Drug Information used in the Managed Care Pharmacy P&T Decision Making Process: Current Practice and Insights

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Objectives

• Discuss overview of forum purpose.
• Provide an overview of the P&T committee's purpose, roles & responsibilities, and structure.
• Review the P&T committee's decision-making process(es).
• Discuss key drug information elements that healthcare professionals evaluate in preparation for P&T review.

Pharmacy & Therapeutics (P&T) Committee

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P&T Committee

• Purpose: Ensure access to clinically sound & cost-effective medications, biologics, and devices

• Roles & Responsibilities:
  • Develops and manages:
    • Formulary(ies)
    • Practices and policies for formulary management activities, such as prior/pre-authorization, step therapies, quantity limitations, generic substitutions and other drug utilization activities that affect access

Utilization of P&T Committees

• Organizations that maintain a formulary will use a P&T committee:
  • Hospitals/Health-Systems
  • Health Plan
  • Pharmacy Benefit Manager (PBM)
  • Long Term Care Organizations
  • Veterans Administration (VA)
  • Department of Defense
  • Medicare/Medicaid
  • Correctional Facilities
  • Indian Health Service

P&T Committee Structure

• Primarily physicians and pharmacists
  • Includes practitioners from a variety of specialties

• May also include:
  • Nurses
  • Other health care providers
  • Legal
  • Contracting
  • Quality assurance
  • Administration
P&T Committee Structure, Cont.

- CMS mandates for Medicare Part D P&T:
  - Various clinical specialties that adequately represent the needs of sponsors’ enrollees
  - A majority of members are practicing physicians and/or practicing pharmacists or both
  - At least one practicing physician and at least one practicing pharmacist are independent and free of conflict with respect to the Part D sponsor and pharmaceutical manufacturers
  - At least one practicing physician and one practicing pharmacist are experts regarding care of elderly or disabled individuals

P&T Committee Management

- P&T committee Charter
  - Conflict of interest statement revealing economic or other relationships with entities affected by drug coverage decisions that could influence committee decisions
  - Consultant agreement

- P&T committee should meet on a regular basis, but no less than quarterly.

- P&T committee decisions regarding formulary development or revision are documented in writing.

P&T Decision Making Process, Cont.

- CMS mandates for Medicare Part D:
  - Drugs’ therapeutic advantages in terms of safety and efficacy must be considered when selecting formulary drugs and placing them on formulary tiers.
  - The P&T committee will make a reasonable effort to review a new FDA approved drug within 30 days of the date of the FDA approval. If a new drug is not FDA approved or if the FDA approval was not within 30 days of the conference, the drug will be placed on the formulary with no restrictions on use until FDA approval.
  - The P&T committee will evaluate and analyze treatment protocols and procedures related to the sponsor’s formulary at least annually.
  - The P&T committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.
  - P&T committees must review for clinical appropriateness protocols and procedures, for the therapeutic use of and access to both formulary and non-formulary drug products.

Answering Basic Questions

- CAN IT WORK?
  - CER
  - RCTs
  - Clinical Guidelines

- DOES IT WORK?
  - FDA
  - USP
  - HSA

- IS IT WORTH IT?
  - Cost Effectiveness
  - Cost Benefit

P&T Committee Decision Making Process

- Formulary management decisions are based on the strength of scientific evidence and standards of practice, including assessing:
  - Peer-reviewed medical and clinical literature including clinical trials and well-established treatment guidelines, comparative effectiveness reports, pharmacoeconomic studies and outcomes data
  - FDA-approved prescribing information and related FDA information including safety data
  - Relevant information on use of medications by patients and experience with specific medications
  - Current therapeutic use and access guidelines and the need for revised or new guidelines
  - Economic data, such as total health care costs, including drug costs
  - Drug and other health care cost data (not all P&T committees review drug specific economic data)
  - Health care provider recommendations
  - Other such information as deemed appropriate in order to achieve appropriate, safe, and cost effective drug therapy.

Systematic Search for Formulary Review

What Type of Evidence Will Be Included?

- Evidence Hierarchy
  - Systematic Review
  - Large Population Trials
  - Cohort Studies
  - Guide Reviews
  - Case-Controlled Studies
  - Expert Opinion
  - Background Information / Expert Opinion

Trusted Sources - CER Systematic Reviews

- Cochrane Database of Systematic Reviews
- Agency for Healthcare Research & Quality
- Drug Effectiveness Review Project (DERP)
- Centre for Reviews and Dissemination
- Database of Abstracts of Reviews of Effects
- Canadian Agency for Drugs & Technologies in Health

*“Trusted Sources” are best known for:
  - Rigorous, systematic methodology
  - Transparency
  - Auditing/critical appraisal of included research to base conclusions
  - Systematic reviews that hold up to critical appraisal by external users

*CER Systematic Reviews are NOT just narrative reviews.*
References & Resources

- AMCP.
  - Concepts in Managed Care Pharmacy Series: Formulary Management.
  - Principles of a Sound Drug Formulary System. Available at: http://www.amcp.org

Financial Considerations

- Rebates
- Cost per ETG or Episode Treatment Group
- Pay for Performance
- Copay Impact
- Benefit Caps
- Industry Relations and Key Contacts

Rebates

- P&T process variations
  - Initial clinical meeting
  - Subsequent financial meeting
  - Hybrid process models
- Pricing of drugs – the AWP conundrum
- State Medicaid changes
  - Health care Reform
  - FFS to Managed Medicaid

Timing is Everything

- Dossier release prior to market entry
- Rebate contracting prior to P&T
- PBM or hospital P&T prior to client or subsidiary P&T
- P&T member packets
- The Wait-and-See approach
- Medicare Part D

Pharmacoeconomic Dossier Model

- Utilization by managed care plans and HR departments?
- Barriers preventing more widespread use of the model
- Real world examples
- Incorporation of generic options within a class
What Clients Want......

- Managed Care vs. Self Insured vs. Facility
- Size Matters
- Economy and Resources
  - Mini Monographs
- Timing of Dossiers and Placement on AMCP eDossier System for Easy Access
- Realistic Economic Modeling
- Reasonable Member / Employee / Patient Impact

Mini-Monographs

- Description (to include Indication, FDA approval, Mechanism of Action)
- Considerations
- Dosing (Dosing, Special considerations, Available formulations)
- Safety
  - Adverse Effects
  - Drug Interactions
  - Contraindications
  - Caution
- Efficacy (Description of trials)
- Effectiveness

Mini-Monographs, Cont.

- Comparison of Alternative agents (May include nationally accepted treatment guidelines)
- Utilization Data
- Cost Comparison
  - Compare estimated ingredient cost of new product if not included in the utilization data.
  - May also provide cost projection/comparison to existing therapies.
- Potential for Duplication
- Recommendation
- Rationale
- References

Evidence-Based Medicine included in P&T Decision Making Process

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Challenges of Health Economic or Outcomes Research (HEOR) in Decision Making

Background and Objectives of Survey

- Online Survey
- To (pharmacy) decision makers in PBM, health plans, managed care, Medicaid/Medicare
- Distributed direct via personal connections and via the Academy of Managed Care Pharmacy (AMCP)
- 76 completed questionnaires
- 9 demographic questions
- 24 question around the use of HEOR in current and future decision making
Survey Topics

1. Participant and Health Plan Related Information
2. Decision Structure
3. Current Use of HEOR
4. HEOR: Data Sources
5. HEOR in Future
6. Outcomes in Contracting
7. Benefit Design
8. Information Used in Decision Making: Now and in Future

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**Does your organization use HEOR data today?**

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**Do you expect an increased use of HEOR data in decision making in the future?**

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**Academy of Managed Care Pharmacy Format for Formulary Submissions**

- A process to obtain a standardized set of data and information about a drug from its manufacturer
- Primarily used by commercial insurance plans to evaluate drug therapy options for reimbursement
- Often supplemented by independent analysis and review by individual health plans
- Provides an opportunity for dialogue between the health plan and the manufacturer regarding definition and willingness to pay for “value”


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**eDossier System**

For eDossier questions, email information@amcp.eDossiers.com.

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**Q&A**