

## Purpose and Scope

To outline the policy and procedure for obtaining medications which are not specifically maintained within the formulary of Spring Grove Hospital Center. This also establishes the distinction between non-formulary (single patient) use of medications and medications added to the formulary, as well as the use of formulary agents outside of FDA approved labeling.

## Policy

- A. It is the policy of the hospital service to maintain an approved formulary listing of drugs and drug products available for use at Spring Grove Hospital Center.
  - B. Patients with needs for special medications not maintained within the formulary constitute a population requiring individualized attention for procuring such medications. Non-formulary medications require special procurement procedures, and such medications shall be provided on an individual "per patient" basis only. Due to their unique nature, medications used to treat HIV, birth control pills, and liquid and IV antibiotics due to their infrequency of use, are classified as non-formulary but do not require the completion of a non-formulary request form to be obtained.
  - C. Formulary drugs written for non-Food and Drug Administration (FDA) approved indications are non-formulary.
  - D. The patient's prescriber will establish the need for a non-formulary drug based on review of the patient's past medical history and/or current medical status, and review of the hospital's Formulary for possible alternative drugs.  
The patient's prescriber will establish the need for using a formulary agent outside of FDA approved labeling.
    1. The physician is responsible for informing the patient of the purpose for using a specific drug, establishing that there is sufficient literature or experience to warrant the use of the drug for that purpose and maintain his/her familiarity with the literature concerning both the use and monitoring of a drug's effects for a non-F.D.A. approved indication or in a manner which differs from approved labeling.
    2. As part of informed consent guidelines, the prescriber (or designated patient educator) shall discuss the use of outside FDA labeling of the prescribed medication with the patient and document this as part of the informed consent interaction.
- E. The Director of Pharmacy, or his/her designee, will assess the appropriateness of a request and will initiate the procedure for the actual procurement and distribution of the non-formulary drug product.
  - F. The Request for Non-Formulary Drug/Non-Approved Use shall constitute a means for: identifying non-formulary drug/non-approved use within the hospital, and as such shall function as an essential form of documentation in such areas as Drug Utilization Review, Quality Improvement, Patient and Staff Safety and in establishing drug use patterns for supporting the addition of a drug to the formulary. The Non-Formulary/Non-Approved Use form will be placed in the Physician's Order section of the patient chart.
  - G. Delivery of non-formulary preparations to the patient care area may not be as prompt as the delivery of formulary items since they are not routinely stocked in the pharmacy and must be procured from outside the Hospital Center **and may take up to 72 hours**. It is advisable, therefore, that the prescriber writes for a formulary substitute if at all possible. If there is an immediate need for a non-formulary agent, the prescriber will contact the pharmacy directly.

## Responsibility

- A. The patient's prescriber shall be responsible for initiating, changing, and terminating all orders for patients placed on non-formulary medications; **and** for completing the "REQUEST FOR NON-FORMULARY DRUG//NON-APPROVED USE" **form at the time the order is written**. Trainees cannot initiate orders for non-formulary medications or sign non-formulary request forms. Residents at the discretion of their supervisor may initiate the orders and complete the form with co-signature.
- B. The nurse and/or prescriber shall be responsible for ensuring that the Medication Order Sheet and the "REQUEST FOR NON-FORMULARY DRUG/NON-APPROVED USE" form are

- faxed/delivered to the pharmacy. The staff member faxing the form should initial and date the form, after ensuring that it was successfully received in the pharmacy.
- C. The Department of Pharmacy Services shall be responsible for reviewing the "REQUEST FOR NON-FORMULARY DRUG/NON-APPROVED USE," and contacting the prescriber if further clarification is needed, procuring the drug entity, and dispensing the drug to the patient care area.
- D. If there is a concern regarding the non-formulary drug request /non-FDA approved use that cannot be resolved between the prescriber and the pharmacist, the Chief Medical Officer or designee will be contacted for approval.
- E. The Director of Pharmacy, or his/her designee, shall review the "request," and if necessary, contact the prescriber to discuss the request. This discussion may include such matters as availability of similar formulary agents, availability and cost of the requested drug, alternative strategies for treatment, risks versus benefits of the requested agent, support for the non-FDA drug use, etc.
- F. The pharmacist/prescriber discussion shall be noted in the "To be completed by Pharmacy" section of the request form. The pharmacist will note either: approved, temporary approval, until—; Denied or referred to the Chief Medical Officer (CMO). If the pharmacist and prescriber agree to utilize an alternative agent or treatment strategy, this shall also be noted on the request form.
- G. The prescriber's supervisor or designee will complete their section if denied by pharmacy and appealed by the prescriber. If required, the somatic physician (for Pas) or the Unit Director (for NPs) or their designee may be contacted to review any unresolved concerns. If still not resolved, the Chief of Somatic Services or CMO may be contacted. For use of formulary agents outside of FDA approval, the CMO or CMO's designee:

### Procedure

- A. Upon initiating an order for a non-formulary drug/non-FDA approved use, the patient's prescriber shall complete the form entitled, "REQUEST FOR NON-FORMULARY DRUG/NON-APPROVED USE," form including the following information:
1. Patient's name, and unit location.
  2. Non-formulary drug requested, including name, dose, form, directions for use.
  3. Indication for use (target symptoms).
  4. Previous attempted therapy.
  5. Rationale for using this agent. Including support for a non-FDA approved use.
  6. Additional monitoring and laboratory tests that will be required.
  7. Anticipated length of therapy in days.
- B. Medication orders for non-formulary drugs should include the following or like, statements: "**...when available.**"
- "Dorzolamide eye drops 2% TID both eyes when available."
- C. The Medication Order Sheet for the non-formulary drug/non-approved drug use shall be attached to the "REQUEST FOR NON-FORMULARY DRUG/NON-APPROVED DRUG USE," and shall be forwarded or faxed to the pharmacy as per standard operating procedures for procuring drug products from the pharmacy.
- D. Upon arrival in the pharmacy, the pharmacist receiving the "request" shall indicate the time and date of receipt and his/her initials and shall forward the "request" to the Director of Pharmacy or his/her designee.
1. Approves the use without conditions and informs the Pharmacy; or,
  2. Directs the prescriber to refer the matter to the Pharmacy and Therapeutics Committee and restricts use pending the Committee's review; or,
  3. Denies the request to use the medication as ordered.
  4. The Pharmacy and Therapeutics Committee informs the Statewide Pharmacy and Therapeutics Committee of all use which falls outside of the product labeling. When reviewing a matter referred by the CMO or designee, the Pharmacy and Therapeutics Committee:
    - a. Recommends that the CMO approve the request.
    - b. Recommends that the CMO deny the request or,


# Non-Formulary Drug Requests

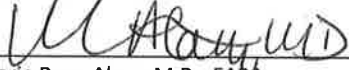
- c. Defers a recommendation and refers the matter to the Statewide Pharmacy and Therapeutics Committee for action.
- H. If it is necessary to obtain the non-formulary drug product, steps shall be initiated to procure the medication from available resources. It may take up to 72 hours to obtain the medication through routine procedures. If there is an immediate need for non-formulary agent (i.e., antibiotic), the prescriber shall contact the pharmacy directly.
- I. Upon receipt of the drug product, it shall be dispensed from the pharmacy in accordance with established policy and procedure. The dispensing pharmacist shall record the time and date of dispensing, and his/her initials on the original request.
- J. The original copy of the request form is maintained in the Physician's Order Section of the patient care chart. The faxed pharmacy copy is maintained in the non-formulary request book in the main pharmacy and a copy forwarded to the designated pharmacist.

### Reference

State of Maryland Request for Non-Formulary Drug/Non-Approved Use

### Approved by

  
 \_\_\_\_\_ 3/28/24  
 Date  
 Monica Chawla, M.D., FAPA,  
 Chief Medical Officer

  
 \_\_\_\_\_ 3/28/24  
 Date  
 Marie Rose Alam, M.D., FAPA,  
 Chief Executive Officer

Date Approved: 11/30/83

Revised: 3/20/86, 12/2/86, 2/26/92, 3/5/95, 5/98, 11/00

Revised: 8/04, 5/06, 5/27/10, 2/27/13, 10/1/14, 10/25/17

Revised: 9/30/20

Reviewed: 3/20/24