MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**205**	
Subject:	**Non-Formulary Medications**	
Section:	**Pharmacy**	
Initial Effective Date:	**06/06/2000**	
Revision Effective Date(s):	**11/18, 07/19, 07/20, 07/21, 07/22, 07/23, 07/24, 7/25**	
Historical Revision Date(s):	**09/01, 09/02, 04/03, 04/04, 10/04, 10/05, 10/06, 10/07, 10/08, 10/09, 10/10, 10/11, 09/12, 10/13, 10/14, 10/15, 06/17, 10/16, 11/17, 01/18, 07/18**	
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 March 2025 version 3.0 Standards 2.0, 3.0 NCQA 2025: UM 11E COMAR 10.09.03.06(D) and 10.67.06.04J(2).**	
Approved:	**AVP Clinical Operations**	**Chief Medical Officer**

Purpose: **To ensure that members shall have access to Non-Formulary pharmaceuticals when medically necessary and in the absence of therapeutically equivalent formulary-preferred alternatives.**

Scope: **MedStar Family Choice – Maryland**

Policy: **In accordance with the organization's dedication to provide quality health care services, this policy will allow members to receive medically necessary, Non-Formulary pharmaceuticals 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 the prescribed medication shall be allowed:
   1.1. In an emergency determined by the prescriber.
   1.2. In an emergency determined by the pharmacist, when possible, in consultation with the prescriber; or
   1.3. If the prescriber does not provide a response to 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.
      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 member, prescribing practitioner, or the dispensing pharmacy staff. Requests can be initiated by phone, fax, or website.
   2.1. The requesting party of a non-formulary pharmaceutical shall be allowed the opportunity to speak with a Medical Reviewer upon request.

3. The authorization process is initiated by the receipt of a request. The pharmacy preauthorization staff will take the member's name, telephone number, prescriber's name, contact information, the requested medication name, strength, dose, and directions for use. The date and time of the request must be recorded.

4. Requests for a non-formulary pharmaceutical will be redirected to a formulary alternative whenever possible.
   4.1. The Medical Reviewer will evaluate the request and identify available formulary alternatives and document the alternative(s) in the clinical software.
   4.2. The preauthorization staff may relay any redirection recommendation(s) to the prescriber only as identified and documented by the Medical Reviewer.
   4.3. If the prescriber agrees that the alternative formulary medication is appropriate, this will be captured within the clinical software documentation.
      4.3.1. The request will be considered void and captured as redirected.
      4.3.2. The 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 is available, then 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 may include, but is not limited to, the following:
   5.1. Absence of any formulary alternatives and the member's condition warrants the non-formulary medication; and

5.2. Confirmation by the Medical Reviewer that the requested dose, formulation, directions for use, and treatment duration is appropriate based on the requested indication; and
5.3. Documentation from the member's prescriber of a clinically significant therapeutic concern that justifies the use of a non-formulary medication instead of **all** clinically appropriate formulary alternatives.
    5.3.1. Confirmation that any failed pre-requisite therapies were dosed according to clinical guidelines and patient adherence to therapy is not contradicted by the pharmacy claims data when available.
        5.3.1.1. Failure to trial of formulary medications should be documented in the medical record including dates of active treatment.
    5.3.2. Adverse or allergic reaction
    5.3.3. Adverse drug-drug interaction between the preferred formulary alternative and then member's concurrent therapy, if the drug-drug interaction cannot be resolved.
    5.3.4. Adverse drug-disease interaction between proposed Formulary medications and a documented disease state.
    5.3.5. Documentation of a member's visual or other physical impairment that would result in medication administration, compliance, and/or safety issues.
    5.3.6. Documentation of a member'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. Will be reviewed following the same criteria as any other non-formulary request, and;
    6.2. To align with amendments to COMAR 10.09.03.07 H (3), prescribers are required to complete a Maryland Department of Health (MDH) MedWatch form.
    6.3. A copy of the form must be included with the request to MedStar Family Choice for review before coverage of a brand name medication with a generic equivalent will be approved.
    6.4. 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 another therapeutically equivalent formulary drug may be required before approval of a brand name product.
    6.5. In the event of a market shortage for generic products, a brand drug may be approved through the duration of the anticipated drug shortage.
    6.6. Links to the MedWatch form and instructions for completion are found on the MDH website, on the Pharmacy Prior Authorization and Step Therapy Table, and are linked here:
        - **Instructions for Completing MDH MedWatch Form**
        - **MDH MedWatch Form**

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

Summary of Changes:	**07/25:** • Removed references to NCQA 5C and 5E because they specifically relate to timeliness which is addressed in Policy 218. • Purpose Statement: Replaced “medications” with “pharmaceuticals”. • Policy Statement: Replaced “prescription medications” with “pharmaceuticals”. • Moved previous Section 4 into subsection 2.1. • Section 4: • Combined • Section 4.3: • Section 4.3.1: • Inserted • Previous • Section 5.3.3: • Inserted subsection 6.1, all others moved down one. • Former subsection 6.3: Removed “and approval”. • Section 6.4: clarified wording to reflect that formulary alternatives should be exhausted before approving a brand, non-formulary product. **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. • Refined the Purpose Statement. • Expanded the Policy Statement. • Added definition of Medical Reviewer. • Clarified that all clinically appropriate formulary alternatives should be exhausted before approving a non-formulary request. • Restricted action of redirection to occur only under the supervision of a Medical Reviewer. • Incorporated all of Policy 201; clarified and expanded procedures for brand-name medication requests. • Aligned requirement for a completed MedWatch form with COMAR standards. • Included MedWatch form and directions for reference.

	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 Section 6 COMAR reference to 10.67.06.04J • Added Health Plan Pharmacist as possible deciding party in addition to a Medical Director. **07/22:** • 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 references to reflect 2022 NCQA Standards • Updated COMAR references to reflect changes to MDH Standards **07/21:** • Updated NCQA Reference to reflect 2021 Standards. • Added Maryland to scope. • Changed Case Management to Clinical Operations in Responsible Departments. **07/20:** • Updated Regulatory References to reflect COMAR recodification and 2020 NCQA Standards. • Updated “visual impairment” to “visual or other physical impairment” in letter f. • Corrected #7 to read medical necessity of the Non-Formulary drug (it previously stated Brand Name drug) • Regarding redirection efforts, clarified “Formulary generic alternative” to just “Formulary alternative” as redirection may not always be to a generic drug. **07/19:** • Updated NCQA Reference to reflect 2019 Standards. • Removed “Maryland” from scope. **10/18:** • Addition in Policy Section: “Members have the option to submit an exception request based on medical necessity by calling MFC directly or submitting a request online via the MFC website. • Added “member” in #1 of Procedure. **07/18:** • Updated NCQA regulatory references to reflect 2018 and changed DHMH to MDH. • Modified Effective Date to Initial Effective Dates; added Historical Revision Dates and Revision Effective Dates; and added Historical Review Dates and Review Effective Dates.

	01/18: • Removal of timeline information (moved to a new Pharmacy Process Policy which was made to comply with decision timeframe specified in updated COMAR 10.09.71.04). **11/17:** • Revisions to comply with decision timeframe specified in updated COMAR 10.09.71.04. **07/17:** • Major revision. Split Policy 205 into 205A&B (previous policy included MD & DC). Updated regulatory references and NCQA, clarified language to indicate documentation requirements, decision and notification tables, changed Physician Advisor to Medical Director, added definitions to align with NCQA UM 5, updated titles, major changes to align with NCQA definitions of level of review. **10/16:** • No changes. **10/15:** • Added denial notice to the DHCF per contract: When a medication request is denied, MFC will make the contractually required notification to the DHCF within 2 business days.