Introduction To Formulary Systems

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Disclaimer

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
- Develop 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)
  - \textit{Off-label indication(s)}
  - Dose and duration
  - Pharmacology
  - Pharmacokinetics
  - Safety information
  - \textit{Concise comparison of PI with primary comparators}
  - \textit{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

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