OUR LADY OF THE LAKE REGIONAL MEDICAL CENTER			
Policy Manual:	**Pharmacy**	**Section:**	Formulary and Medication Procurement
Title:	**Formulary Management**	**Policy Reference #:**	PH-11-08
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PURPOSE:

To define the process for managing the Our Lady of the Lake (OLOL) Formulary.

DEFINITIONS:

Pharmacy & Therapeutics (P&T) Committee: a committee of physicians, pharmacists, and other healthcare professionals responsible for evaluating, appraising, and selecting from among the numerous available drug entities and products those that are considered clinically necessary for use at OLOL. The committee is also responsible for ensuring the safe and effective use of medications at OLOL. The Committee uses the best available information in making decisions and adopts best practice guidelines from evidence-based literature and research experience with new medications.

Formulary: a continually updated list of medications and related information representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis and treatment of disease and promotion of health available for use throughout the hospital and OLOL clinics.

Non-formulary medications: any medication, brand name, or dosage form that is not on the OLOL formulary. Non-formulary medications are not stocked in the pharmacy but will be obtained and dispensed with appropriate approval.

Authorized prescribers: an attending physician, fellow, resident, or intern. Nurse practitioners and physician assistants may prescribe formulary medications based on their scope of practice in accordance with Louisiana law, OLOL Medical/Dental Staff Bylaws and Rules and Regulations, and based on their individual collaborative practice agreement that each clinician has with their supervising physician.

Automatic therapeutic substitution: Authorized interchange of therapeutic alternates in accordance with previously established and approved written guidelines or protocols within the formulary system.

Therapeutic equivalents: two or more drugs which differ in composition or in their basic chemical entity but are considered by the P&T Committee to have the same safety and efficacy.

Subcommittees of the P&T Committee:
System Oncology Subcommittee
Children's Hospital P&T Committee
Formulary and Informatics Committee
Antibiotic Stewardship Committee
Medication Use Committee

POLICY:

I. Our Lady of the Lake Formulary is a list of accepted medications and dosage forms available for use throughout the hospital and clinics. The formulary system ensures that the most safe, efficacious, and cost-effective medications are readily available.

II. Attending-level members of the medical staff , the P&T Committee Chair and the Director of Pharmacy or his/her designee may submit a request for a medication or dosage form to be added to or deleted from the formulary utilizing the formulary addition request form.

III. Upon receipt of a request to change the formulary, a message will be sent from the Chair of the P&T Committee (or his/her designee) to the requestor acknowledging that the request has been received and will be discussed at an upcoming meeting. A formulary monograph will be prepared within 60 days of receiving the request.

IV. Medications are added to the Formulary if one of the following conditions apply:
   a. The new drug has greater safety and efficacy with equal cost,
   b. The new drug has equal safety and efficacy with lower cost,
   c. The new drug is believed to be safer or more effective at a higher cost and the incremental increase in safety and/or efficacy outweighs the increased cost
   d. The new drug is the only therapy currently available for management of a particular disease state or patient population and is safe and effective

V. The requestor will be notified by the Chair of the P&T Committee regarding the decision of the Committee.

VI. Pursuant to a Formulary decision, medications are categorized as one of the following:
   a. Formulary, stocked
   b. Formulary, not stocked: not stocked; but can be made available upon request and may take up to 3 business days following the final approval
   c. Formulary, restricted: restrictions may be imposed on all uses, or selected indications, patient populations, patient status (e.g. outpatient), diagnoses or laboratory criteria, or ordering physician specialty
      i. Formulary, restricted to service- approval required: prescribing is restricted to approval by selected services
      ii. Formulary, restricted to service- formal consultation required: prescribing is restricted pursuant to a formal documented consultation
   d. Non-formulary: not stocked, but can be made available on a case-by-case basis with appropriate approval.
   e. Non-formulary, not available: not stocked, not available

VII. The primary means of disseminating information from the Committee is via the Drug Information Resource Center website (www.formweb.com/ololrmc) under P&T Committee tab.

PROCEDURES:

VIII. Accessing the OLOL Formulary
   a. The Formulary is accessible through the OLOL Drug Information Resource Center at

www.formweb.com/ololrmc. The Formulary is updated at least monthly.

IX. Handling requests to modify the Formulary

a. Upon receipt of a completed formulary addition/deletion request form, a formal drug monograph will be prepared by a clinical pharmacist within 60 days of receipt of the request. Clinical pharmacists will conduct literature searches and review information provided by the manufacturer to prepare the drug monograph. Formulary monographs will be prepared to address the following:

i. FDA-approved indications
ii. Unlabeled indications
iii. Pharmacology
iv. Pharmacokinetics
v. Selected clinical trials
vi. Adverse reactions
vii. Drug-drug and drug-food interactions
viii. Contraindications
ix. Warnings and precautions
x. Pregnancy and lactation
xi. Abuse potential
xii. Potential for medication errors
xiii. Dosage and administration
xiv. Nursing implications
xv. Dosage forms available
xvi. Cost comparison/reimbursement
xvii. Guidelines for use
xviii. Methods to monitor patient response (when applicable)
xix. Safe medication practices
xx. Formulary recommendations

b. Monographs will be reviewed and achieve a consensus recommendation by medication evaluation team and the P&T Chair prior to formal presentation to the P&T Committee. The physician medication evaluation team member is responsible for obtaining the approval from his/her respective service line prior to formal presentation of the monograph to the P&T Committee.

Once approved by the P&T committee, all decisions will be sent to the Med Exec Committee for approval. Once approved by Med Exec Committee, the procurement, order set change/development, staff education, and implementation can begin.

X. Handling requests for Non-Formulary medications

a. Physicians must complete the non-formulary medication order pathway for inpatient requests or use the non-formulary request form for outpatient requests to obtain a non-formulary medication. Clinical pharmacists will review requests upon receipt. To facilitate the review process, physicians shall provide clinical justification for the use of the non-formulary medication. Possible clinical justifications include:

i. Newly marketed medication that has not been requested for formulary addition
ii. Patient has documented adverse reaction to the formulary medication (prescriber to specify medications and reaction)
iii. Documented therapeutic failure with formulary agents (prescriber to specify

medications used)

iv. Patient stabilized on a specific medication prior to admission and clinical consequences if not continued.

b. Requests for non-formulary drugs will be handled per the Non-formulary Drug Request policy. (PH-11-09)

XI. Handling requests for Formulary-Restricted medications being used outside of their P&T-approved restrictions

a. Physicians must complete the non-formulary medication order pathway. Requests will be handled following the process for request of Non-Formulary medications.

XII. Handling requests for medications with a Non-formulary, Not available status

a. Physicians must complete the non-formulary medication order pathway. Requests will be handled following the process for request of Non-Formulary medications. However, The P&T Committee Chair or a member of the Medical Staff Office must approve procurement and dispensation of the requested medication.

XIII. Handling Automatic Therapeutic substitution

a. The P&T Committee has authorized the Department of Pharmacy to automatically substitute certain prescribed non-formulary medications with therapeutically equivalent formulary medications. If a prescriber specifically requires the non-formulary medication be dispensed, he/she must complete a non-formulary medication order. The aforementioned process for handling requests for Non-Formulary medications will be followed.

XIV. Handling Drug Shortages

a. Medication shortages are monitored by administrative and clinical staff of the Department of Pharmacy. Contingency plans, product allocation steps and other procedures are coordinated with physicians, pharmacy, and nursing leadership including the P&T Committee and members.

Resultant plans for formulary changes and substitutions occurring as a result of drug shortages will be found on the Drug Information Resource Center website (www.formweb.com/ololrmc) and will be communicated via email.

REFERENCES

MM 02.01.01 EP1. Members of the medical staff, licensed independent practitioners, pharmacists, and staff involved in ordering, dispensing, administering, and/or monitoring the effects of medications develop written criteria for determining which medications are available for dispensing or administering to patients. *The Joint Commission Medication Management Standards*

MM 02.01.01 EP2. The hospital develops an approves criteria for selecting medications, which, at a minimum, include the following: Indications for use, Effectiveness, Drug Interactions, Potential for errors and abuse, Adverse drug events, Sentinel event advisories, Other Risks, and Costs. *The Joint Commission Medication Management Standards*

MM 02.01.01 EP3. Before using a medication new to the hospital, the hospital determines a method to monitor the response to the patient. *The Joint Commission Medication Management Standards*

MM 02.01.01 EP4. The hospital maintains a formulary, including medication strength and dosage. *The Joint Commission Medication Management Standards*

MM 02.01.01 EP5. The hospital makes its formulary readily available to those involved in medication management. *The Joint Commission Medication Management Standards*

MM 02.01.01 EP12. The hospital develops and approves written medication substitution protocols to be used in the event of a medication shortage or outage. *The Joint Commission Medication Management Standards*