Introduction To Formulary Systems

Linda Sturm, RPh, MHA, BCPS
Director of Clinical Services
Formulary Resources, LLC
“Wonderful! Just wonderful! ... So much for instilling them with a sense of awe.”
Definition: Formulary

- List of “preferred” medications
- Medication-related information
- Updated regularly
- Represents the clinical judgement of physicians, pharmacists, and others
- Utilization management tool

Types of Formularies

• Categorized according to reimbursement structure
  – Open – educational, all drugs covered
  – Closed – Non-formulary drugs are not covered unless “medically necessary”
  – Partially/Selectively Closed – Certain drugs &/or classes excluded
  – Tiered – open with variable coverage
What Do Formularies Do?

- Promote the safest, most effective use of drugs, related products, and treatments that will provide the desired goals of therapy at the most reasonable cost.

- Vehicle for communication of health promotion information.
Formulary Forms

- Hard copy (book)
- Hard copy (card)
- Web-based
- PDA
Formulary Disadvantages

• Lots of them
• Content not consistent within a region
• Difficult for providers to utilize
• Difficult for lay persons to understand in context with health insurance benefits
Definition: Formulary System

• Ongoing evidence-based process
• Carried out by health care professionals
• To establish policies on the use of drugs, related products, and therapies
• Identifies drug products and therapies most medically appropriate and cost-effective for the health interests of a given population
• Periodic reanalysis

P&T Committees

• Membership
• Size
• Ethics / Conflict of Interest
• Meeting frequency
P&T Committee Functions

- Objectively evaluate and select drugs for formulary
- Establish policies and procedures to educate practitioners about drug products, usage, and committee decisions
- Oversee quality improvement and DUE
- Implement generic substitution and therapeutic interchange programs
- Develops policies and procedures for access to non-formulary drug products

Background / History

• 1950’s Hospitals
• Health plans rapidly adopted use
• 1991 Australian PBAC & CCOHTA (Canada) formulary guidelines developed
• 1998 Regence BlueShield
• 1999 NICE formulary guidelines and tech assessments developed
• 2000-1 AMCP/RBS formulary guidelines adopted nationally
Information Traditionally Used for Formulary Decisionmaking

- Published literature (if available)
- FDA
- Package insert
- “Formulary kit” marketing materials
- Incomplete information
- Anecdote and bias
- Drug impact only
AMCP Formulary Submission Guideline Goals

- Establishment of a comprehensive, standardized, evidence-based process for the evaluation of clinical and economic data
- Provide manufacturers with a consistent format for providing necessary information
- Improve the timeliness, quality, scope and relevance of information available to P&T committees
AMCP Formulary Submission Guideline Goals

- Streamline the data acquisition and review process for P&T support personnel
- Help employers/purchasers feel more comfortable that there is good science behind formulary inclusion decisions, ensuring value
AMCP “Dossier” Content

- Product Information
- Supporting Clinical and Economic Information
- Modeling Report
- Product Value and Overall Cost
- Supporting Information/Appendix
Product Information

• Typical package insert information PLUS
  - Approved indication(s)
  - *Off-label indication(s)*
  - Dose and duration
  - Pharmacology
  - Pharmacokinetics
  - Safety information
  - *Concise comparison of PI with primary comparators*
  - *Pharmacogenomic testing*
Place In Therapy

- Epidemiology
- Pathophysiology
- Health Economics
- Comparator agents/therapies
- Place in therapy (recognized guidelines)
- Expected outcomes
Supporting Clinical and Economic Information

• Key clinical study results (published or not)
  – Labeled
  – Off label

• Key economic study results

• Other key outcome study results (eg. QoL, PRO)

• Disease management intervention strategies

• Economic evaluation supporting data
Modeling Report - Ideal

- To predict system-wide consequences of formulary changes
- A mechanism to demonstrate the potential impact of a drug on *all* costs and outcomes
- Compares new drug to existing therapies
- Must be relevant to the MCO, based on that plan’s costs, demographics, etc
Product Value and Overall Cost

- Executive summary
- Clinical value arguments
- Economic value argument
- “Other” arguments
Supporting Information/Appendix

• References (publications and internal documents)

• Spreadsheet models

• Checklist
Adoptees – Over 110 Million Covered Lives!

- The Regence Group
- Premera Blue Cross
- Group Health Cooperative
- Oregon Health Plan
- Blue Shield of California
- Anthem Rx Management
- Prime Therapeutics
- Louisiana Medicaid
- Mayo Health Plan
- Advance PCS
- Wellpoint
What An MCO Does With Dossiers

- Quick review for completeness
- Request for any incomplete sections
- In-depth analysis
- Preparation of P&T monograph with/without recommendation
- P&T review and decision
- Implementation
Criteria for Decisionmaking

• Relative efficacy

• Drug Use Evaluation (effectiveness)

• Relative safety

• If all else is equal, cost (Drug cost, total medical costs, or societal costs)?
Potential Factors in Formulary Decisions

- Effectiveness
- Safety
- Efficacy
- Consumer expectations
- Productivity, satisfaction and QOL
- Budget Impact
- Physician support
- PBM, physician and pharmacist contracts
- Discounts and Rebates

- Politics and public image
- DTC advertising
- Acquisition cost
- Cost-effectiveness
- HEDIS and NCQA
- Regulatory Issues
- Disease management programs
- Formulary Decision
Types of Formulary Decisions

- Add/Don’t add
- Remove
- Defer
- Prior authorization
- Step edits (contingent therapy)
- QLLs
- Therapeutic interchange
- Mandatory generic substitution
- Communication requests
Communication of Decisions – Who Needs To Know?

- Internal Staff
- Groups/Purchasers
- Government
- Members
- Providers
- Manufacturers