reference to April 2022 MDH Standards • Updated NCQA Reference to 2022 Standards **07/21:** • Updated NCQA Reference to reflect 2021 Standards. • Added Maryland to scope. • Changed Case Management to Clinical Operations in Responsible Departments **05/21:** • Updated expert process for evaluating new medications. **07/20:** • Updated Regulatory References to reflect 2020 NCQA Standards. **07/19:** • Updated NCQA Reference to reflect 2019 Standards. • Removed “Maryland” from scope. **07/18:** • Revised #6 to more precisely reflect which medications are chosen for review (outpatient administration and/or from retail pharmacy). • 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. **07/17:** • Updated titles and regulatory references. **10/16:** • No changes. **10/15:** • No changes.