

CHAPTER 6

PHARMACY AND THERAPEUTICS COMMITTEE

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Chapter 5 discusses access issues for patients including affordability and limits on access such as prior authorization. This chapter explains how and why access to different medications may be restricted on a formulary developed by a Pharmacy and Therapeutics Committee.

While drug formularies have reportedly existed in the United States for over 200 years, their roles and purposes have changed, reflecting the increased complexity of the medications themselves, the healthcare systems within practice settings, and the roles and responsibilities of stewards of these lists.¹ A common name given to a group responsible for oversight of a formulary is the Pharmacy and Therapeutics (P&T) committee. As the name implies, this committee involves pharmacists and those involved in the therapeutic application of these products. A typical committee is comprised of those who prescribe drugs (e.g. physicians), those who purchase and prepare drugs (e.g. pharmacists) and those who administer drugs (e.g. nurses), in addition to other personnel depending on setting (e.g. finance or risk management). Membership will vary based on practice setting but is usually representative of the primary medical services provided within that health care system. In addition to determining formulary selection criteria, P&T committees also oversee how products are purchased, stored, ordered, prepared/dispensed, administered, and monitored. Any policies or protocols addressing medication use, such as adverse drug event monitoring and reporting and approval of guidelines or care pathways, also fall under the P&T committee oversight. In the outpatient setting, prescription drug plans have their own P&T committees that use specific formulary management tools, such as prior authorization, step therapy, and copayment tiers.²⁻³

A formulary, by definition, is a “continually updated list of medications and related information, representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis, prophylaxis, or treatment of disease and promotion of health”.² The term medication has been interpreted broadly in some settings to include all products delivered in the context of care for diagnosis, prevention, and treatment. Given this definition, agents such as alternative remedies (herbals and supplements), nonprescription products, blood derivatives, and contrast media would also be included in some settings.³ While formularies

previously operated more as inventory control, now they are intended to function as systems to insure that drug products are used in a rational, safe, and cost-effective manner to support affordable and sustainable drug benefits.^{4,5} These systems are used in hospitals, home care, and long-term care settings, in addition to payer settings such as Medicare, Medicaid, insurance companies, and managed care organizations.

DRUG FORMULARY EVALUATION

In order for a formulary to have the best available medications available for use, it must be confident in the process of review of the medications.⁶⁻⁷ The first step for inclusion of a given drug on a drug formulary is through evaluation of evidence. Common elements of a drug review note the FDA approved indications and potential areas of off-label use, a review of the differences with similar agents on formulary with respect to pharmacokinetics and pharmacodynamics, a critique of individual trials used to support a therapeutic benefit, analysis of potential for harm incorporating both drug and formulation characteristics, and ultimately cost.³ **Table 5-1** expands on common elements within a new drug review. A P&T committee could simply decide to add or not add to a formulary, but more commonly will offer recommendations for additional criteria, such as strategies for ensuring appropriate use.

Questions to consider when determining whether to add drugs to a formulary should be based on quality of evidence and comparisons to therapeutic alternatives. One model cited in the literature is the Formulary Leveraged Improved Prescribing (FLIP) Project.⁷ In this model, five areas are addressed when reviewing a drug.

Evidence of Need – Is this Drug Truly Needed? ⁵

Depending on your setting of practice and the prevalence of conditions commonly treated by your practitioners, some indications of drugs may not be relevant. For example, glucarpidase, an antidote to methotrexate toxicity, is probably not needed in a community hospital that mostly sees patients in need of orthopedic and cardiovascular procedures. However, tranexamic acid, an agent used off-label to reduce postoperative blood loss, may be of interest to this setting. It is always worthwhile to reflect on what is available on your formulary and to describe the shortcomings of existing therapy with respect to safety, tolerability, or effectiveness. Framing your search based on shortcomings of existing therapy will help with discerning value, if any, of the drug you are considering.

Efficacy – What is the Evidence to Support Claims for Drug? ⁵

This is where being able to read, appraise, and apply clinical studies becomes particularly

important. Depending on sources of information, claims of efficacy will be considered differently if coming from high- or low-quality studies or those with high versus marginal differences. For example, a single-center, uncontrolled trial showing improvement in pain scores and decreased hospital length of stay is less generalizable than a multi-center, randomized, active-controlled trial demonstrating these same endpoints. Similar to the question of evidence of need, individual evidence should be assessed for relevance to the population you treat. There may be potential for off-label use of a product and it is important to note what evidence, if any, is available to support this since it may factor into decisions to restrict or regulate use.

Safety – What are the Safety Issues that Should be Weighed? ⁵

In addition to the safety information present in the labeling of a drug (e.g. contraindications, warnings, adverse effects), the potential for medication errors once it becomes available on formulary should be taken into consideration. The potential for look-alike/sound-alike errors or complicated administration or preparation requirements are a few examples of potential safety concerns beyond the package insert. As drugs are studied in relatively small sample sizes in relation to the size of the population they will be used, it is worth noting any safety signals or areas under review that may become more apparent once a drug is used in a larger population. Lastly, it is worth comparing the safety composite of the drug under review with existing therapeutic options on formulary.

Misuse Impact Potential – What is the Potential for Misuse or Overuse? ⁵

This question begins to address the issues of pharmaceutical advertisements and detailing. If a drug is heavily marketed to consumers or prescribers, there may be unrealistic expectations leading to demand for use in areas where the product may or may not be needed. Off-label use of drugs is very common and this is an area that a P&T committee should periodically review to ensure that products are being used optimally based on evidence of safety and effectiveness rather than on unrealistic expectations.

Cost Issues – Is the Drug Worth the Costs?

A common theme that arises with approval of new drugs is that while they must demonstrate that they can have an effect in a carefully controlled trial setting, these effects may or may not be seen in the uncontrolled real world when they are used in general practice. While a cost may be appropriate based on perceived utility in a controlled study, these costs may be considered excessive if a drug fails to demonstrate effect in a variety of patients in the general population with a given disease. Additional cost factors to consider include preparation and

storage costs, monitoring costs, and labor costs with administering product.

After preparing a review, the information gathered is commonly shared among other healthcare professionals who would be impacted because they prescribe or would administer the product. From a cost standpoint, it is not unusual to have a financial party assess the relative cost-benefit of the potential impact on use of resources outside of pharmacy. Decisions about a drug are often driven based on the final composite analysis of benefit, risk, and cost in relation to agents on formulary. If it provides an improvement in benefit, risk, or cost and the other variables are not impacted (or improved) then a drug will likely be added to formulary. Similarly, if it worsens benefit, risk, or cost and other variables are not impacted (or worsen), then a drug likely won't be added to formulary. However, it is rare that final analyses are this clean and there is usually some trade-off amongst these variables. When drugs are added to formulary with potential increased risk of safety and/or cost, it is not uncommon to have additional criteria to ensure they are used in a safe and cost-effective manner.

STRATEGIES FOR MANAGING THE FORMULARY

Ensuring medications are used in an optimal manner often involves educational, managerial, or regulatory strategies.³ Multi-disciplinary development of these strategies will increase the likelihood of success instead of creating them from one practitioner's perspective.^{3,7-9}

Educational strategies are intended to inform or persuade healthcare practitioners to use a medication in a particular manner. Examples of this approach could be provision of a newsletter, preparation of consultative review documents, or one-on-one clinical supervision or consultation. This approach is often received well by clinicians who don't perceive it as restrictive. A practical application of this could be providing an algorithm of how to treat a patient with blood pressure or high cholesterol. However, this approach is one of the least effective when trying to change behavior or practice. If a medication is not being used optimally from a benefit versus risk or cost standpoint, this approach will likely not result in changes in how that medication is used. For example, if a given clinician is adamant about using a PCSK9 inhibitor (~\$14,000 per year) first line in their hyperlipidemia patients, providing an algorithm that has this class used after statin therapy won't force them to change.

Another approach is to use managerial strategies to guide or structure decisions. Guided strategies allow the product to be used, but with hardwire processes so they are used in particular way. Examples of this approach include clinical protocols or order sets, use of

tiered or step-wise approach, procurement selection based on cost, therapeutic interchanges, protocols converting intravenous to oral administration, and patient cost-sharing. Some examples could include converting all ACE inhibitors to lisinopril at an equivalent blood pressure dose (i.e. therapeutic interchange) or using an oral proton pump inhibitor instead of an IV proton pump inhibitor (i.e. IV to PO interchange) when patients can absorb oral therapies. This approach is less well-received by clinicians than educational strategies because it involves barriers or requiring them to “follow the rules” if they wish to use a particular medication or class of medications. The managerial strategy is commonly, but not always, employed because of cost or safety concerns. If multiple medications are available to treat a given condition and differences, if any, are considered marginal, then steering therapy to least costly agents first is an example of a tiered approach. Another simple approach that pharmacy can take is to procure a generic instead of a branded medication. In order to limit formulary options or possibly save on costs, therapeutic interchanges may allow for one medication to be used in place of another either within its therapeutic class or even out of the same class. This is commonly seen in hospital settings and requires approval by a P&T committee.

Lastly, a less-accepted approach, but very effective, is to introduce restrictions or limitations. Examples of this regulatory approach could include banning certain drugs from an institution, requiring prior authorization before use of medications, or restricting use of medications to a certain provider. Limiting providers from writing for more than five continuous days of ketorolac therapy or restricting daily doses of acetaminophen to <3 or 4 grams is an effective way to ensure safe use of these medications. Restricting use of an antimicrobial to an infectious disease physician or requiring that certain criteria be met before certain medications can be used (i.e. prior authorization) are often disliked by clinicians but can help ensure appropriate use.

SUMMARY

A P&T committee is a multidisciplinary group of professionals within an organization that oversee the selection and use of medications. The goal of this committee is to provide a formulary that represents the optimal therapy for patients based on relative efficacy and safety. As medications and healthcare systems become more complex and costly, P&T committees are focusing efforts to ensure medications on formulary are used efficiently by providing strategies for appropriate use.^{2,3}

Uses/indications	FDA approved indications, other potential uses based on clinical trials or agents with similar mechanisms of action
Pharmacology	Summary of drug and/or drug class noting similarities or differences within a class or versus other agents with similar indications
Pharmacokinetics	Depth varies depending on disease state. For example, infectious disease drugs may have more coverage in this area than a blood pressure drug. Highlight absorption, distribution, metabolism, elimination (ADME) of drug and note information on specific subsets of patients (e.g. renal & hepatic dysfunction, male vs female, pediatric vs adult vs elderly, bariatric vs normal weight)
Guidelines and/or systematic reviews	Review indications of drug noting prevalence of disease, current approaches to therapy, and areas of need. Note role of current therapy in the disease approaches, if known.
Comparative efficacy	Review clinical trials of drug noting quality of study methods, relevance of populations studied, applicability of outcomes evaluated and magnitude and precision of results. Contrast findings with other therapies available for indication
Comparative safety	Highlight contraindications, warnings/precautions, drug interactions and adverse reactions that a practitioner needs to be aware of to effectively manage a patient on this drug. Note actions that a clinician can take to mitigate risks as well as similarities and differences with other drugs within class or drugs approved for same indication. Contrast findings with other therapies available for indication
Monitoring	Recommended laboratory or other types of monitoring necessary for patients to be effectively and safely managed
Dosing and administration	Recommended dosing regimens both for FDA indicated and potential off-label use. Special populations such as pediatrics, organ impairment (i.e. renal, hepatic), or obesity may have different

	dosing strategies available from the literature. Compatibility information for parenteral products and splitting or compounding information for oral products would go here.
Availability	How product is supplied noting specialty distribution programs, when applicable. Some products are not orderable through normal supply chains and are shipped directly to patients.
Pharmaco-economic analysis	In addition to the acquisition cost of drug, presenting cost as a function of per unit dose, per day, or per duration of therapy in relation to other therapies. If available, note potential economic impact on other areas such as consumption of additional labs/supplies or ED/hospital visits.
Potential misuse impact	If approved, is there significant education required to ensure product is used optimally (i.e. safely and efficaciously). Are there medication errors associated with this drug or this class and can policies or procedures be put into place to mitigate these. Is product likely to be used in off-label areas

Table 5-1. Common elements of drug monograph

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