MedStar Family Choice

DISTRICT OF COLUMBIA

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**205.DC**	
Subject:	**Non-Formulary Medications**	
Section:	**Pharmacy**	
Initial Effective Date:	**10/01/2020**	
Revision Effective Date(s):	**07/21, 07/22, 07/23, 07/24**	
Review Effective Date(s):		
Responsible Parties:	**Health Plan Pharmacist, P&T Committee**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**NCQA 2024: UM 5C, 5E; UM 11E District of Columbia Contract: Section C.5.28.15.3 EQRO Systems Performance Review**	
Approved:	**AVP Clinical Operations**	**Senior Medical Director (Chief Medical Officer-DC)**

Purpose: **To ensure that enrollees shall have access to non-formulary medications when medically necessary and in the absence of therapeutically equivalent formulary-preferred alternatives.**

Scope: **MedStar Family Choice, District of Columbia (DC)**

Policy: **In accordance with the organization's dedication to provide quality health care services, this policy will allow Enrollees to receive medically necessary non-formulary prescription medication(s), if no therapeutically equivalent formulary-preferred alternative option is available.**

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

Procedure:

1. An emergency, 72-hour supply of a covered outpatient drug shall be allowed.
   1.1. In an emergency as determined by the prescriber;
   1.2. In an emergency as determined by the dispensing pharmacist, if possible, in consultation with the prescriber; or
   1.3. If the prescriber does not respond to an initiated preauthorization request within 24 hours.
   1.4. The dispensing pharmacist can process an Emergency Override for a 72-hour supply of medication without contacting MedStar Family Choice DC.

1.4.1. The 72-hour emergency procedure should not be used for routine or continuous overrides.
1.4.2. The pharmacist should use their professional judgement regarding whether there is an immediate need every time the emergency supply option is used.

2. The request for a non-formulary prescription authorization may be initiated by the Enrollee, prescribing practitioner, or the dispensing pharmacy staff. Requests can be initiated by phone, fax, or website.

3. The authorization process is initiated by the receipt of a request. The pharmacy preauthorization staff will take the Enrollee's name, telephone number, date and time of the request, prescribing practitioner's name, contact information, and the requested medication name, dose and directions.

4. Requests for a non-formulary medication will be redirected to a Formulary alternative whenever possible.
   4.1. The Medical Reviewer will evaluate the request to identify available Formulary alternatives and document the suggested alternatives in the clinical software.
   4.2. Preauthorization staff will relay redirection information to the prescriber as documented.
      4.2.1. All redirection activities by Preauthorization staff are done under the supervision of a Medical Reviewer.
   4.3. If the prescribing practitioner agrees the formulary medication is appropriate, this will be captured in the clinical software documentation.
      4.3.1. The request will be captured as void due to redirection by the Medical Reviewer.
      4.3.2. Preauthorization staff will communicate the decision to the requestor.
   4.4. If redirection to a formulary alternative is not successful or if no therapeutically equivalent formulary alternative option is available, the non-formulary request will be evaluated for medical necessity by a Medical Reviewer.

5. Non-formulary medications will be approved by the Medical Reviewer if medical necessity can be established. This determination of medical necessity will include, but is not limited to, the following:
   5.1. Absence of Formulary alternatives and the Enrollee's condition warrants the non-formulary medication; and
   5.2. Confirmation by the Medical Reviewer the requested dose, formulation, directions for use, and treatment duration is appropriate based on the requested indication; and
   5.3. Documentation from the Enrollee's prescriber of a clinically significant therapeutic concern that justifies the use of a non-formulary medication instead of **all** appropriate formulary alternatives.
      5.3.1. Adverse or allergic reaction
      5.3.2. Adverse drug-drug interaction between proposed formulary medication and Enrollee's concurrent therapy.

5.3.3. Adverse drug-disease interaction between proposed formulary medications and a documented disease state.
5.3.4. Documentation of the individual Enrollee's failure to respond to formulary medications as documented in the medical record. This should include the dates formulary therapy was instituted and the length of the trial.
5.3.5. Documentation of an Enrollee's visual or other physical impairment that would result in medication administration, compliance, and/or safety issues.
5.3.6. Documentation of an Enrollee's swallowing or gastrointestinal absorption impairment that would result in medication administration, compliance, and/or safety issues.

6. Requests for non-formulary, brand name medication when a generically equivalent is available:
   6.1. Prescribers are required to complete the Food and Drug Administration (FDA) MedWatch reporting form, as appropriate.
   6.2. A copy of the form must be included with the request to MedStar Family Choice DC for review and approval before coverage of a brand name medication with a generic equivalent will be approved.
   6.3. Mere submission of the form is no guarantee that the request will be honored. When a generic version of the drug made by a different manufacturer is available, a trial with the other generic drug may be required before approval of the brand name product.
   6.4. In the event of a market shortage for generic products, a brand drug may be approved through the duration of the anticipated drug shortage.
   6.5. Links to the FDA MedWatch form and instructions for completion are found on the FDA website, on the Pharmacy Prior Authorization and Step Therapy Table, and are linked here:
      - **FDA MedWatch Online Voluntary Reporting Form**

7. Requests for non-formulary medications follow the procedures and timelines as outlined in pharmacy policy 218.DC: Pharmacy Process Policy.

Summary of Changes:	**07/24:**
	• Updated Section listing from "P&T Committee" to "Pharmacy"
	• Moved P&T Committee from "Responsible Department" to "Responsible Parties"
	• Updated Approver section Names and Titles
	  ○ Sharon Henry, RN AVP Clinical Operations
	  ○ Erica McClaskey, MD, MS, FAAFP Senior Medical Director
	• Updated to NCQA 2024 regulatory reference.
	• Reformatted procedure section to improve clarity and removed redundancy

	• Changed all MFC-DC abbreviations to “MedStar Family Choice DC”
	Content incorporated from Pharmacy Policy 201.DC Brand Name Prescription Authorization
	  ○ Clarified and expanded the procedure for evaluating brand-name medication requests (7)
	  ○ Added MedWatch form and directions for reference
	• Updated DC Contract reference to correct section.
	• Added expectation for the dispensing pharmacist to use professional judgement prior to each emergency supply dispense (1.4.2)
	• Clarified that redirection to formulary-preferred medication by preauthorization staff is done under supervision of a Medical Reviewer (4.1)
	• Added additional details about the non-formulary review process for evaluating NF requests for medical necessity (6).
	
	07/23:
	• Updated NCQA Reference to 2023 Standards
	• Added Health Plan Pharmacist as possible deciding party in addition to a Medical Director.
	
	07/22:
	• Updated Responsible Parties to Plan Pharmacist.
	• Changed Approved from Patrice Toye, MD CMO to Raymond Tu, MD Senior Medical Director (CMO).
	• Updated NCQA Reference to 2022 Standards
	
	07/21:
	• Changed Case Management to Clinical Operations in Responsible Departments.
	• Changed responsible persons from Dr. Patryce Toye & Dr. Danielle Gerry to Raymond Tu, MD & Seema Kazmi, PharmD.
	
	10/21:
	• New policy.