CME ARTICLE

Understanding, Creating, and Working with Formulary Systems

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AUDIENCE
This article is intended for medical and pharmacy directors and provider relations and human resource personnel who are new to the managed care environment.

GOAL
To help medical and pharmacy directors in understanding, developing, and implementing formularies.

OBJECTIVES
1. Define a formulary system.
2. Explain the formulary system's organization, functions, and output.
3. Discuss the role of the pharmacy and therapeutics committee as well as the characteristics of its constituents and its methods of decision making.
4. Outline issues associated with restricting or closing a formulary in a managed care plan.

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In the past two decades, the rising cost and complexity of pharmaceutical therapies have led to more stringent cost controls. Expenditures for drugs are expected to grow fairly rapidly through 2007 due to rising numbers of prescriptions and changes in the mix of prescriptions.[1] In 1998 drug sales rose 16.6%, more than 4 times the overall increase in healthcare spending, according to IMS Health, Inc., Plymouth Meeting, PA.[2] Alan Hillman, Director of the Center for Health Policy at the University of Pennsylvania, says that rising drug costs are going to "break our bank around the year 2005."[2]

Managed care companies, seeking opportunities to gain control of pharmaceutical costs, have responded by embracing the formulary system. A formulary may be described as a list of drugs, created by an institution or insurer, which should be used for patients using that institution or belonging to that plan. The best formularies are the result of a complex and well-thought-out process and are frequently updated to represent the current clinical judgment of physicians and other experts.[3]

Formularies can be described as closed or open. In closed formulary systems, physicians' prescribing choices are restricted to a predetermined list of drugs. In open systems, prescribing may include drugs that are not on the predetermined list. Prescribing habits in open formulary systems may be monitored by the organization.

Although the rising costs of pharmaceutical care are largely a recent problem, formularies have been in use for several hundred years. As early as the 18th century, hospitals and medical schools used formularies as a means of inventory control and as a teaching tool to guide the prescribing habits of physicians.[4]

As hospital formularies became more common and were more strictly enforced, it became clear

that institutions could gain economic concessions from pharmaceutical manufacturers just by placing or removing a drug from the formulary.

The modern formulary process includes methods to evaluate and select medications, policies for acquisition and dispensing of drugs, and the development and dissemination of clinical information to assist prescribers in providing high-quality medical care. This process is generally overseen by a pharmacy and therapeutics (P&T) committee.

Formularies exist to manage the cost of pharmaceutical care and increase the quality of that care. Ideally, formularies promote appropriate prescribing, establish a common standard of practice and contribute to outcomes research.[5] Further, they are recognized as the single best way to manage drug costs and product quality.[4] This article will discuss some basic concepts and definitions used in developing and working with formulary programs. This article is designed to serve as a primer for medical and pharmacy directors new to managed care and to the structure and system of formularies.

··· THE P&T COMMITTEE ···

The P&T committee's mission is to ensure safe and effective drug therapies at the lowest cost. According to Shea et al, the P&T committee "maximizes clinical success while minimizing adverse drug events and the overall cost of patient care."[6] To do this, P&T committees take on a broad range of responsibilities, some of which are listed in Table 1.[7] The size and meeting frequency of the committees vary according to the resources of the managed care plan. Committees should include a diverse membership to represent the patients and healthcare providers they serve. The committees should meet regularly, often enough to update the formulary and review drug utilization data and educational needs.

P&T Committee Composition

The committee, at its most basic, is composed of the managed care staff, pharmacists, and physicians from the community. In larger organizations, it may also contain doctors of pharmacy, nurses, legal and ethical experts, and lay representatives of the plan's membership. The committee chairman is often chosen from among the medical directors of the hospital or managed care plan creating the formulary. Our own P&T committee appoints members for staggered 2-year periods and offers members an honorarium.

The committee members are chosen from the practicing physicians who are providers in the plan. These physicians should represent the spectrum of specialties from primary care to intensive care and from cardiology to infectious diseases. This eclectic group brings the experience and training backgrounds necessary for the development of a well-designed formulary. Physicians who are selected for service in the P&T committee ideally should have several characteristics in common:

Table 1. Functions of the Pharmacy and Therapeutics Committee

Function	Explanation
Therapeutic substitution programs	A pharmacy program in which prescribed nonformulary drugs are substituted for other drugs that are on the formulary; this substitution is performed by a plan's pharmacist and occurs after a discussion with, and approval by, the prescriber
Pharmacy education programs	Education programs directed at pharmacists, physicians, and members; the content of the programs varies by audience, but is aimed at improving the understanding and use of medications on the plan's formulary
Pharmacy quality and utilization management systems	A systematic examination by the managed care plan of the prescribing habits of plan providers to determine their compliance with or deviation from the practice of good medicine and pharmacy
Outcomes research	Assessing the impact that drug decisions have had on the overall healthcare of the insured population

- Board certification in their specialty;
- Knowledge of pharmacotherapeutics of that specialty;
- Ability to advocate for the needs of the community physicians and the membership;
- Strong written and oral communication skills;
- Ability to work as a team and develop consensus; and
- Status of "influential physician" or "thought leader" in the physician community.

We have found that subcommittees formed to deal with areas of specialized medical knowledge, such as ophthalmologic pharmacy, cardiology, or infectious disease, are useful ways to gain consensus. Subcommittee recommendations can be forwarded to the main committee for review and discussion.

The relationship between the managed care plan and its affiliated physicians can sometimes become contentious when the plan asks the physicians to adopt clinical policies such as a formulary. Therefore, it is important to have physician representation on the committee to ensure decisions are made with the clinical needs of both the patient and physician in mind.

What Data Should the P&T Committee Review?

The Academy of Managed Care Pharmacy recommends that a P&T committee regularly review the following[3]:

- Medical and clinical literature including clinical trials;
- Relevant patient utilization and experience;
- Current therapeutic guidelines and the need for revised or new guidelines;
- Economic data; and
- Provider recommendations.

Other data have an important, but lesser, effect on decision making. These include current physician prescribing patterns, patient compliance, patient convenience, ease of delivery, associated medical costs (eg, laboratory tests, follow-up office visits), total cost of care, and drug acquisition costs and supplier services.

Costs and consequences associated with adverse drug reactions demand careful assessment, because "drug misadventuring"[8] can be very expensive in terms of dollars and patients' health.[9] Drug misadventures include the following events: overdosing, underdosing, nontreatment, selecting the wrong drugs, drug-drug interactions, adverse drug reactions, and noncompliance. They are responsible for as many as 28% of all hospital admissions and 17% of all physician office visits, with a combined per year cost of more than $58 billion.[9,10]

It is our experience that appointing a coordinator to select and review data will increase the likelihood that decisions are based on objective evidence. According to one study, P&T committees underutilize objective data in developing recommendations.[11] To help overcome this problem, we have appointed pharmacists or doctors of pharmacy to serve as coordinators of this data.

Information used in drug assessments comes from a variety of sources and have been rated in the following order of importance: (1) pharmacy benefit management assessments; (2) other health maintenance organization drug assessments; (3) peer-reviewed literature; (4) evaluations performed by industry; (5) articles in non-peer-reviewed literature; and (6) government reports. The overall utility of the information was based on its timeliness and comprehensiveness.[12]

Decision Making in the P&T Committee

Formulary decision making is based on the triad of efficacy, safety, and cost data. When a drug is deemed to be clinically effective and safe, it will be considered for inclusion in the formulary. When multiple drugs with good efficacy and safety profiles are available, costs may play a larger role in the decision making.

In some organizations decision analysis is used to aid in formulary management. The decision analysis process assigns probabilities and costs to various treatments and outcomes, and decisions are made based on these data.[13] This process requires the availability of outcomes and cost data for the region in question, as well as access to analysts familiar with the decision analysis. In our experience, this process is infrequently used. This may be because of inadequate resources of the committee, unavailability of necessary data, or unfamiliarity of the committee's practitioners—who may not be well versed in subtleties of statistics and probability—with the process. Another barrier to using evidence-based decision making are basic questions about the reliability of current statistical methodologies for interpreting modern medical research data.[14]

An industrywide awareness of the need for both economic and clinical evaluations of drug therapies has spawned the science of pharmacoeconomics. Pharmacoeconomics uses a systematic approach to

identify the overall costs and impact on clinical outcomes of drug therapies.[15] Pharmacoeconomic guidelines take into account the characteristics of the patient population being treated and the redistribution of patients into different categories once a new drug product is introduced. By looking at the new system or disease framework into which each patient will fit and creating mathematical models for outcome and cost probabilities, more objective decisions can be made (see Table 2).

Pharmacoeconomic assessments have been mandated for new drug products in Australia since 1993. They also have been used in Canada, New Zealand, and the United Kingdom. Use in the United States has been limited.

Table 2. Items Needed to Conduct a Pharmacoeconomic Analysis

Item	Description
Product description	Brand name, chemical name, pharmacology, general therapeutic function and indications.
Place in therapy	What the drug is used to treat (eg, anti-infective, antihypertensive, hypoglycemic)
Comparator products	A list of comparable products in use (eg, other angiotensin-converting enzyme inhibitors, other ß-blockers or thrombolytics in the same or related drug class)
Therapy intervention framework	How this drug will fit (if at all) into current therapeutic practice? (eg, Will it be used as a substitute for another less effective drug? Will it replace a surgical procedure? Will it treat a heretofore-untreatable disease or condition?)
Supporting clinical data	Copies of either original clinical data or peer-reviewed articles containing the data.
Supporting pharmacoeconomic data	Data examining all the costs associated with this treatment and with treatment with comparator products (eg, acquisition cost, administration costs, lab tests, physician follow-up visits)
System impact assessment: costs and outcomes	Provision of data that answers the following quetions: If this drug is put on the formulary, how will it affect the clinical course of the population at risk? How will it affect the plan's finances? The members? The communities?
Overall assessment	Statement of thesis, summary of data submitted, conclusions
Bibliography	List of all citations
Supporting materials	Copies of all clinical and financial data referred to in presentation as well as any peer-reviewed papers, charts, diagrams, histograms, atlases, etc

··· THE PHARMACY BENEFIT AND ITS EFFECTS ON FORMULARY DESIGN AND MANAGEMENT ···

The pharmacy benefit defines what pharmacy coverage an insured member is entitled to according to the insurance contract. Pharmacy benefits are not a mandatory part of commercial health insurance coverage and are generally added as a rider on the insurance policy for extra premium costs. The extent and cost of the benefit are negotiated between the insurer and the employer. The structure of the pharmacy benefit may vary dramatically between healthcare plans and employer groups, and pharmacy benefits may be provided by an institution different than the one providing other healthcare. The Medicaid program requires provision of some pharmacy benefits to eligible members.

Financial Incentives

In an effort to limit the cost of pharmacy benefits, healthcare plans have encouraged members to adhere to the formulary through financial incentives. Financial incentives can include mandatory use of generic drugs, deductible fees, pharmacy limits, and simple and tiered copayment programs. Through its design, the structure of the pharmacy benefit can become a tool in formulary management.

A mandatory generic program is a stipulation in the insurance contract that when a prescription is written for a member, and a generic version of the drug is available, the member is only covered for the generic version of the drug. An even more restrictive version of this

program is designed to cover only generic drugs. The costs of brand name drugs become a member's responsibility.

Deductible fees are those fees a member must incur during the purchase of medications before his or her insurance will begin to cover medication costs. As most members will not reach their deductible amount before the end of the year, members are largely responsible for most drug costs. Because members have to pay out-of-pocket expenses, it may encourage them to discuss drug therapies and their costs with their physicians.

Pharmacy benefit limits (also known as a pharmacy cap) put a total dollar amount on the drug benefit. For example, $1000 or $1500 might represent the total yearly benefit for a member's medication purchases. These limits have the same effect as deductibles in that members have a financial incentive to encourage physicians to order the most cost-effective drug, dose, and duration available.

Nearly all commercial prescription plans require that some copayment be charged to the patient for each prescription as a deterrent against frivolous use. A tiered copayment program is the latest and most popular method for controlling pharmacy costs. In this system, the copayment is increased inversely with the drug's perceived desirability by the plan. Increasing tiers of copayment indicate increasing amounts of out-of-pocket expenses for drugs. The findings of a study by Hillman et al suggest that higher copayments were associated with significantly lower drug spending in independent practice associations.[16]

Formulary directors can manage the utilization of drugs they think are least cost-effective by assigning them the higher tiers of copayment. For example, generic formulary drugs would have the lowest copayment (tier 1). "Legend drugs" (brand name drugs that are on the formulary) would have a medium-range copayment (tier 2), and brand-name drugs that are not on the formulary would have the highest copayment (tier 3). This allows the plans to offer members and physicians a de facto open formulary, while encouraging them to choose the most cost-effective drugs available.

Recently, some healthcare plans have applied copayments as high as $50 to the third tier. Critics have stated that a $50 copayment is much too high and essentially constitutes no coverage for low-income members. Although the tiered copayment method does decrease drug costs, the effects on clinical outcomes are unclear.[16]

The Exception Process

Although the formulary should constitute a comprehensive list of all necessary medications for the managed care plan's membership, it may not always be adequate for the needs of individual members. To accommodate special needs for medications that are not on the formulary, the exception process exists. The exception process allows the managed care plan to pay for medically necessary medications not contained in the formulary. For example, a physician may prescribe an oral contraceptive for a patient's acne. Since birth control is frequently not a covered benefit, the drug would not be on the formulary. The exception process would provide the drug to the patient as a covered item, requiring the treating physician to outline to the medical or pharmacy director the prior attempts at control and the rationale behind the request. The pharmacy director usually supervises this process, either within the managed care plan or at the level of pharmacy benefit management. The process requires the prescribing physician to submit documentation that substantiates the need for the off-formulary medication for his or her patient. The documentation may take the form of a letter of medical necessity, a copy of progress notes documenting failure of other medications, or copies of the current medical literature. Journal articles submitted should support the use of the requested drug instead of others for the patient's condition, not merely suggest that it also may be effective.

Prior Approval Process

The prior approval process exists to control medications that are on the formulary and are judged by the medical or pharmacy director to be too toxic, too expensive, or too prone to abuse for typical utilization management techniques. Some examples of drugs on prior approval status are anorexiants, human growth hormone, and recombinant erythropoietin. The pharmacy director allows payment for the medication if the prescriber can validate appropriate indications and dosing requirements. The pharmacy director oversees the process either through the managed care plan or at the level of pharmacy benefit management, and the documentation requirements are similar to those for the exception process.

··· IMPLEMENTING CLOSED OR RESTRICTED FORMULARIES ···

Closed formularies are those that require the plan's providers to choose only medications from

the plan's formulary. Purchases of medications that do not appear on that list are not normally reimbursed by the plan. Closed formularies appear to offer a health plan the greatest savings in pharmacy costs. By reducing the use of expensive drugs or drugs of questionable clinical efficacy, they also allow the healthcare plan to negotiate more favorable acquisition costs from the manufacturers through volume discounts. As a result, health maintenance organizations reported a growth in closed formularies from 23.9% in 1995 to 39.1% for 1998.[17] Although critics have stated that a restriction of pharmaceutical choices will adversely affect members, one study has found no evidence to date showing that the use of formularies adversely affects patients' access to pharmaceutical care.[18]

Closed formularies and the health plans that adopt them can be viewed negatively by employers, physicians, and plan members alike. Physicians often think that closed formularies reduce clinical autonomy. Members become concerned and angry when their prescriptions are denied. In response, some state legislatures have proposed laws to limit certain formulary management tools.[19]

In implementing a closed formulary, the medical director and pharmacy director have a formidable assignment. In addition to the complex tasks of creating the formulary and managing the P&T committee, they must educate both internal (sales and marketing, claims, customer service, and provider relations) and external clients (customers, members, and providers).

In our experience, getting the support of local physicians is the single greatest difficulty in the formulary process. Acceptance of the formulary is increased when physicians understand that their peers create the formulary through a fair and reproducible process. This communication can be accomplished with the following methods:

- Direct mail of letters from the medical director to participating physicians;
- Articles in physician newsletters;
- Group meetings with the physician staff;
- Individual meetings between member physicians and the medical or pharmacy director; and
- Academic detailing.

Inviting all plan physicians to apply for membership on the plan's P&T committee is helpful. When choosing physicians for the P&T committee, some thought should be given to choosing those that are considered thought leaders in the community. Choosing "influential" physicians goes a long way toward increasing the credibility of the P&T committee and aiding physician approval of the formulary.

Financial Planning for Closing the Formulary

Adequate financial planning is essential when implementing a closed formulary. The previously described interventions, while seemingly unremarkable, can be costly. General mailings to members and providers, database analysis for members at risk, newsletters, and so forth can be expensive items and need to be budgeted for well in advance. Interventions should be started a year before closing a formulary. Therefore, planning and budgeting have to occur 2 years before the closing and need to be spearheaded by the medical or formulary director.

··· CONCLUSION ···

A formulary is not just a list of drugs that managed care plans expect their providers to use; it is a complex process for managing both drug costs and the quality of drug prescribing. The best P&T committee utilizes a fair, reproducible, and scientific method for choosing the formulary, and it is bound by the same principles in evaluating exceptions and appeals. The implementation of a closed formulary is not to be taken lightly. It requires a large amount of planning, adequate budgeting, and frequent communication with all involved parties. Sensitivity to the public and physician misconceptions of "cost cutting for the sake of corporate profits" is needed. Plans need to deal with these misconceptions and educate patients and physicians that formularies are a means of stabilizing members' premiums and that they can increase the quality of prescribing.

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