Name of Policy:	**Formulary System**
Policy Number:	3364-133-01
Department:	Pharmacy
Approving Officer:	Senior Hospital Administrator
Responsible Agent:	Director of Pharmacy
Scope:	University of Toledo Medical Center

THE UNIVERSITY OF TOLEDO MEDICAL CENTER

Effective Date: 6/1/2023
Initial Effective Date: April 19, 2004

_____ New policy proposal
_____ Major revision of existing policy
__x__ Minor/technical revision of existing policy
_____ Reaffirmation of existing policy

(A) Policy Statement

Through the recommendations of the Pharmacy and Therapeutics Committee, the University of Toledo Medical Center has adopted a formulary system for selection of drugs, nutritional supplements, and nutraceuticals to be used at this institution.

(B) Purpose of Policy

Deliver care to all UTMC patients that meet

1. University quality care
2. Meets the Institute of Medicine goals of high quality care
3. Meets the Institute for Health Care Improvement Triple Aim: Better Heath and Better Care at Lower Cost

(C) Procedure

Role of the Pharmacy and Therapeutics Committee

The Pharmacy and Therapeutics Committee is responsible for the effective and efficient operation of the formulary system. The Committee is responsible to the Medical Staff as a whole, and its policy recommendations are subject to approval by the Medical Executive Committee. The Pharmacy and Therapeutics Committee is responsible for in the formulation of broad professional policies relating to drugs, nutritional supplements, and nutraceuticals in the hospital, including their evaluation, selection, procurement, storage, distribution, administration, and use.

Application of the Formulary System

The formulary system applies to all prescribers practicing at UTMC. The formulary applies to the hospital and all provider-based clinics on campuses on the University of Toledo and reported on the hospitals CMS Cost Report. The formulary does not apply to retail pharmacy operations and practice plan (UTP) clinics.

The formulary will be available electronically and reflected through the computerized provider order entry system. Displayed formulary will include medication strength and dosage.

All protocols or order sets involving medications or biological therapies will be reviewed by the Pharmacy & Therapeutics Committee prior to utilization and periodically, as appropriate.

"Formulary" Designation

Only those drugs, nutritional supplements, and nutraceuticals approved by the Pharmacy and Therapeutics Committee on the basis of safety, efficacy, and cost to be most advantageous in patient care shall be designated as formulary agents. Safety will include: propensity for errors, look alike-sound alike issues with existing formulary agents, abuse potential, monitoring and sentinel events. Once approved these drugs, nutritional supplements, and nutraceuticals will be listed on the formulary; only formulary drugs, nutritional supplements, and nutraceuticals are routinely stocked and available from the pharmacy, and/or central supply.

The drug, nutritional supplement, or nutraceutical is officially added to the formulary when the Pharmacy and Therapeutics Committee meeting minutes are approved by the Medical Staff Executive Committee. Once considered by the Medical Staff Executive Committee, a drug, nutritional supplement, or nutraceutical will be designated as one of the following

1) Formulary
2) Formulary with restrictions or guidelines
3) Non-formulary, but can be requested using the non-formulary orderable in Epic
    a. Awaiting review
    b. Reviewed designated non-formulary, process to request
4) Non-formulary – not available for use

Restricted Formulary Agents

Formulary agents may be restricted in their use, either by
Criteria for use restrictions:

1. Medications with approved criteria for use must meet the criteria for use to be used as an inpatient or an outpatient. Examples of criteria could be but are not limited to:
    a. Laboratory values and other diagnostic testing
    b. Step therapy or failure of preferred alternatives
    c. Prior authorizations
    d. REMS Criteria
        i. Prescriber, pharmacist, or institutional enrollment
2. Unless specifically approved otherwise: Outpatient medications are restricted to FDA approved indications.
    a. Off-label utilization of outpatient medications will be handled as a non-formulary medication
3. The pharmacist will review orders for restricted medications to assure criteria are met prior to dispensing
4. Pharmacy will not dispense medications prior to criteria being evaluated unless the delay will lead to immediate patient harm.
5. If the patient does not meet criteria for use the pharmacist will clarify the criteria with the prescribing physician and appropriate steps taken meet safety, compliance, and financial criteria.
6. If not resolved above, the attending physician may request a review of the case with clinical pharmacist or director of pharmacy as a first line appeal.
7. An attending physician may perform a second line appeal to override criteria for use to the following physicians
    a. Chief Medical Officer
    b. Chair of Pharmacy and Therapeutics Committee
    c. Chief of Staff

Restricted by service or training:

1. A consult or other review process outlined by the Pharmacy and Therapeutics Committee and approved by Medical Executive Committee must be obtained by the approved service
2. No appeal process

Restricted Medications by Area

1. Medications restricted to outpatient utilization will not be available in the inpatient electronic record for ordering.
2. If an order is hand written and sent to the pharmacy
    a. The pharmacist will call the prescribing physician and notify them this medication is not available for inpatient utilization through approval by the Pharmacy and Therapeutics and Medical Executive Committees.
    b. The pharmacist will discuss options with the prescriber available for inpatients and work with the physician to coordinate outpatient care
3. If not resolved above, the attending physician may request a review of the case with clinical pharmacist or director of pharmacy as a first line appeal.
4. If not resolved above, the attending physicians may appeal to the following physicians:
    a. Chief Medical Officer
    b. Chair of Pharmacy and Therapeutics Committee
    c. Chief of Staff

5. Within the inpatient hospital, medications may be restricted to areas of care where appropriately trained staff and monitoring is available: these criteria may not be appealed.
6. Formulary status indicates the medication is available for usage based on FDA indications and literature available for off-label utilization at the time of the review. Medications may be restricted at time of approval, but approval does not indicate approval for any indication.
    a. A pharmacist in conjunction with a second clinical pharmacist or manager may require off label utilization of formulary medication to be reviewed as a non-formulary medication if the off label utilization is not the generally accepted standard of care.

Adding or Deleting Agents to/from the Formulary

1. The Pharmacy and Therapeutics Committee may initiate its own review of a drug, nutritional supplement, or nutraceutical. Routine drug class reviews may also trigger formulary additions or deletions. When a drug, nutritional supplement, or nutraceutical is added to the formulary, consideration will routinely be given to deleting other items.
2. The clinical pharmacist performs proactive review of new FDA-approved medications
3. Attending physicians may request drugs, nutritional supplements, and nutraceuticals to be added to or deleted from the formulary by submitting a request to one of the Co-chairs of the Pharmacy & Therapeutics Committee. The provider will disclose any Conflict of Interest in the request. See attached. The Physician who requests the addition to the formulary may attend the Pharmacy and Therapeutics Committee meeting when it is considered

The Pharmacy department provides an objective evidence-based medical evaluation for each agent requested for formulary addition to assist the Committee in its deliberations. Items that will be considered in evaluation of medications for formulary addition:

1. Indications for use (FDA-approved and off-label potential uses)
2. Effectiveness
3. Drug interactions
4. Pharmacokinetic profile
5. Potential for errors and abuse
6. Adverse drug events/reactions
7. Sentinel event or safety advisories (e.g. ISMP)
8. Population-specifics (e.g. pediatric, geriatric, pregnancy & lactation)
9. Cost
10. Other agents available on formulary

Communication of Formulary Decisions

The formulary is available in Epic as the location formulary (orderable items) and reflects decisions made by the Pharmacy and Therapeutics Committee. In addition to the Epic formulary, physicians and other health care providers are informed of committee decisions through the official Pharmacy and Therapeutics Committee publication “Pharm Report”.

Obtaining Non-Formulary Agents

When a non-formulary drug, nutritional product, or nutraceutical is prescribed, a pharmacist or dietitian contacts and informs the prescribing physician that the drug, nutritional supplement, or nutraceutical is non-formulary and not stocked in the pharmacy or dietary. The pharmacist or dietitian informs the physician of other formulary alternatives available.

If the house staff physician feels that the non-formulary agent is still needed:

1) The pharmacist or dietitian has the responsibility of contacting the attending physician for the medical service, recommending alternative therapy, and requesting necessary information to determine appropriateness. The pharmacist or dietitian may verbally complete the information request if not included in the medication order. This should be documented in an iVent.

2) The clinical pharmacist will perform an initial immediate review within 1 business day evaluating the medication on the available data for efficacy, safety, and cost compared to the physician's justification on the non-formulary request form.
3) If the initial review indicates the medication for that patient is safer, more effective, and costs under $100 per inpatient course of therapy the medication is ordered for delivery the next business day if not already stocked.
4) If the initial review indicates the medication is equal or less safe, equal or less effective, or costs more than $100 course of therapy
    a. The clinical pharmacist will review the data with the pharmacy director or attending physician as appropriate and come to a decision.
    b. If a decision is not obtained above: appeals may be sought in the following order of availability:
        i. Chief Medical Officer
        ii. Chair of Pharmacy and Therapeutics Committee
        iii. Chief of Staff
    c. The medication may be placed on the P&T agenda for review with-in 90 days for initial evaluation or reevaluation.
5) Patients may not be admitted with the sole intention of being treated with a non-formulary agent without the approval of following.
    a. Chief Medical Officer and
    b. Chief Executive Officer and
    c. Director Pharmacy or Chair of Pharmacy of Pharmacy and Therapeutics Committee

Non-formulary drugs are normally obtained within business 48 hours but may take longer depending on when the order is received and product availability. The Pharmacy and Therapeutics Committee may deem some products not to be ordered, dispensed, or stocked, even on a non-formulary basis, such as unapproved nutraceuticals and nutritional supplements.

Monitoring of Non-Formulary Agent Prescribing

The pharmacy department compiles and analyzes data regarding non-formulary drug and nutraceutical use on a regular basis, and the clinical dietitian will monitor non-formulary nutritional supplement use.

The Committee determines appropriate action necessary to maintain the integrity of the formulary system. This may include reconsidering a drug, nutritional supplement, or nutraceutical for formulary addition, undertaking an educational effort to reduce inappropriate prescribing, or imposing prescribing restrictions.

Other reviews:

The pharmacy and therapeutics committee will perform class reviews based on the same criteria medications are added or removed from the formulary. Class reviews can result in addition, removal, or therapeutic substitutions per policy 3364-133-36

The Pharmacy and Therapeutics Committee will review the Formulary and the look- alike-sound-alike medication list at least once a year and periodically perform medication use evaluations.

The Pharmacy and Therapeutics Committee will review safety data, develop and implement medication use policy and procedures to increase patient safety, and monitor for effectiveness

(D) Definitions

Formulary system - An ongoing process whereby an organization's pharmacy and medical staffs, working through the Pharmacy and Therapeutics Committee, evaluate and select from among the drug, nutritional supplements, and nutraceutical products available and consider those most useful in patient care. These products then are routinely available for use within the organization.

Formulary - A continually revised compilation of drug, nutritional supplements, and nutraceutical products, plus important ancillary information about the use of the products and relevant organizational policies and procedures.

Approved by:		**Review/Revision Date:**
		4/04
		7/04
/s/	05/16/2023	8/07
Lindsey Eitniear, PharmD, BCPS, AAHIVP	Date	10/12/2010
Director of Pharmacy		12/21/2010
		09/01/2011
		5/1/2013
/s/	05/16/2023	11/1/2015
Russell Smith, Pharm D, BCPS, MBA, CPEL	Date	2/1/2019
Senior Hospital Administrator		6/15/2020
		5/16/2023
Review/Revision Completed By:		
Pharmacy		
		Next Review Date: 6/1/2026
Policies Superseded by This Policy:		

THE UNIVERSITY OF TOLEDO
MEDICAL CENTER

REQUEST FOR ADDITION TO UTMC FORMULARY

Date_____

Type or print all information requested below (use extra sheets if necessary).
Forward completed form, along with supportive literature, to:
Lindsey Eitniear, Pharm D, BCPS, Director of Pharmacy, Ext. 3875 (Drugs)
Michelle Lovett, Clinical Dietitian, Fax 3112 (Nutritional Supplements)

Generic Name_____ Trade Name_____

Manufacturer(s) _____

Dosage Form(s) and Strength(s) _____

Therapeutic Indications(s) _____

_____

Toxicities, Contraindications, Precautions (include potential drug interactions) _____

_____

_____

Comparable agent presently on the UTMC Formulary_____

_____

Reason(s) this agent is superior to others presently on the UTMC Formulary_____

_____

_____

Should this agent replace other agents on the UTMC Formulary? _____

If yes, please specify_____

_____

On a separate page, list the objective criteria for use of this agent. Also list the criteria for discontinuation of this agent.

Summarize the published data, which supports above information (Provide references and reprints of supporting literature).

Proposed by_____

Requesting Attending Physician

The purpose of this statement is to permit the identification and evaluation of potential conflicts-of-interest related to formulary request involving proprietary products. ***Answering "Yes" to any of the following questions does not necessarily mean that the situation in question is improper; it means only that disclosure and evaluation, and in some cases, institutional approval and oversight, may be required***.

1. To your knowledge, do you, or does any member of your family or any business partner, have, or expect to acquire, a financial interest in any business entity:

a. Which is providing proprietary products for the proposed request? Yes ☐ No ☐
b. Whose business is substantially related to the subject matter of the proposed request? Yes ☐ No ☐

Name of company involved: _____

Position you hold in company, if applicable: _____

The type and amount of family financial interest: _____

Please provide additional detail on the nature of the company's business in space provided below.

If the answer to any of the preceding questions was Yes, please provide the details of the situation on the lines below or attach additional information if necessary.

_____
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