Introduction To Formulary Systems

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Disclaimer

Definition: Formulary

- List of medications
- Medication-related information
- Regularly updated
- 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?

- Promotes the safest, most effective drugs, related products, and therapies that will provide the desired goals of therapy at the most reasonable cost
- Vehicle for communication of health promotion information

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

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## P&T Committees

- Membership
- Size
- Ethics / Conflict of Interest
- Meeting frequency

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## 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 of the Development of a Formal Formulary Submission Process

- 1950’s Hospitals
- Health plans rapidly adopted use
- 1991 Australian PBAC & CCOHTA (Canada) formulary submission guidelines developed
- 1998 Regence BlueShield
- 1999 NICE formulary guidelines and tech assessments developed
- 2000-1 AMCP/RBS formulary submission guidelines adopted nationally
- 2010 AMCP formulary submission guidelines version 3.0 released.

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 Materials/Appendix

Product Information

- Typical package insert information PLUS
  - Approved indication(s)
  - Off-label indication(s)
  - Dose and duration
  - Pharmacology
  - Pharmacokinetics
  - Safety Information
### Place In Therapy
- Epidemiology
- Pathophysiology
- Health Economics
- Comparator agents/therapies
- Place in therapy (recognized guidelines)
- Expected outcomes

### Supporting Clinical and Economic Information
- Key clinical and economic study results for approved and unapproved indications (published or not)
- 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 standard of care, that plan's costs, demographics, etc.
### Product Value and Overall Cost

- Executive summary
- Clinical value arguments
- Economic value argument
- “Other” arguments

### Supportive Materials/Appendix

- References (publications and internal documents)
- Spreadsheet models
- Checklist

### 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
Traditional Criteria for Decisionmaking

- Efficacy
- Drug Use Evaluation (real-world effectiveness)
- Safety
- If all else is equal, cost (Drug cost, total medical costs, or societal costs)?

Value-based Formulary Decisionmaking

- Decisionmaking based primarily on relative value
- Employs cost-effectiveness analysis (CEA) from systematic reviews & meta-analyses, modeling, trial-based CEA, real-world database analyses, etc.
- In order to fairly assess CE across disparate therapies and disease states need a common base for comparison (e.g., QALY, LYG, etc.)
- Pre-established CE thresholds that influence tiering and benefits

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
- Value tiering
- Communication requests

## Formulary Forms

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

## Communication of Decisions – Who Needs To Know?

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