MedStar Family Choice

DISTRICT OF COLUMBIA

| ADMINISTRATIVE POLICY AND PROCEDURE | | |
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| **Policy #:** | **209.DC** | |
| **Subject:** | **Pharmacy Benefits Management** | |
| **Section:** | **Pharmacy** | |
| **Initial Effective Date:** | **10/01/2020** | |
| **Revision Effective Date(s):** | **07/21, 7/22, 07/23, 07/24** | |
| **Review Effective Date(s):** | | |
| **Responsible Parties:** | **Health Plan Pharmacist, P&T Committee** | |
| **Responsible Department(s):** | **Clinical Operations** | |
| **Regulatory References:** | **District of Columbia Contract: Section C.5.28.13<br>NCQA 2024: UM 11A(1,2,4), UM 11B(1,2,3,5); UM 11D, ME 5D<br>United States Code of Federal Regulations 1396r-8(d)(2)(h)** | |
| **Approved:** | **AVP Clinical Operations** | **Senior Medical Director (Chief Medical Officer-DC)** |

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

**Scope:** **MedStar Family Choice DC**

**Policy:** **The MedStar Family Choice DC 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 Enrollees and providers have access to the most current Pharmacy Benefit information, MedStar Family Choice DC adheres to standard processes for communicating all formulary updates per NCQA and DC Department of Healthcare Finance (DHCF) requirements.**

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

**Procedure:**

1. **FORMULARY MANAGEMENT**
   1.1. The MedStar Family Choice DC 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 DC may exclude from coverage any medication ordered for an excluded benefit, as limited in 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 only Food and Drug Administration (FDA)-approved for an excluded benefit will be excluded from the Medstar Family Choice DC formulary.
1.4. Medications carved out to DHCF.
    1.4.1. Medications ordered for HIV treatment and prevention are covered under the DHCF benefit for certain Enrollees as described in pharmacy Policy 223.DC HIV Treatment; Prior Authorization for PrEP and PEP for HIV Prophylaxis.
1.5. Medstar Family Choice DC 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 DC staff members;
    1.6.3. DHCF requirements;
    1.6.4. Recommendations from pharmacy vendors or vendors associated with Medstar Family Choice DC;
    1.6.5. Suggestions from Medstar Family Choice DC 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 DC 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: 3007 Tilden Street, NW - POD 3N Washington, DC 20008.
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.DC: Pharmacy & Therapeutics Committee.

1.10.1. Annual formulary review encompasses a complete review of all utilization management requirements as described in Section 3 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 certain maintenance medications as approved by the P&T Committee.

2.2.1. Enrollees 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.
2.2.2. Enrollees are not required to use Mail Order Pharmacy Services for any reason.

2.3. Exceptions to standard 30- or 90-day supply limits:

2.3.1. 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.

2.3.2. Oral contraceptive medications may be dispensed for up to a 365-day supply.

## 3. UTILIZATION MANAGEMENT

3.1. The P&T Committee will determine which formulary medications will have utilization management (UM) requirements, which may include but are not limited to:
- 3.1.1. Step Therapy (ST) protocols,
- 3.1.2. Prior Authorization (PA) criteria,
- 3.1.3. Managed Drug Limitations (MDL) and/or Quantity Limits (QL),
- 3.1.4. Age, gender limitations,
- 3.1.5. Any other clinical protocols that will impact Medstar Family Choice DC Enrollees.

3.2. Step therapy is a process that requires Enrollees to trial one or more formulary medications prior to accessing the medication prescribed by the provider.
- 3.2.1. Specific ST criteria is included in the Prior Authorization and Step Therapy Table.
  - 3.2.1.1. Application of ST requirements may be automated by the pharmacy benefits manager (PBM).
  - 3.2.1.2. If the claims history does not support an automatic approval of the medication, a manual PA request will be required.
    - 3.2.1.2.1. The request will be processed as described in pharmacy Policy 218.DC: Prior Authorization Process.

3.3. Prior authorization is a prospective process that requires prescribers to obtain approval from Medstar Family Choice DC before a specific medication is dispensed to the Enrollee.
- 3.3.1. Specific PA criteria is maintained in the Prior Authorization and Step Therapy Table.
- 3.3.2. The PA criteria is established and approved by the P&T Committee.
- 3.3.3. Criteria is reviewed at least annually to evaluate and update the content.
- 3.3.4. Aggregate PA data will be reviewed annually to determine the clinical utility of the requirements and may be brought to P&T for evaluation.
- 3.3.5. PA criteria includes, but is not limited to:
  - 3.3.5.1. Medication name (brand, generic, dosage form, and strengths)
  - 3.3.5.2. Any Medstar Family Choice DC specific requirements, including covered indications.
  - 3.3.5.3. Duration of authorization.
  - 3.3.5.4. Renewal Criteria – continuation of therapy beyond first approval.
- 3.3.6. Medstar Family Choice DC 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.
- 3.3.7. When a formulary medication is FDA-approved for an indication that is an excluded benefit as described in Policy 205.DC: Non-Formulary Medications, Medstar Family Choice DC will require PA to validate the ordered indication.

3.4. 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:
  3.4.1. FDA-labelled maximum daily doses.
  3.4.2. FDA-labelled maximum therapy durations.
  3.4.3. Clinical guidelines for use.
  3.4.4. To identify and prevent clinical inertia.
  3.4.5. Potential safety or utilization concerns.
3.5. Age, gender, or other limitations are UM features that may be applied to formulary medications to align with FDA-approved product labelling.
3.6. Specialty medications are defined based on cost, complexity of therapy, unusual storage requirements, and/or limitations on distribution channels.
  3.6.1. Due to the complexity of Specialty medications, Medstar Family Choice DC reserves the right to delegate formulary and/or utilization management to the contracted PBM.

## 4. COMMUNICATION OF PHARMACEUTICAL UTILIZATION CHANGES

4.1. Formulary changes will:
  4.1.1. Be posted quarterly to the Medstar Family Choice DC website.
    4.1.1.1. Negative formulary changes (e.g., removal from the formulary or addition of PA or ST requirements) will be posted to the Medstar Family Choice DC website no less than 30 days prior to implementation of the change.
  4.1.2. Be disseminated in the Medstar Family Choice DC Provider Newsletter.
  4.1.3. Be disseminated in the Medstar Family Choice DC Enrollee Newsletter, if applicable.
4.2. Current PA and/or ST requirements will be posted quarterly to the Medstar Family Choice DC website.
4.3. Enrollees 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.
  4.3.1. The content of the Enrollee notification letters shall be submitted to DHCF, and approval received prior to mailing.
4.4. 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.
  4.4.1. Prescribers will be provided with the names of individual Enrollees effected by the formulary change.
4.5. The Formulary Preface is maintained as part of the Formulary Document.
  4.5.1. The preface is updated not less than annually.
  4.5.2. The current formulary document is maintained on the Medstar Family Choice DC website and is updated quarterly, but no less than annually.
  4.5.3. Includes information describing how to use the pharmaceutical management procedures and utilization requirements:
    4.5.3.1. Generic substitution processes.

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

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

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

4.8. "Frequently Asked Questions" resources for navigating the Pharmacy Benefits are available on the Medstar Family Choice DC website for both Enrollees and providers.

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

4.8.1.1. Explanation of medication limits,

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

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

4.9. Medstar Family Choice DC updates Enrollee pharmacy benefit information on its website and in materials used by telephone staff, prior to the effective date of a formulary change.

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

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

## 5. TIMING OF FORMULARY CHANGE IMPLEMENTATION

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

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

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

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

5.2.1. 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.

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

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

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

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

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

5.3.2.1. Brand drugs when a generic equivalent becomes available.

5.3.2.2. Innovator biologics when a biosimilar therapeutic equivalent becomes available.
5.3.2.3. Upon FDA removal of a medication from the marketplace.
5.3.2.4. Upon manufacturer withdrawal of a drug product.

5.3.3. The P&T Committee may elect to permit continued coverage of medications removed from the formulary for current utilizers.

5.3.3.1. If current utilizers are permitted access to medication, no Enrollee-specific notification of the formulary change is required.

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| **Summary of Changes:** | **07/24:**<br>• Content incorporated from retiring Pharmacy Policies:<br>  ○ 200.DC: Additions and Deletions to the Formulary (1)<br>  ○ 210.DC: Step Therapy (2.5)<br>  ○ 212.DC: Prior Authorization (2.6)<br>  ○ 214.DC: P&T Website Update (3)<br>  ○ 215.DC: PA Table Review (1.10.1; 2.6; 3.1&2)<br>  ○ 222.DC: Specialty Pharmacy (2.9)<br>  ○ 204.DC: section about 90-day supplies (2.2&3)<br>• Changed title from “Review, Selection & Evaluation of Meds Included in the Closed Formulary” to “Pharmacy Benefit Management” to reflect updated scope<br>• Updated Regulatory references<br>  ○ Expanded NCQA listings to include specific factors, added ME 5D<br>  ○ Added US Code of Federal Regulations reference as described in DC Contract<br>• Aligned the Purpose and Policy statements with updated scope<br>• Added description of benefit excluded medications (1.3) and medications carved out to DHCF (1.4)<br>• Established that brand product coverage switches to generic once available (1.5.1)<br>• Added statement that all formulary requests will be brought to P&T within 2 meeting cycles (1.9.3)<br>• Included description of MDL/QL as part of UM (3.4)<br>• Added that provider notification may occur via electronic mail (4.4) |

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| | • Updated Section listing from “P&T Committee” to “Pharmacy”<br>• Moved P&T Committee from “Responsible Department” to “Responsible Parties”<br>• Updated Approver section Names and Titles<br>  ○ Sharon Henry, RN AVP Clinical Operations<br>  ○ Erica McClaskey, MD, MS, FAAFP Senior Medical Director<br>• Updated to NCQA 2024 regulatory reference<br>• Reformatted procedure section to improve clarity and removed redundancy<br>• Changed all MFC-DC abbreviations to “MedStar Family Choice DC”<br><br>**07/23:**<br>• Updated NCQA Reference to 2023 Standards<br><br>**07/22:**<br>• Updated Responsible Parties to Plan Pharmacist.<br>• Changed Approved from Patryce Toye, MD CMO to Raymond Tu, MD Senior Medical Director (CMO).<br>• Updated NCQA Reference to 2022 Standards.<br><br>**07/21:**<br>• Changed Case Management to Clinical Operations in Responsible Departments.<br>• Changed responsible parties from Dr. Patryce Toye & Dr. Danielle Gerry to Raymond Tu, MD & Seema Kazmi, PharmD.<br><br>**05/21:**<br>• Updated expert process for evaluating new medications.<br><br>**10/20:**<br>• New Policy. |