Formulary Process

Christine L. Ahrens, Pharm.D.
Cleveland Clinic

Goal and Objectives

• To understand the formulary process from the hospital perspective
  – To list the various panels or committees that review medications
  – To understand how a medication is requested for formulary review
  – To describe what data are included in the formulary review process
  – To describe the formulary implementation and subsequent follow-up
Formulary

- Health-System
- Closed formulary
- Restrictions
- Medications administered to:
  - Inpatients
  - Outpatients (e.g., vaccines, biologic infusions)
- Formulary does not include medications dispensed from owned health-system retail pharmacies

Formulary Specialty Panels and Medical Staff P&T Committee

- NeuroSciences
- Critical Care/Surgery
- Cardiovascular
- Hematology/Oncology
- Internal Medicine
- Pediatrics
- Transplant

- Medical Staff P&T Committee
  - Local P&T Committee
Specialty Panels and P&T Committee

• Specialty Panels
  – Medical Staff and clinical pharmacy specialists that are experts in medical subspecialty
  – Representatives from across health-system
  – Meet once per quarter
  – Recommendations are sent to Medical Staff P&T Committee

• Medical Staff P&T Committee
  – Review and make final decision on recommendations from all Specialty Panels
  – Local P&T Chairs from all health-system hospitals and Specialty Panel Chairs, Pharmacy, and Nursing
  – Meet once per quarter

P&T Committee / Specialty Panels

• Co-Chair / Membership
  – Two co-chairs; main campus and community hospital

• Quorum
  – Majority (>50%) of main campus and majority of community hospital members
  – Absence of quorum: discussion of all agenda items, written summary via email with any votes required.

• Voting
  – 2/3 majority vote and majority of both main campus and community hospital members present.

• Meeting Logistics
  – TBD by co-chairs and committee members
  – Packets sent in advance of meeting date
  – Audio conference / Go to Meeting availability
Local P&T Committees

• Decisions from Medical Staff P&T Committee are given to local hospital P&T Committees for implementation
• Local P&T Committees cannot change any decision made by the Medical Staff P&T Committee
• Local P&T Committees can be more restrictive if needed
  – Medical Staff P&T Committee: Restricted to Cardiology
  – Local P&T Committee: Restricted to select Cardiologists
• Appeals process

Proposed Appeals Process

• CCHS Medical Staff P&T decisions would be final
  – Sole appeal process goes directly to the Specialty Panel for reconsideration and recommendation to the CCHS Medical Staff P&T Committee for approval
  – Once the appeal decision is approved by CCHS Medical Staff P&T committee, individual hospitals P&T Committees would be expected to implement
Benefits of System-Wide Formulary Management

- **Standardization**
  - CPOE, Standard IV concentrations, Smart Pumps drug libraries, Formulary
  - Improved ability/efficiency for multiple site physician, nursing, pharmacy and allied health care practitioner practice/staffing

- **Appropriate Utilization**
  - System wide utilization initiatives to assure appropriate use

- **Cost Improvement**
  - Volume / market share contracting

- **Risk Reduction**
  - Reduced potential for medication errors
Potential issues with current structure:

• Review and approval timing issues (hospitals making decisions at different times)
• System approvals and denials overturned at the local level
• Leading to:
  – lack of standardization
  – inappropriate utilization
  – increased cost
  – increased risk of medication errors

Proposed CCHS Pharmacy & Therapeutics Committee
Formulary Review & Approval Process
Individual Hospital P&T Committee Functions

- The following P&T functions would remain at the local level
  - Implementation of Formulary decisions
  - Communication, implementation, and maintenance of the Formulary System
  - Medication systems policy and procedure development
  - Joint Commission and Medication Safety issues
  - Evaluation of Medication incidents
  - Education of all health care professionals

Requested Action

- Each MEC Chair to present the proposed new reporting and implementation structure to their local MEC’s for approval
Non-Formulary

• Pharmacy will not order, stock, or dispense a medication until it has undergone official formulary review and a decision is made
  – Considered non-formulary

• Chronic, oral or injectable maintenance medication
  – Case-by-case basis

Beginning....

• Any FDA-approved medication may be requested for formulary review
  – No cost thresholds
  – Medications already on the market
    – Months to years
  – Medications recently approved
    – No requirement to be on the market for a certain period of time
Exception

• Line extensions
  – New dosage form
• Drug Information Center determines if a formulary request form needs to be submitted and subsequently, a complete formulary review
  – Cost
  – Potential for inappropriate use
  – Antiepileptic: New intravenous formulation used in patients that are taking other oral medications and not because the patient is NPO

Formulary Request Form

• Only Staff Physicians can request a medication to be reviewed for formulary
  – No medical residents, fellows, nurses, respiratory therapists, etc.
• Pharmacy can be pro-active
• One standard form for the entire health-system
• Only takes one request form to initiate review for entire health-system
Formulary Request Form

• Requesting health-system hospital
• Medication name
• Specific request: Add/Change/Delete
• Indication(s)
• Replace existing formulary drug(s)

Formulary Request Form

• Efficacy (2)
• Safety (1)
• Cost (3)
• Usage
• Restrictions
• Conflicts of interest
• Signatures
Middle….

- Formulary request form is reviewed by the Drug Information Center
  - Inpatient/Outpatient versus Retail
  - Completeness, including signatures
- Assign to appropriate Specialty Panel
  - Medication may be reviewed by more than one Specialty Panel
- Assign pharmacy clinical specialist to prepare the drug evaluation monograph

Drug Evaluation Monograph

- Standard template
  - ACMP Dossier is not used
  - Material provided by manufacturer may or may not be used
    - Data on file, if needed
    - Monographs written from scratch
- Basics
  - Generic name/brand name/manufacturer
  - Standard or Priority review by FDA (1S, 1P)
  - Similar medications
Drug Evaluation Monograph

• Pharmacology
  – Similar or different from other FDA-approved medications or standards of care

• Pharmacokinetics
  – Absorption
  – Distribution
  – Metabolism
  – Excretion

Drug Evaluation Monograph

• Efficacy
  – Published clinical trials
  – Phase 2 or Phase 3 (preferred)
  – Trial(s) reviewed by the FDA
  – No specific number of clinical trials needed
  – Abstracts
  – Expert opinion by Medical Staff
  – Comparison to standard of care or current formulary medications
Drug Evaluation Monograph

• Safety
  – Black Box Warnings
  – Contraindications
  – Warnings/Precautions
  – Adverse reactions
  – Drug interactions
  – Pregnancy and lactation
  – Comparison to standard of care or current formulary medications

Drug Evaluation Monograph

• Risk Evaluation and Mitigation Strategies (REMS)
• Components of specific REMS
  – Medication guide
  – Elements to assure safe use (ETASU)
    – Medical Staff registration/certification
    – Pharmacy registration
    – Criteria met prior to dispensing medication
    – Required paperwork
    – Where medication is dispensed from or stored
    – Specialty pharmacies
• Impact on formulary recommendation….potentially
Drug Evaluation Monograph

• Risk Evaluation and Mitigation Strategies (REMS)
  – At most hospitals, it is pharmacy’s responsibility to manage and coordinate REMS
  – However, Medical Staff and nursing involvement is critical
  – Use computerized prescriber order entry (CPOE) system as much as possible
  – Most difficult is to implement or incorporate REMS into operations
  – At last count:
    – 160 medications with REMS
    – Majority are Medication Guide only
    – But growing portion with ETASUs and more complex requirements

Drug Evaluation Monograph

• Dose and administration
  – Taper required
  – Change of IV line site required
  – Renal/Hepatic/Geriatric dose adjustments

• Storage
  – Refrigerated
  – Expiration dating

• Preparation
  – Education for pharmacy technicians, pharmacists, nurses, and physicians
  – Impact on medication storage: pharmacy versus automated dispensing cabinet
Drug Evaluation Monograph

• Cost
  – Contract
  – Reimbursement
    – Inpatient (Diagnostic Related Group or DRG based)
    – Outpatient
      – Coverage by the patient’s insurance (pre-approval)
  • Cost centers
    – All medications are purchased under the pharmacy cost center as well as medication is received by the pharmacy department (integrity)
    – Cost transfers to other Departments may occur but are rare

Drug Evaluation Monograph

• Contact other hospitals of similar size and scope and inquire if they have reviewed and added the medication to formulary

• Pharmacy clinical specialist makes a recommendation (add/add with restrictions/deny) in the monograph

• Reference section
End…

- Clinical Pharmacy Specialist presents drug evaluation monograph including recommendation to Specialty Panel
- Specialty Panel makes a motion
- Add/Add with restrictions/Deny
- Majority vote
- Recommendations then goes to Medical Staff P&T Committee for final decision

P&T Committee Decisions

- Added 15%
- Added with Restrictions 10%
- Change in Current Restriction 7%
- Deleted 0%
- Not Added 8%

N=73

Number of drugs considered for review = 73
Time

• Entire formulary review process takes a minimum of 3 months based on when the Specialty Panels and Medical Staff P&T Committee meet, but process could take up to 6 months
• Expedited review for medications that meet select criteria (impact on patient care)

Follow-up

• Drug use evaluation may be requested after period of time (6 months to 1 year)
• REMS
• Computerized prescriber order entry system (CPOE) drug files and alerts
• Pharmacy carousels or automated dispensing cabinet storage or both
• Education
Summary

• Medications undergo a specific formulary review process before being ordered, stocked, and dispensed from the pharmacy
• Each hospital or health-system will have different panels or committees that review medications for the formulary (multiple panels to one committee)
• Each hospital will have a process for requesting medications for formulary review (standard form or proactive approach)

Summary

• A formulary monograph will include data on safety (1), efficacy (2), and cost (3) as well as pharmacology, kinetics, and dose and administration
• Often there is follow-up that is requested by the P&T Committee once a medication has been added to the formulary
• Hospital formularies are dynamic and under continual review
Cleveland Clinic

Every life deserves world class care.