Department of Veterans Affairs
Medical Center
Wilkes-Barre, Pennsylvania 18711

POLICY 119-12-164
April 25, 2012

NON-FORMULARY DRUGS

1. SCOPE/EFFECT: This Medical Center Policy affects all practitioners with clinical privileges who are affiliated with this Medical Center and its Satellite Clinics. This policy affects employees in the following Services: Primary Care Service, Medical Service, Mental Health and Behavioral Service, Surgical Service, Geriatrics and Extended Care Service, Pharmacy Service, and Business Office and Health Administration Service.

2. PURPOSE: To establish policy and procedure for the request and procurement of non-formulary drugs in this Medical Center and Satellite Clinics.

3. POLICY:

a. Formulary management is an integral part of Department of Veterans Affairs (VA) Medical Center's comprehensive health care delivery process. The VA National Formulary (VANF) is the only drug formulary authorized for use in Veterans Health Administration (VHA). The use of Veterans Integrated Service Network (VISN) Formularies or local drug formularies at individual medical care facilities is prohibited. The formulary management process must provide pharmaceutical and supply products of the highest quality and best value, while ensuring the portability and standardization of this benefit to all eligible Veterans.

b. Requests for non-formulary drugs will be honored by Pharmacy Service when authorized signature and justification for use of the agent is provided. This provision will not be used routinely to circumvent formulary policy. Justification for non-formulary drug approvals will be based on:

(1) A known allergy or hypersensitivity to a formulary preparation exists.

(2) Therapy with formulary preparations has failed to provide an expected response.

(3) A relative or absolute contraindication of a formulary medication exists.

(4) A patient who is being treated with a non-formulary medication is admitted to the Medical Center or treated on an outpatient basis, and it is the medical judgment of the attending physician that quality of care will be compromised by changing the medication.

c. Non-formulary drug requests from Fee physicians will be reviewed by the same process.

d. Definition

(1) A non-formulary drug is any medication which has not been approved for formulary addition or is not on clinical trial as determined by the National Formulary.

(2) A "restricted" drug is any medication approved by the VISN or Pharmacy and Therapeutics Committee for use in a specific patient population, disease state and/or under the supervision of a specific physician within a particular medical section or service.

4. PROCEDURE:

a. Effective January 15, 2009, all VISN Formularies are abolished. VANF is the sole drug formulary used in VA.

b. VISN's are not permitted to modify Pharmacy Benefits Management/Medical Advisory Panel (PBM-MAP) Criteria for Use documents.

c. The VANF Drug Listing must be grouped according to the VA Classification System or other nationally developed or licensed classification system adopted by the PBM and is updated when changes are required.

d. Individual VA Medical Centers are prohibited from marking VANF drugs and supplies as non-formulary in their local drug file as a means to enforce restrictions or control utilization.

e. VANF recommendations are based on the review of only those drug products approved by the Food and Drug Administration (FDA).

f. Products with FDA approval in a category that is not regulated by FDA are to be preferentially selected for addition to the VANF over non-FDA approved products.

g. All decisions for VANF listing are made by consensus of the MAP and VISN Formulary Leaders (VFL) Committee. In situations where consensus cannot be reached, the recommendation of the MAP prevails.

h. When consensus is reached by the MAP and VFL committee regarding a given agent, the contracting requirements (as determined by PBM) are sent to the National Acquisition Center (NAC) to issue a solicitation, receive all bids, and make an award.

i. All reviews of New Molecular Entities (NME) must emphasize safety and efficacy in patient populations similar to the Veteran population.

j. Drugs and supplies are not added to the VANF solely for the purpose of performing a clinical trial; however, the VANF is not intended to impede the use of any pharmaceutical agent in legitimate scientific studies.

k. Requests for drug or drug class reviews may be submitted to the PBM by a VISN Formulary Committee, the VFL Committee, the MAP, a VHA Chief Medical Consultants, or VHA Chief Medical Officers.

l. Requests for change in VANF status may be submitted to the PBM by a VISN Formulary Committee, the VFL Committee, the MAP, a VHA Chief Medical Consultant, or VHA Chief Medical Officer. ***NOTE:*** *An individual or group of physicians may submit a request for VANF addition through their VISN Formulary Committee(s).*

(1) All requests for change in VANF status must contain:

(a) Minutes of the VFL Committee or other acknowledged meeting in which action was taken on the product (if applicable).

(b) Literature citations that support the recommendation.

(2) All requests for addition to the VANF must contain:

(a) Criteria for drug use that addresses indications, monitoring, and any efficacy or safety outcomes specific to the Veteran population;

(b) Completion of VA Form 10-0450, VHA National Formulary Request for Formulary Review (see App. A);

(c) Completion of VA Form 10-0450, Conflict of Interest Disclosure Form, by the parties presenting the drug for formulary addition (see APP. B); and

(d) The signature of the VISN Formulary Leader, VHA Chief Medical Consultant, or Chief Medical Officer. ***NOTE:*** *Requests are to be forwarded to; Pharmacy Benefits Management Service (119D) P.O Box 126, Hines, Il 6014.*

m. Requests for the change of VANF status, with regard to pharmacy-dispensed medical and surgical supplies, may be initiated by the medical center's Commodity Standards Committee, but must be submitted to the VISN Formulary Committee for review prior to forwarding to the PBM for consideration by the MAP and VFL Committees.

n. The PBM must send an acknowledgement of receipt of the request to the submitting committee or individual within 30 days of receipt of a request for change in formulary status or review of a drug class. This response must be in writing and if a national review is to be conducted, must identify the target date for completion.

o. The PBM must notify the VFL of requests received, and seek evidence-based feedback from all VISN Formulary Committees before any decision regarding VANF

addition or deletion is made. ***NOTE:*** *If a review is conducted, a draft is distributed to VISN Formulary Committees for wide dissemination and comment.*

p. In therapeutic classes or therapeutic sub-classes where national standardization contracts have been awarded, additional items from the same class or sub-class may not be added to the VANF, but when medically necessary are to be made available through the non-formulary process.

q. Prescribing a non-formulary or restricted drug for an inpatient/outpatient will be electronically done via Computerized Prescription Record (CPRS). Justification will be provided according to the Non-formulary Medication Protocol (Attachment A), with complete documentation on the Non-formulary Medication Request Form (Attachment B). Forms not completed properly will be returned to the initiator.

r. The justification, based on criteria herein, will be stated clearly. Vague or generalized statements (e.g., "It works") are not acceptable.

s. The medication order will need to be placed in CPRS in addition to the non-formulary request. If the non-formulary medication cannot be found in CPRS, the consult should be placed and if approved the provider will be contacted to enter the order. If the medication is not approved, the medication order will need to be cancelled by the provider.

t. Fee Basis Prescriptions

(1) Medication orders for patients on Fee Basis status will be filled with formulary medications only.

(2) Pharmacy service will contact Fee Basis prescribers for approval to substitute NF requests. Approval, if granted, will be documented on the pharmacy narrative.

(3) The Fee Basis provider may submit a request for formulary deviation when a required pharmaceutical agent is not on formulary. The request, in writing, will be submitted to the Pharmacy, accompanied by the rationale for deviation according to criteria within.

(4) The Clinical Pharmacists will review the request, and approve/disapprove.

u. All physician-initiated appeals of a non-formulary drug request are received and adjudicated by the facility Chief of Staff.

v. There will be no administrative action taken to discontinue a pharmacological initiated by an authorized provider at one VA medical center, when a patient transfers their care to a second VA medical center or when care is transferred back to the primary facility. However, VA providers need to exercise good clinical judgment to discontinue a

medication started at a different VA medical center when they have determined that it is not the best agent for a given clinical situation.

5. RESPONSIBILITY:

a. The Pharmacy and Therapeutics Committee's responsibilities include restriction of use to specific prescribers, approval of one time clinical evaluations, requests for and use of non-formulary drugs by individual prescribers and fee basis practitioners.

b. The Pharmacy Chief is responsible for maintenance of the formulary system and compliance to formulary policies through Pharmacy Staff.

c. The Service Directors are responsible for dissemination of and compliance to formulary policies for prescribers within their respective services.

6. CUSTOMER SATISFACTION: Provides assurance for patients that this Medical Center and its Satellite Clinics will provide therapeutically equivalent products for the quality of care and safety of our patients.

7. REFERENCES: Handbook 1108.08

8. RESCISSION: Medical Center Policy 119-09-164, dated April 30, 2009 same subject.

9. DISTRIBUTION: Electronic Access for All Employees

10. ATTACHMENTS: A, B

Non-Formulary Medication Protocol:

1. Non-Formulary Medication Procedure

a. All providers must follow the non-formulary drug management protocol for all non-formulary drug requests. Providers include residents, consultants, attending physicians, and other health care providers with prescriptive authority.

b. Non-Formulary requests must be completed in entirety with the appropriate documentation and authorization before pharmacy will dispense it.

c. Provider must designate themselves or another provider to assess the patients clinical response to the non-formulary drug. Discontinuation of the non-formulary drug should occur if no improved response is found by the designated date.

2. Consults must be completed for inpatients and outpatients.

☑ SERVICE CONNECTED % - NONE FOUND
RATED DISABILITIES - NONE FOUND
PERIOD OF SERVICE - OTHER OR NONE

COMBAT SERVICE - NONE FOUND
Is patient an OEF/OIF returnee? * ○ Yes ○ No

Reason for Request: *

THIS FORM IS USED TO REQUEST A NON-FORMULARY MEDICATION FOR CLINICAL USE FOR AN INDIVIDUAL PATIENT

SECTION A: Medication Requested (To be completed by Physician)
1. Generic name/strength/dosage form: *
2. Trade name: *
3. Diagnosis or medical problem to be treated: *

☑ SECTION B: Justification (To be completed by Physician)
1. Reason for medical necessity: (choose one/document specific comments)

○ a. Contraindication to formulary agent(s): (specify contraindication and agent(s)

○ b. Adverse reaction to formulary agent(s): (specify reaction)

○ c. Therapeutic failure of all formulary alternatives: (specify agent(s) tried)

○ d. No formulary alternative

○ e. Excessive risk is associated with a change to a formulary alternative: (explain)

○ f. Other: (specify)

☑ 2. Anticipated duration and location of therapy: (chose all that apply)

☐ One time use
☐ Extended use until
☐ Chronic use
☐ Inpatient unit
☐ Outpatient clinic

3. Treatment goal/endpoint: