Policy Number	OHS.PHARM.012
Date of Issue	02/02, 06/05
Review Dates	
Revision Dates	April 2013, July 2014
Policy Owner(s)	Pharmacy

Formulary

I. Purpose

The purpose of this policy is to establish that the Pharmacy Department will maintain a formulary of medications for use in the hospital (inpatient and outpatient) as needed. The formularies will be approved by the Pharmacy and Therapeutics (P&T) Committee.

II. Scope

All Ochsner Health System patient care areas of the hospital are covered by this policy. .

III. Policy Statements

A. The P&T Committee approves all medications included on the formulary for the hospital, inpatient and outpatient departments including the outpatient infusion centers.

1. The hospital formulary is located on the Intranet and readily available to all those involved in medication management. It can be accessed via a link from the EMR or from the site specific pharmacy link. The formulary will be updated after every addition or deletion. In the event of a computer outage, a hard copy of the formulary will be available in the pharmacy.

B. The Pharmacy Department will only purchase products that are U.S.P., N.F. and FDA approved. Products will only be purchased from pharmaceutical manufacturers, wholesalers, and/or established channels of distribution.

1. The Pharmacy will not purchase herbals or homeopathic remedies for hospital patients that are not U.S.P., N.F. or FDA approved unless the product is approved by the P&T Committee.
2. Patients will not be allowed to take their own herbal or homeopathic remedies while in the hospital (inpatient or outpatient) since the remedy may interfere with the patient's care and safety.
3. The Pharmacy may utilize outsourced prepared preparations if all assessments, contracts, and due diligence has been completed per outsourcing policies.

C. The use of sample medication for hospitalized (inpatient or outpatient) patients is prohibited, except those approved samples allowed in the outpatient departments per sample policy.

D. The pharmaceutical manufacturer's recommendations for administering medication will be used unless more stringent guidelines have been adopted.

1. The P&T Committee will approve all guidelines, policies, and procedures for medications that are not covered in the manufacturer's information or an approved standard of practice validated in the literature.

E. The Pharmacy will address off label uses of medications on a case-by-case basis.

1. If the use is considered by the pharmacist to be a questionable risk to the patient, the pharmacist will ask the prescriber to provide literature to support the use.

F. Non-formulary medications will be made available for patient's use from the hospital pharmacy. However, there may be a delay in initiating therapy since the medication may not be kept in stock.

G. The P&T Committee will conduct ongoing reviews of the Hospital Formulary to determine whether changes are needed.

IV. Procedures/Standards and Roles & Responsibilities

A. Additions to the Formulary

1. Physicians/Providers who are members of the medical staff may request additions to the hospital formulary. The requesting physician/ provider may be asked to appear at the P&T Committee meeting to discuss the formulary request.

a. A Formulary request form located on the Intranet will be completed along with sufficient clinical information to allow review by the Committee.

i. Hospital formulary requests are forwarded to the Director or Pharmacy.

ii. The Director of Pharmacy or designee will submit the request via the online request process. (refer to operational standard) A system review will occur prior to proceeding to the P&T Committee.

b. The pharmacy department will review the requested medication and determine if there are any potential risks for abuse or medication errors. The evaluation is provided to the P&T Committee. The evaluation will consist of the following items as a minimum:

i. Name of medication will be evaluated for look alike sound alike errors

ii. Packaging will be evaluated for appropriate storage

iii. Potential for high risk errors

iv. Abuse potential

v. Similar drugs on the formulary will be evaluated to determine if any agent should be deleted from the formulary.

2. The P&T Committee will review the submitted materials for formulary addition. The P&T Committee will evaluate the following information when considering the requested addition to the formulary:

a. Indication for use, including FDA approved indications and unlabeled uses
b. Effectiveness of the agent
c. Drug interactions
d. Adverse effects
e. Black box warnings
f. FDA risk evaluation and mitigation strategy (REMS)
g. Sentinel event advisories
h. Potential for errors and abuse (i.e. look-alike and sound-alike drugs) and abuse
i. Cost
j. Population(s) served (i.e. pediatrics, geriatrics)

3. If the requested agent is approved for addition to the formulary, changes are made to the on-line formulary, and appropriate computer systems.
4. The medical staff will be notified of hospital formulary changes by Directors of Pharmacy or designee.
5. Once the requested agent is approved for addition to the formulary, all adverse drug reactions, drug/food interactions and medication errors will be reported in Ochsner's SOS system and reviewed by the P&T Committee. Each facility will determine the time frame a new agent will be monitored after approved as an addition to the formulary. This will be determined on approval.

B. Pharmaceutical Waste Characterization

1. When medications are added to the formulary, the NDC number, drug description, and dose will be submitted to a third party vendor for waste characterization.
2. When medications are characterized as hazardous, changes to the pharmacy computer system and automated dispensing machines will be completed to alert staff regarding proper disposal.

C. Formulary Status

1. The P&T Committee may recommend certain "restrictions" for medications on the formulary. These restrictions will be defined via a best practice advisory (BPA) in the EPIC system.

2. The formulary status of a medication is based on adverse effects, patient safety, special administration techniques, cost and other data regarding the medication.
3. Precautions to decrease errors may also be recommended by the P&T Committee, such as special distribution procedures, required order sets, and double-check systems.
4. Formulary restrictions will be noted in the facility specific on-line formulary and computer system.

D. Generic Medications

1. Generic entities approved on the formulary will be utilized unless the Physician completes a nonformulary electronic request and documents DAW in the reason field.
2. Generic medications utilized will have 'A ratings' (deemed bioequivalent by the FDA).
   a. The only exceptions are those agents identified as drugs with narrow therapeutic indexes (refer to Policy: OHS.PHARM.023 Narrow Therapeutic Index Drugs).

E. Therapeutic Interchange

1. The P&T Committee will evaluate medications in the same therapeutic class to determine if therapeutic interchange is warranted. The committee will evaluate the medications for therapeutic interchange utilizing physician specialists, literature, and comparative data of the medications. Emphasis will be placed on the following: equal efficacy (based on evidence-based clinical trials), evidence of effectiveness (based on positive clinical outcomes in usual patient care conditions), humanistic outcomes (i.e. side effects, quality of life, patient satisfaction) and drug acquisition costs.

   a. Computer notifications will automatically notify the end user entering the order of the interchange unless it is a facility specific Therapeutic Interchange. The end user will then choose one of the interchanges. Site specific interchanges follow the site operational standard.

2. The pharmacy department reviews all therapeutic interchanges annually and makes recommendations to the P&T Committee as necessary

F. Non-Formulary Medications

1. The end user will complete a nonformulary electronic request form for all nonformulary medications ordered except home medications.

2. If the end user chooses to continue a nonformulary home medication instead of the alternatives provided then an exception code will be required (reason to continue the nonformulary medication).
3. There will be a delay in the initiation of therapy when non-formulary medications are ordered since these medications are not routinely kept in stock.
4. The use of non-formulary medications are reviewed by the P&T Committees.

G. Formulary Review

1. Review of the hospital inpatient and outpatient formulary approved drug list is on-going.
2. Medication shortages and backorders are reviewed at the P&T Committee.

a. The P&T Committee will take actions, such as restrictions to certain population, if deemed necessary.

b. Medications shortages and backorders will be communicated to the Provider groups most affected by the outage. Pharmacy will offer substitutions to prescribing providers when unavailable medications are prescribed. The pharmacy and the P&T Committee will develop substitution strategies for shortages that are deemed long term.

3. The P&T Committee routinely reviews adverse drug reaction reports, medication error reports and other safety information. The P&T Committee may make changes to the formulary status of medications based on these reports.
4. The pharmacy departments routinely conduct drug class reviews and presents findings to the P&T Committee.
5. The pharmacy departments will review FDA warnings to determine if any formulary modifications are necessary.
6. The pharmacy will review medications that have not been routinely used and make recommendations to the P&T Committee for change in formulary status is necessary.
7. The pharmacy departments review the formulary annually and make recommendations to the P&T Committee as necessary.

V. Enforcement and Exceptions

A. Medications not listed on an outpatient department Formulary may be used on a one-time basis with the administrative approval of the Director of Pharmacy and the Director of Ambulatory Nursing.

1. The ordering Physician must request the medication be added to the outpatient Formulary for subsequent uses.

B. Requests for exceptions to this policy must be submitted to the Director of Pharmacy and MUST:

1. Describe the reason for requesting the exception.
2. Describe the specific impact on the Covered Individual and the Company.
3. Describe the specific impact on the Covered Individual if the request is denied.

C. Prior to approval of any exception request, Covered Individuals will continue to comply with this policy.

D. Failure to comply with this policy may result in disciplinary action up to and including termination of employment for employees or termination of contract or service for third-party personnel, students or volunteers.

VI. Definitions

A. Formulary Status is determined based on adverse effects, patient safety, special administration techniques, cost and other data regarding the medication. Special precautions may also be put in place to decrease the potential for errors such as a special distribution procedure, a required order form, a double check system, or other measures deemed appropriate.

B. Therapeutic Interchange is defined as the dispensing of a drug that is therapeutically equivalent to but chemically different from the drug originally prescribed by a physician or other authorized prescriber.

C. System P&T Committee: The P&T Committee for System.

D. P&T Committee: The facility or local P&T Committee.

VII. Internal References

Request for Addition to the Formulary
Non-Formulary Request Form
Guidelines to Request a New Drug be placed on a Clinic or Hospital Based Outpatient Drug list
OHS.PHARM.022 Outsourcing Sterile Compounding Services
OHS.PHARM.019 Patient Home Medications
OHS.PHARM. Sample Medications
SOS.PHARM.006 Best Practice Advisory (BPA) Operational Standard
SOS.PHARM.007 Therapeutic Interchange Operational Standard
SOS.PHARM. 008 Formulary Addition Operational Standard

OHS.PHARM.023 Narrow Therapeutics Index Drugs

VIII. External References

The Joint Commission; Medication management Standard MM.02.01.01: The hospital selects and procures medications.

ACCP Position Statement: Guidelines for Therapeutic Interchange -2004

IX. Approved

Warner Thomas, President and Chief Executive Officer
Michael Hulefeld, Executive Vice President and System Chief Operating Officer
Michael Louviere, Executive Vice President, Supply Chain

Reviewers

System Pharmacy & Therapeutics Committee, 7/23//2014
Ochsner Baptist Medical Staff Operating Committee 5/28/14
OMC West Bank Medical Staff Operating Committee 6/18/13
OMC Jefferson Highway Medical Staff Operating Committee 7/2/13
OMC Staff Executive Committee 7/8/13
Medical Advisory Committee 8/20/14

X. Policy History

Former Policy 8610pc-29 Hospital Formulary
8610pc-87 Ambulatory Clinic's 2Departmental Formulary