**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.

**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

**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 prescribes both house staff and attending physicians as well as other practitioners with prescribing authority.

**“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

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**Table:**

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<tr>
<th>New policy proposal</th>
<th>Minor/technical revision of existing policy</th>
<th>Major revision of existing policy</th>
<th>Reaffirmation of existing policy</th>
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1) Formulary
2) Formulary with restrictions or guidelines
3) Formulary not stocked
4) Non-formulary, but can be requested using a non-formulary request form
   a. Awaiting review
   b. Reviewed designated non-formulary, process to request
5) 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, director of pharmacy, and department chair 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. Vice President of Medical Affairs
   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, director of pharmacy, and department chair as a first line appeal.
4. If not resolved above, the attending physicians may appeal to the following physicians:
   a. Vice President of Medical Affairs
   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 should 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 completing a formulary request form. The section on Conflict of Interest and Disclosure must be completed. See attached. The Physician who requests the addition to the formulary will be requested to 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.

1) New drug reviews: Specific Format
   a. Executive Summary
   b. Overview: Recommendation
   c. Brand/generic
   d. Recommendation
   e. Pharmacology and MOA
   f. FDA approvals
   g. Potential off label
   h. Dosage forms and storage
   i. Pharmacokinetic
   j. Special populations
   k. Comparative efficacy
   l. Clinical trial analysis and critique
   m. Med safety assessment
   n. Financial analysis
      i. Define perspective
      ii. Cost and consequence
      iii. Probability of each outcome: based on literature and local data
   o. Guided use
      i. Criteria for use
      ii. Restricted by service
      iii. Restricted by training
      iv. Restricted by area
      v. Approval by medical director or designee
   p. Off-label use
      i. Only when evidence published
      ii. Consent form
   p. Follow-up assessment plan
Communication of Formulary Decisions

The formulary is available on-line as a searchable database and reflects decisions made by the Pharmacy and Therapeutics Committee. In addition to the on-line 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 providing the attending physician with a non-formulary request form. The pharmacist or dietitian may verbally complete the non-formulary request form if the physician is unable.
2) The completed form is sent to the Pharmacy Department or Dietary and forwarded to a clinical pharmacist or clinical dietitian.
3) 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 physicians justification on the non-formulary request form.
4) 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.
5) 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, attending physician and department chair 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. Vice President of Medical Affairs
      ii. Chair of Pharmacy and Therapeutics Committee
      iii. Chief of Staff
   c. The medication may be placed on the P&T agenda for review within 90 days for initial evaluation or reevaluation.
6) Patients may not be admitted with the sole intention of being treated with a non-formulary agent without the approval of following:
   a. Vice president of Medical Affairs and
   b. Vice president of Clinical Services and
   c. Director Pharmacy or Chair of Pharmacy of Pharmacy and Therapeutics Committee

Non-formulary drugs, nutritional supplements, or nutraceuticals 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.
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:
Lindsay Eitniear, Pharm D, BCPS, Clinical Pharmacist, 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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