Nebraska Medicine POLICIES AND PROCEDURES MANUAL ☒ System ☐ Department	Section: Medical Staff (MS) Subject: Additions/Deletions to Formulary Number: MS46 Attachments: Attachments A-B-C Date Effective: 1/30/04 Date Reviewed: 5/17/04, 10/16/06, 4/21/08, 7/19/10, 5/11, 09/12, 02/14, 1/18, 03/2020

Additions / Deletions to Formulary

Background/Rationale:

The Medical Staff Pharmacy & Therapeutics (P&T) Committee, with Pharmaceutical and Nutrition Care, is responsible for establishing and managing a formulary for Nebraska Medicine (MS-7; Bylaws article V. Section M. Part 2(a)).

Policy:

This policy defines the standards and procedures for inclusion of pharmaceutical and nutritional products on Nebraska Medicine's Formulary. Medications/nutrition products may be considered for addition to the medication/nutrition formulary at the request of an active or consulting staff physician or pharmacist/clinical nutrition therapist (for appropriate formularies) for Nebraska Medicine. Nebraska Medicine maintains two medication formularies: the Inpatient Formulary and the Outpatient Formulary (infusion centers and clinics). The retail pharmacies associated with the organization have an open, yet conservative, formulary based on patient needs.

Definitions:

Formulary management is a collaborative, interdisciplinary effort to evaluate, appraise, and select the most clinically and economically effective and safe pharmacologic and therapeutic nutritional products for use in the care of patients.
A formulary is, in the most basic terms, a list of medications that are available for use within the institution.

Procedure:

I. Requesting an addition to the formulary

A. The requesting physician/pharmacist/nutrition therapist completes a "Formulary addition application" (Attachment A). It is recommended that requestors cite primary literature or include FDA reviews (http://www.FDA.gov/cder) as part of the completed form. (see Attachment B for 'appropriate evidence') Full disclosure with regard to conflicts of interest on the part of the requestor is required. Incomplete forms will not be considered.

B. The requestor forwards the completed, signed form to the Secretary of the Medical Staff Pharmacy & Therapeutics (P&T) Committee via Nebraska Medicine Drug Information Services at Zip 8138 or via e-mail at TNMCDrugInfoSvc@spmail.nebraskamed.com, along with a supporting bibliography and/or references.

II. Formulary request review process

A. Upon receipt of the written request, a Drug Policy & Formulary Management pharmacist will generate a preliminary review of the request against the criteria for adding a drug (Attachment B) to formulary. Requests for addition to the formulary will be reviewed via the review process described herein unless an emergency review is required. In the case of emergency review (eg, emergent need for alternative addition(s) to formulary due to drug shortage), P&T leadership will be called upon to provide immediate review of the formulary request.

1. For requests not meeting criteria, the requestor will be notified as soon as possible by Nebraska Medicine's P&T Secretary or designee to determine if there is additional information to be considered. If the request still does not meet criteria, the Drug Policy & Formulary Management pharmacist, will prepare the criteria review evaluation and

present it to the Committee's Leadership for consideration. Leadership will then provide a recommendation regarding the request. This recommendation will be presented to the Medical Staff P&T Committee. If the drug is determined to not meet criteria for full committee review, the requestor will be notified .

2. For requests that meet criteria, a monograph or other review document will be prepared and/or reviewed by a Drug Policy & Formulary Management pharmacist evaluating the request based upon published literature (see Attachment B for 'appropriate evidence').
    a. When a request has met criteria, the requesting physician will be notified of the receipt of the request and the dates of the expected reviews.
    b. The requesting physician may opt to be present for the presentation of the request to the Committee. Votes by the Committee on the request will be taken only after the requestor has been excused from the meeting.

3. The action request (addition or deletion) will be presented to and reviewed by the Committee The Committee will determine if their recommendation is to:
    a. Deny addition to the inpatient and/or outpatient formulary, or
    b. Approve addition to the inpatient and/or outpatient formulary, or
    c. Approve addition to the inpatient and/or outpatient formulary for restricted or conditional use as follows:
        i. Restricted use approval

        Agents may be added to the formulary with restrictions for their use at the sole discretion of the Committee. Restricted agents should meet one or more of the following criteria:
        1) Has a limited therapeutic use and/or requires specific clinical or other expertise/knowledge to utilize the agent safely and appropriately
        2) Has the potential for significant inappropriate use that would lead to unnecessary medication exposure and/or excessive costs
        3) Is a high risk agent with the potential for serious adverse events or toxicities

        Agents may be restricted by various means which include, but are not limited to, a specific use/indication, by medical service or provider type, clinical/prescribing criteria, or location (specific area or unit within an institution, specific clinic, outpatient or inpatient, etc.). Certain restricted medications may require a second signature sign-off and will be noted in the electronic health record.

4. The Medical Staff P&T Committee's actions on formulary additions and deletions will be forwarded to the Nebraska Medicine Medical Staff Executive Committee.

5. The requestor will be notified, in writing, of the Committee's action.

6. If a drug is on the formulary, it is approved for all FDA-approved indications and for all uses listed in CMS- approved compendia (e.g., AHFS-DI, Clinical Pharmacology, Lexicomp, NCCN) unless otherwise specified in policy or restricted by the Committee.

7. The Committee recognizes that some of the documents approved in the formulary review process include the use of a medical therapy that is not approved by the FDA in its dose, route of administration, frequency of administration, or medical condition for which it is intended to treat. As such, the individual licensed practitioner using this medical therapy in this manner assumes responsibility for its administration and has determined in his/her clinical judgment that the off label use of this medical therapy is appropriate for the patient's clinical condition.

8. A request for a medication cannot be re-submitted for consideration within 6 months of the last submission or formal Committee vote, whichever is later, unless there is significant new information.

III. Requesting a deletion from the formulary

A. The requesting physician/pharmacist/nutrition therapist completes a "Formulary Deletion Request" Form (Attachment C). The form is available by accessing the Pharmaceutical and Nutrition Care website via the Intranet. Refer to I.A.above.
B. A Drug Policy & Formulary Management pharmacist will conduct a preliminary review.

1. Drugs and nutrition products may be deleted from formulary when:
    a. New evidence is available raising concerns regarding the product as a risk to patient safety or the product is considered inferior (less desirable due to stability, sterility, storage, or multitude of other concerns) to alternative (formulary) agents,
    b. Repeated regulatory recalls or shortages occur,
    c. Significant regulatory warnings concerning a product are issued,
    d. Excessive therapeutic overlap within a drug class exists,
    e. Non-utilization for a significant period of time indicates the drug need not be routinely available from pharmacy, and/or
    f. A product is removed from the market.

2. Requests which meet the “criteria for deletion” (III. B. 1. a-f) will be reviewed by the appropriate Drug Policy & Formulary Management pharmacists. The action request will be presented to and reviewed by the Committee and they will determine if the recommendation is to:

    i. Approve the request to delete the drug/nutrition product from the inpatient and/or outpatient formulary
    ii. Deny the request to delete the drug/nutrition product from the inpatient and/or outpatient formulary

C. The requestor will be notified in writing of the Committee’s action.

III. Appeals of Formulary Decisions

Formulary decisions, regarding adding or deleting a pharmaceutical or nutritional products, made by the Committee may be appealed, in writing, to the Co-Chairs of the Medical Staff P&T Committee. Such request for appeal shall include new additional evidence in published medical literature that should be considered by the Committee.

Any denials of additions and deletions that can be appealed must be approved by the Medical Executive Committee.

Staff Accountability

Pharmacy & Therapeutics Formulary Subcommittee (11/2020)
Bylaws Committee (02/2020)
Medical Executive Committee (02/2020)
Board of Directors (03/2020)

Department Approval		**Administrative Approval**	
Signed | s |:	John T. Haas, MD and Lori J. Murante, PharmD	Signed | s |:	Lindsay Gage, MD
Title:	Co-Chairpersons	Title:	Chief of Staff
Department:	Pharmacy & Therapeutics Committee		