



Continuing Education



The formulary system

Learning Objectives

State the goal of a formulary and describe the functions of hospital formularies.

Describe issues influencing managed healthcare formularies.

Explain open and closed formularies and tiered copayment plans.

Describe the structure and functions of the pharmacy and therapeutics committee.

Identify criteria and tools used for considering new products for the formulary.

This first article in a three-part series discusses hospital and managed healthcare formularies, open and closed formularies, the pharmacy and therapeutics committee, and criteria for considering new products for the formulary.

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The formulary is a list of drugs that are approved for use by the medical staff working in a particular healthcare facility or within a managed care organization. It may also be a list of drugs approved for reimbursement by an insurance company or health maintenance organization. The goal of the formulary is to encourage more effective use of drug therapies by physicians. Its focus should be on improving the efficiency of delivery of healthcare services and optimizing patients' health relative to resource constraints.

The formulary system is the method the hospital medical staff uses to evaluate and select drug products for inclusion in the formulary that are considered most appropriate and useful in patient care. Only selected drugs are routinely available from the hospital pharmacy, which means that not all brands of all products and not all products in a given therapeutic class are stocked.

Carrying fewer competing drug products may reduce the number of products with which physicians and pharmacists must be familiar. This allows them to develop more detailed knowledge and more experience using the listed products. In this way, the hospital formulary has the potential to sim-

plify the prescribing process, improve the quality of prescribing and reduce medication errors.

The managed healthcare formulary

In general, drug formularies in staff-model HMOs are strictly followed. To reduce costs, some HMOs request bid prices from competing pharmaceutical manufacturers for therapeutically similar drugs. These bid prices are then factored into the decision on whether to select a particular drug for the formulary.

Physician and pharmacy compliance with formularies is often affected by the economics of patient reimbursement. If nonformulary products are prescribed or dispensed, patients may have to pay for them out of pocket or incur higher copayments than if formulary products are used.

To simplify prescribing decisions, physicians who contract with several different managed care plans will tend to prescribe those products that are on the formulary of the greatest percentage of the patients they treat. They may also tend to prescribe from the most restrictive formulary, as that is the plan that will be monitoring their prescribing patterns most closely. The retail pharmacy, however, must stock all of the drug products listed on each formu-

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lary to maximize sales.

Medicare and Medicaid are public programs that have also begun implementing formularies to control the healthcare costs of their enrollees. Aging patients tend to use more pharmaceutical products, particularly for chronic conditions such as arthritis, hypertension and type 2 diabetes, and the population of Medicare recipients is growing. Almost all HMOs with Medicare beneficiaries have formularies. Formularies also affect patients in long-term care institutions such as nursing homes. Physicians treating Medicare patients must follow these formularies in order to be reimbursed for services.

Medicaid is the single largest purchaser of prescription drugs. Increasing Medicaid enrollments and expenditures have led many state Medicaid programs to implement cost-containment strategies, including managed care plans and tightly controlled preferred drug lists.

Open and closed formularies

There are two basic types of formularies:

Open formularies. Open formularies allow physicians to prescribe nonformulary pharmaceutical products without financial penalty or other consequences and allow virtually any drug to be stocked in the institution's pharmacy upon physician request. These types of formularies place few limitations on the addition of new drugs to the formulary list and are used more as guidelines or educational tools for prescribers.

Closed formularies. A closed formulary usually consists of a limited list of approved drugs and imposes strict controls on the use of nonformulary drugs. Closed formularies commonly require physicians to receive preapproval for prescription of nonformulary drugs. To encourage physicians in outpatient settings to prescribe formulary drugs, administrators may not provide reimbursement for nonformulary drugs.

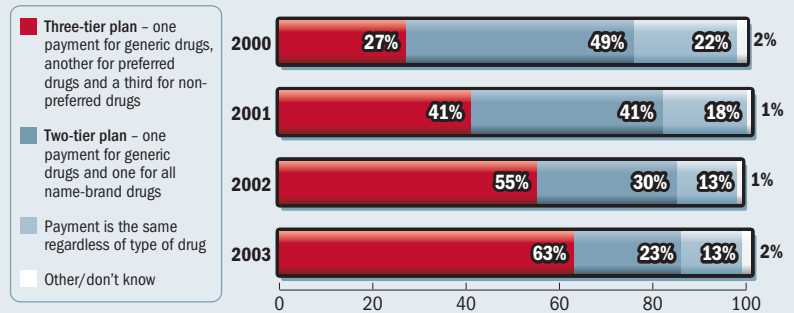
Most formularies operate between the extremes of open and closed formularies and may combine aspects of both types. Physicians may be able to prescribe whatever drugs they choose, but generic substitution is typically permitted and encouraged.

In general, formulary policies tend to influence physicians' prescribing practices through incentives (such as financial rewards or penalties) rather than by dictating pharmaceutical choices. Formularies that are too restrictive run the risk of creating a backlash from healthcare professionals who have been trained to think for themselves and make their own prescribing decisions.

Both open and closed formularies use tiered copayment plans to encourage patients to use generic or branded drugs that are on the formulary. In a one-tier system, members make the same copayment for all formulary drugs. A two-tier system involves one copayment for generic drugs and a higher copayment for brand-name drugs. A three-tier copayment system typically charges the least amount for generic

Tiered copays

The distribution of covered employees in tiered copayment programs from 2000 to 2003



Note: Numbers do not add up to 100% due to rounding.

Source: Kaiser Family Foundation/Health Research and Educational Trust Survey of Employer-Sponsored Health Benefits, 2003

drugs, a higher amount for brand-name drugs and the highest amount for brand-name drugs that are not on the plan's formulary.

Tiered-copay formulary systems face resistance from both patients and physicians. Consumers complain about the shifting of costs from the plan to the patient through higher copayments for second- and third-tier drugs. Physicians object to having to consult a complex formulary before prescribing, having to rewrite prescriptions for patients who need to avoid higher copayments and ceding their clinical autonomy to a formulary plan.

The pharmacy and therapeutics committee

The pharmacy and therapeutics (P&T) committee is the decision-making body of the formulary system. The committee's basic objectives are to:

- Specify drugs of choice and alternatives to include on formularies, based on safety and efficacy.
- Minimize therapeutic redundancies.
- Maximize cost-effectiveness.

Most P&T committees include representatives from the pharmacy, medical and nursing staff, as well as administration. In most cases, a clinical pharmacist or a director of pharmacy serves as the secretary to the P&T committee and is responsible for developing the agenda and preparing and distributing the minutes of the meeting.

Other medical specialties are critical for the P&T committees of HMOs, including primary care, family practice, internal medicine, pediatrics and gynecology. These physicians prescribe most of the medications for members of the health plan. Other HMO P&T committee members may include pharmacists, HMO executives and others in the HMO who are involved with quality assurance or economic issues. Many HMO P&T committees also include one or more representatives from the pharmacy benefit management company that manages the formulary.

Requests for the addition of new products generally come from medical or pharmacy staff who would like to use the products. Other hospital staff members, such as nurses and respiratory therapists, usually refer their requests through a physician or pharmacist practicing in their area. Requests are accompanied by supporting documentation and product recommendations from interested physicians and other healthcare personnel. The pharmacy director may then discuss the request with the chairperson of the P&T committee, and together they will make a preliminary decision on whether the drug will be considered by the full P&T committee.

The next step in the formulary approval process involves gathering

and assembling additional information about the drug. Usually, a member of the pharmacy will conduct a literature search and consult pharmaco-economic research and drug use evaluations. Frequently, a drug class review is prepared, which evaluates the relative merits of all drugs in a therapeutic category. A recommendation is then made for a particular drug (or drugs) to be on the institution's formulary.

The data are presented and discussed at the scheduled meeting of the P&T committee, and the committee votes to grant or deny approval of the drug to the formulary. Group dynamics ultimately influence the decisions made by P&T committee members regarding formulary approval. One study suggests that organizational factors such as nonprofit status, the incentive structure for the director of the pharmacy, the size and makeup of the P&T committee, and an organization's relationships with drug manufacturers may also influence formulary decisions.

If a product receives formulary approval, it may undergo a six-month probationary period, after which it is evaluated for permanent placement on the formulary. During the six-month probationary period, healthcare representatives must ensure that appropriate physician feedback is given to members of the P&T committee. Representatives must also maintain communication with the pharmacy department to ensure that the drug is being used correctly. Incorrect use of a drug during its trial period could jeopardize its future on the formulary. The pharmacy staff monitors how the drug actually works, possible adverse effects, physician acceptance and ease of use. Even if a product is approved for inclusion on a hospital's formulary, restrictions may be placed on how it is used and who can have access to it.

Decision-making criteria and tools

The P&T committee must examine a number of factors when considering the addition of a particular product to the formulary, including:

Clinical efficacy and safety. The P&T committee will compare the efficacy and safety of the new drug against those already on formulary to decide which has more therapeutic value (for example, which drug produces less severe adverse effects).

Cost considerations. The overall costs associated with using the product must be evaluated; this includes issues such as the monitoring time required from medical staff, the impact on the length of patients' stay in the hospital and how quickly patients can return to normal activities.

Pharmacoeconomic studies. These analyses assess the impact of drug therapy and related medical interventions, particularly in the case of very expensive new biotechnology products. These studies are vital because the alternative with the lowest acquisition cost is not always the most economical.

Outcomes research. This involves the collection and analysis of data on the consequences of various

Article Summary

- **The formulary is a list of drugs that are approved for use by the medical staff working in a particular healthcare facility or within a managed care organization.**
 - The goal of the formulary is to encourage more effective use of drug therapies by physicians.
 - The hospital formulary has the potential to simplify the prescribing process, improve the quality of prescribing and reduce medication errors.
- **In general, drug formularies in staff-model HMOs are strictly followed.**
 - Physician and pharmacy compliance with formularies is often affected by the economics of patient reimbursement.
 - Medicare and Medicaid have also begun implementing formularies to control the healthcare costs of their enrollees.
- **The two basic types of formularies are open and closed formularies.**
 - Both types of formularies use tiered copayment plans.
- **The P&T committee is the decision-making body of the formulary system.**
 - The basic objectives of the P&T committee are to specify drugs of choice and alternatives to include on formularies, minimize therapeutic redundancies, and maximize cost-effectiveness.
 - Most P&T committees include representatives from the pharmacy, medical and nursing staff, as well as administration.
 - Adding a new product to the formulary involves a formal request, information gathering and presentation to the P&T committee.
 - During a product's probationary period, healthcare representatives must ensure that appropriate physician feedback is given to members of the P&T committee.
- **The P&T committee must examine a number of criteria when considering the addition of a particular product to the formulary.**

therapeutic interventions or approaches. Because it is based on data obtained in the actual clinical setting rather than clinical trials, many P&T committee members will be interested in participating in outcomes research or discussing the results of outcomes research performed at similar healthcare organizations.

Clinical practice guidelines. In selecting drugs for the formulary, the P&T committee will have to consider whether or not the drugs are part of existing clinical practice guidelines for certain diseases.

To assist in the decision-making process, a number of tools are used, including:

Prospective and retrospective studies. In a prospective study, patients are monitored on an ongoing basis, with data being gathered during the study period. A retrospective study involves the use of pre-existing data such as claims data, medical records and billing invoices.

Computer modeling. Modeling studies use a computerized decision analysis that compares treatment alternatives and outcomes. These studies can be used to demonstrate the expected results of adding a particular drug to the formulary.

Decision analysis. This is a systematic analytical process for identifying, characterizing, comparing and combining the many variables that can influence the formulary decision.

Decision analysis computer software. There are a number of programs available, including one that turns the subjective opinions of individual P&T committee members into numerical data, which the committee can then use in the decision-making process.

The next article will focus on managing the pharmacy benefit.