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**Value & Access
Partner Spotlight Presentation**

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Best Practices for Pharmacy & Therapeutics (P&T) Committees

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Pharmacy & Therapeutics (P&T Committees)

- Health plans have a fixed amount of money each year to serve their population
- Costs of treatment are weighed against the entire budget
- P&T Committees are managed by the health plan, and:
 - Serve as expert knowledge area consultants
 - Manage the formulary system
 - Work in conjunction with the health plans' medical and pharmacy departments
- Mandate for plans administering Medicare Part D or Medicare Advantage to have a P&T Committee made up of practitioners. Yet, no set process.

Model Best Practices Process

- Created for P&T Committees to consider when managing the formulary system
- Make equitable coverage decisions focusing on:
 - evidence-based processes
 - promoting treatments offering the best therapeutic outcomes
 - minimizing potential risks and costs to patients
- Important for stakeholders to be aware of best practices and processes



Two Segments of the Checklist

- Responsibilities of the medical leadership (health plan) in creating/managing a P&T Committee
- Responsibilities of the P&T Committee



Responsibilities of the medical leadership (health plan) in creating/managing a P&T Committee

- Ensure that the right people are on the P&T Committee and kept current on upcoming treatments
 - Actively practicing primary care physicians (particularly those focused on high-risk areas)
 - Practicing pharmacists and other health care professionals
 - Specialists covering the clinical needs of the majority of enrollees
 - Require full disclosure of conflicts of interest (and recusal where there is a known conflict of interest) from health plan and pharmaceutical manufacturers

Responsibilities of the medical leadership (health plan) in creating/managing a P&T Committee (cont'd.)

- Provide guidelines on the authoring and reviewing of P&T Committee documents
 - This is the most highly ranked factor that could have a perceived beneficial effect on P&T committee functions
- Implement standardization across all sites
 - There is a higher likelihood of evidence-based practice with contribution by multiple party decision-making vs. single subject matter expert experience/opinion

Responsibilities of the P&T Committee

- Gather unbiased, evidence-based information on the following factors to make recommendation to medical leadership on whether the agent should be covered:
 - Clinical Efficacy
 - Safety
 - Patient convenience, adherence & satisfaction
 - Economic
 - Pricing – Can only come into consideration when there are multiple agents to choose from. With all else being equal, and the physician feeling that either/any of the agents could be prescribed, it is up to the health plans to negotiate pricing with the manufacturer.

Responsibilities of the P&T Committee (cont'd.)

- If the medical staff leadership accepts a “yes” recommendation, determine how the agent should be made available
 - Agent should be made widely available without prior authorization form
 - Prior authorization required
- If prior authorization is required, outline the criteria that must be met, and the process that patients must go through to ensure that safety and efficacy standards are being met, including:
 - Testing
 - Treatment
 - Other considerations

Responsibilities of the P&T Committee (cont'd.)

- If prior authorization is required, outline the drug utilization management process
 - Medical Director reviews and responds to requests within 14 calendar days (expedited requests within 24 hours)
 - If prior authorization criteria are met, enter authorization into pharmacy billing system for filling, within a sufficient time period to ensure continued therapy under enrollee's appropriate benefit tier.
 - If prior authorization is denied because criteria is not met, notify both the requesting provider and enrollee including the reason for denial and the process for appealing the decision.

Responsibilities of the P&T Committee (cont'd.)

- If step therapy is required, outline the drug utilization management process
 - List specific step therapy criteria on formulary.
 - If claim for required medication is currently in health plan's system, process the step therapy medication without approval from plan's pharmacy customer service.
 - If a record of the required medication is not available, the prior authorization process should be followed (submit a request form to pharmacy services).

Responsibilities of the P&T Committee (cont'd.)

- Non-formulary medications
 - Base reviews on diagnosis, formulary product(s) previously tried, evidence of efficacy, and medical necessity.
 - Generally, approve requests if enrollees have tried and failed formulary products due to either an inadequate response or a medical contraindication to their use, and for enrollees who are previously stable on certain medications that have been determined to be medically necessary.
 - Review and respond to requests in compliance with applicable regulations, not to exceed 14 calendar days. Review expedited requests within applicable regulation, (typically 24 hours)
 - If request does not meet criteria (diagnosis and results of previous therapy), medical director will review.
 - If prior authorization criteria are met, enter authorization into pharmacy billing system for filling, within a sufficient time period to ensure continued therapy under enrollee's appropriate benefit tier. Notify requesting individual of approval. Notify member following regulatory protocol.
 - If prior authorization is denied because criteria is not met, notify both the requesting provider and enrollee in writing, or if the enrollee has agreed to receive information in this manner, electronically, including the reason for denial and the process for appealing the decision.

Responsibilities of the P&T Committee (cont'd.)

- Make prior authorization forms and information easily available to physicians, so they can make an immediate decision and start the process
 - Load form on physician desktop
 - Make available on portal
- Appeals Process
 - Communicate decisions on Medicare Part D enrollee appeals according to CMS policy and procedures.
 - Standard redetermination involving requests for covered drug benefits = 7 calendar days.
 - Expedited redetermination = 72 hours within receiving request.
 - Health plan will forward the enrollees request to appropriate reviewing entity within 24 hours of the expiration of the appropriate adjudication timeframe if a decision is not made.
 - Communicate decisions on Non-Part D enrollee appeals pursuant to regulatory rules.
 - Standard appeals involving requests for covered drug benefits = 30 calendar days.
 - Expedited appeals = within 72 hours of receiving request.
 - Make the opportunity available for enrollees to review the status or discuss the request with a decision maker and provide contact information.
 - Grant a temporary override to new enrollees processing through a grievance and appeal.
- Review formulary on a quarterly basis

Download the Checklist

<http://bit.do/NF-Value-Access>

Best Practices for Pharmacy & Therapeutics (P&T) Committees

Health plans have a fixed amount of money each year to serve their entire population and must weigh the costs of treatment against the entire budget.

The P&T Committee is managed by the health plan and:

- o Serves as expert knowledge area consultants
- o Manages the formulary system (the list of medications and related information in the diagnosis, prophylaxis, or treatment of disease & promotion of health)¹.
- o Works in conjunction with the health plan's medical and pharmacy departments

While plans that administer Medicare Part D or Medicare Advantage are mandated to have a P&T Committee made up of practitioners, there is not a set process.

The following checklist is presented as a model process for P & T Committees to consider when managing the formulary system in making equitable coverage decisions, focusing on evidence-based processes to select and promote treatments offering the best therapeutic outcomes, while minimizing potential risks and costs to patients.

Responsibilities of the medical leadership (health plan) in creating/managing a P&T Committee

- Ensure that the right people are on the P&T Committee and kept current on upcoming treatments
 - o Actively practicing primary care physicians (particularly those focused on high-risk areas)
 - o Actively practicing pharmacists and other health care professionals
 - o Specialists covering the clinical needs of the majority of enrollees
 - o Require full disclosure of conflicts of interest from health plan and pharmaceutical manufacturers (and recusal where there are known conflicts of interest)
- Provide guidelines on the authoring and reviewing of P&T Committee documents?
 - o This is the most highly ranked factor that could have a perceived beneficial effect on P&T Committee functions.
- Implement standardization across all sites
 - o There is a higher likelihood of evidence-based practice with contribution by multiple party decision-making vs. single subject matter expert experience/opinion.³

Responsibilities of the P&T Committee

- Gather unbiased, evidence-based information on the following factors to make a recommendation to medical leadership on whether the agent should be covered:
 - o Clinical Efficacy
 - o Safety
 - o Patient convenience, adherence & satisfaction⁴
 - o Economic
 - Pricing – Can only come into consideration when there are multiple agents to choose from. With all else being equal, and the physician feeling that either/any of the agents could be prescribed, it is up to the health plans to negotiate pricing with the manufacturer.

Health Plan Accountability

- Who stakeholders can reach out to for holding plans accountable

Line of Business	Regulator
Medicare	CMS
Medicaid	State Departments of Health
Commercial	State Insurance Commissioner Depending on State, Other Entities <ul style="list-style-type: none">• Department of Financial Services

Possible Next Step

- National Association of Insurance Commissioners (NAIC) Health Carrier Prescription Drug Benefit Management Model Act (aka Model 22)
 - Comprehensive
 - Enacted in 2018
 - No means of enforcement
- Outreach to NAIC proposing a spot survey
 - Level of implementation
 - Opportunities for leadership by states



Questions & Answers
