Principles for Sound Pharmacy and Therapeutics (P&T) Practices: What’s Next?

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Welcome

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How to Ask Questions
The live, hands-on AMCP Partnership Forums bring key decision makers in managed care, integrated care, the pharmaceutical industry, and others together to discuss and collaborate on tactics and strategies to drive efficiencies and outcomes in integrated care and managed care.
AMCP Partnership Forums

- Adopt a proactive, collaborative approach
- Provide a voice
- Gain consensus and remove barriers
- Allow stakeholders to work together on common goals and interests
- Garner high visibility
- Find common ground and actionable results
2019 AMCP Partnership Forums

- **Pharmacy and Therapeutics (P&T) Practices: What’s Next?**
  March 28 | Marriott Marquis, San Diego, Calif.

- **Optimizing Prior Authorization for Appropriate Medication Selection**
  June 25–26 | Hilton Mark Center, Alexandria, Va.

- **Digital Therapeutics: What Are They and Where Do They Fit in Pharmacy and Medical Benefits?**

- **What’s Next for Specialty Medication Benefit Design and Reimbursement**
2020 AMCP Partnership Forums

Live Forums in Alexandria, Va.
- Helping Patients Anticipate and Manage Drug Costs | March 12–13
- Preparing for and Managing Rare Diseases | September 8–9
- Biosimilars: Policy, Practice, and Post Marketing Surveillance to Support Treatment and Coverage Decisions | December 15–16

Workgroup
- Addressing Barriers to Value-based Payment Models in Integrated Delivery Networks
Faculty

Mandy Leonard, PharmD, BCPS
System Director, Drug Use Policy and Formulary Management
Cleveland Clinic

Conor Hanrahan, PharmD, BCPS, CPHIMS, CPPS
Medication Policy, Outcomes, and Stewardship Director
Intermountain Healthcare
Agenda

- P&T committee: Responsibilities and process evolution
- Forum findings and recommendations
- Q&A
- Next steps and action items
P&T Committee:
Responsibilities and Process Evolution
Principles of a Sound Formulary System

Guiding Principles

• Formulary system decisions are based on scientific and economic considerations that achieve appropriate, safe and cost-effective drug therapy.

• The formulary system encompasses drug selection, drug utilization review, and other tools to foster best practices in prescribing, dispensing, administration, and monitoring of outcomes.

• The P&T committee, or equivalent body, comprised of actively practicing physicians, pharmacists, and other health care professionals, is the mechanism for administering the formulary system, which includes developing and maintaining the formulary and establishing and implementing policies on the use of drug products.
Principles of a Sound Formulary System

Guiding Principles

• Physicians, pharmacists, and other health care professionals provide oversight of the formulary system.

• The formulary system must have its own policies, or adhere to other organizational policies, that address conflicts of interest and disclosure by P&T committee members.

• The formulary system should include educational programs for payers, practitioners, and patients concerning their roles and responsibilities.

• The formulary system should include a well-defined process for the physician or other prescriber to use a non-formulary drug when medically indicated.
P&T Committee Responsibilities

Primary Function

• The central role of the P&T committee is to maintain the drug formulary to promote treatment safety, efficacy, and value to organizations.

Additional Roles

• Developing clinical care plans
• Setting treatment guidelines
• Establishing critical pathways
• Instituting disease management protocols
## P&T Committee Stakeholders

<table>
<thead>
<tr>
<th>Physicians</th>
<th>Pharmacists</th>
<th>Nurses</th>
<th>Other health care professionals</th>
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<tbody>
<tr>
<td>Administration</td>
<td>HEOR</td>
<td>Leadership (Chairs or department leads)</td>
<td>Specific clinical specialties, as needed</td>
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<tr>
<td>Medication use process experts</td>
<td>Patient representatives</td>
<td>Safety and quality-improvement professionals</td>
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**Caveat for Medicare**
- Requirement for “an independent practicing physician and independent practicing pharmacist”
P&T Committee Decision Making

Objective Evaluation of Key Characteristics
- Clinical
- Economic
- Humanistic
Guideline and Evidence Assessment
Research and Assessment

Types of Evidence Supporting the Creation of an Objective Formulary Monograph

• Randomized controlled trials (RCTs)
• Network meta-analyses
• Clinical and treatment guidelines
• Manufacturer dossiers
• Other published literature
Coverage Evidence Cited

Evidence cited in coverage policies

- SPEC Database comes from 17 Payers covering 130 million covered lives

- Randomized controlled trials: 17%
- Guidelines: 15%
- FDA label: 13%
- Health technology assessments: 13%
- Editorials and other reviews: 11%
- Other clinical studies: 11%
- Real-world evidence: 11%
- Evidence syntheses: 11%
- Economic evaluations: 7%
- Other: 4%
- Other: 1%
Other Sources of Information

Additional Types of Information that are Gaining Traction

• Health technology assessments
• Economic evaluations
• Real-world evidence
• External groups or expert opinion publications
• Patient advocacy group reports
Best Practices of Successful P&T Committees
Team and Meeting Logistics

Key Considerations

• Broad inclusion of competencies
• Specific roles for each participant
• Clear definition of “value”
• Maintained objectivity
• Standardized process
• Anonymity and confidentiality
• Protected time
Evidence for P&T Committees to Include and Consider

Recommendations Regarding Evidence

• Assess results of randomized clinical trials objectively
• Review claims information and real-world data if available
• Factor in cost-effectiveness research and modeling
• Include patient perspectives in the evidence case
• Leverage patient-reported outcomes within studies
• Consider expert opinions and reports from external organizations
Training and Education

Training and Development Considerations for all P&T Committee Members and Supporting Staff

- Present fair and relevant information
- Provide training various types of research approaches
- Develop clinical data interpretation skills
Key Barriers and Challenges
Disclosing and Managing Potential Conflicts of Interest (COIs)

COIs are often financial in nature, but may have several layers of complexity as activities can change over time.

Guidance for Managing COIs

- Set clear definitions and policies for COIs
- Hold all members equally accountable
- Establish timeframes for COI disclosures
Transparency of Rationale for Formulary Decisions

- *P&T committee meetings are confidential in nature, but stakeholders often want more information about formulary decisions*

Suggestions on Approaches to Formulary Transparency

- Establish annual compliance training
- Share background information on literature used
- Provide information about the general background of committee members
- List the rules and mandates followed during the P&T processes
- Note potential COIs for P&T committee members
Principles and Best Practices:
Committee Composition and Meeting Logistics

The P&T committee, comprised of actively practicing physicians, pharmacists and other health care professionals, is the mechanism for administering the formulary system, which includes developing and maintaining the formulary and establishing and implementing policies on the use of drug products.²
Principles and Best Practices

Committee Composition and Meeting Logistics cont’d

Best practices for the P&T committee:

• Include a broad range of member expertise (e.g. specific clinical specialties, medication use processes, safety and quality-improvement) to provide unique perspectives

• Designate specific roles to be included in P&T committee (e.g. administration, HEOR, chair or department lead, nursing lead, and patient representation)

• Align on a clear working definition of value for the P&T committee

• Maintain objectivity within the P&T committee, holding each member accountable in the decision-making process

• Standardize and formalize P&T committee processes

• Develop protocols around anonymous voting and confidentiality for the P&T process

• Provide administrative time for data/monograph review prior to meetings and ample time during the P&T meeting for review and discussion
Principles and Best Practices

Evidentiary Considerations

Formulary system decisions are based on scientific and economic considerations that achieve appropriate, safe and cost-effective drug therapy.\(^2\)

Consider or include the following types of evidence in reviews:

- Randomized clinical trials, making sure to assess the study design and results objectively
- Real-world data, to provide additional context in coverage decision reassessments and formulary updates
- Cost-effectiveness research and modeling, to assess the value of a therapy
- Patient perspectives, to provide insight into the practical use of therapies and impact on quality of life outcomes.
- Expert opinions and reports from external organizations are helpful for reevaluations, new indications, and instances where limited data are available.
Principles and Best Practices

Training and Education

The formulary system should include educational programs for payers, practitioners, and patients concerning their roles and responsibilities. Consider building educational programs to support the competencies of new stakeholders.

Provide training to all committee members and staff on the following:

• How to develop and present fair and relevant information in an accessible manner
• Methods, benefits, and limitations of various types of research approaches like health technology assessments, cost-effectiveness research, and economic evaluations
• Clinical data interpretation skills
• Value and cost-benefit assessments
Future Opportunities

Key Opportunities for P&T Committees

• Education and training on new data sources
  • Real-world evidence
  • ICER reports
  • Patient-reported outcomes
• Incorporation of new data into formulary decisions
• Development of best practice case studies
Summary

- Evaluating P&T committees processes and the usage of new types of evidence and perspectives continuously is critical.

- Training P&T committee members is also important, which can include guidance on how evidence should be used and viewed, as well as policies and protocols.

- Establishing organizational policies on transparency around P&T committee processes and decisions are crucial for establishing successful P&T committees.
How to Ask Questions
The purpose of this report is to present the key findings and recommendations from the AMCP Partnership Forum: Principles for Sound Pharmacy and Therapeutics (P&T) Committee Practices: What’s Next? held in January 2020. The forum brought together pharmacy and therapeutics (P&T) committee members from across the pharmaceutical industry to discuss best practices in P&T committees and their role in today’s evolving health care system. The 25 committee members identified four main areas for improvement:

1. **Committee Process:** Enhancing the effectiveness of P&T committees through streamlined processes and improved decision-making.
2. **Stakeholder Engagement:** Strengthening engagement with all stakeholders to ensure comprehensive and balanced decision-making.
3. **Patient-Centered Medicine:** Integrating patient-centered outcomes into P&T committee decisions to improve medication selection.
4. **Interdisciplinary Collaboration:** Fostering collaboration across disciplines to enhance the overall value of P&T committee recommendations.

**Abstract:** The AMCP Partnership Forum: Principles for Sound Pharmacy and Therapeutics (P&T) Committee Practices: What’s Next? brought together P&T committee members from across the pharmaceutical industry to discuss best practices in P&T committees and their role in today’s evolving health care system. The 25 committee members identified four main areas for improvement:

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4. **Interdisciplinary Collaboration:** Fostering collaboration across disciplines to enhance the overall value of P&T committee recommendations.

**Conclusion:** The forum concluded with a call for continued collaboration among stakeholders to ensure that P&T committees continue to evolve and adapt to the changing landscape of health care.
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