

Formulary Management

Formulary management is an integrated patient care process which enables physicians, pharmacists and other health care professionals to work together to promote clinically sound, cost-effective medication therapy and positive therapeutic outcomes. Effective use of health care resources can minimize overall medical costs, improve patient access to more affordable care and provide an improved quality of life.

What Is a Formulary?

A drug formulary, or preferred drug list, is a continually updated list of medications and related products supported by current evidence-based medicine, judgment of physicians, pharmacists and other experts in the diagnosis and treatment of disease and preservation of health. The primary purpose of the formulary is to encourage the use of safe, effective and most affordable medications.

A formulary system is much more than a list of medications approved for use by a managed health care organization. A formulary system includes the methodology an organization uses to evaluate clinical and medical literature and the approach for selecting medications for different diseases, conditions and patients. Policies and procedures for the procuring, dispensing, administering and appropriate utilization of medications are also included in the system. Formulary systems often contain additional prescribing guidelines and clinical information which assist health care professionals to promote high quality, affordable care for patients. Finally, for quality assurance purposes, managed health care systems that use formularies have policies in place to give physicians and patients access to non-formulary drugs where medically necessary.

Formulary management systems are routinely used by health plans, pharmacy benefit management companies (PBMs), hospitals and government agencies, including the Veterans Health Administration, Department of Defense, and Medicare and Medicaid programs. Formularies have evolved into a tool for assuring the selection of medications demonstrated to be safe, effective and affordable while maintaining or improving quality patient care.

Formulary Development

The medications and related products listed on a formulary are determined by a pharmacy and therapeutics (P&T) committee or an equivalent entity. P&T committees are comprised of primary care and specialty physicians, pharmacists and other professionals in the health care field. Often P&T committees also include nurses, legal experts, and administrators. P&T committee members are often independent of the benefit plan sponsor and are required to reveal any conflicts of interest. Some managed care organization chose to keep the identity of P&T committee members confidential so that outside influence is avoided.

The P&T committee is responsible for developing, managing, updating and administering the formulary. The P&T committee also designs and implements formulary system policies on utilization and access to medications. Utilization management strategies such as quantity limits, step therapy and prior authorization criteria may be reviewed and approved by P&T committees. Access policies include medical exception process protocols to allow patients coverage for non-formulary drugs under defined circumstances.¹

P&T committees evaluate medications after Food and Drug Administration (FDA) approval. Due to the multiplicity of medications on the market and the continuous introduction of new medications, a formulary must be a dynamic and continually revised listing. In order to keep a formulary current, the P&T committee meets regularly to review newly released drugs and/or classes of drugs. The P&T committee reviews some or all of the following:

- Medical and clinical literature including clinical trials and treatment guidelines, comparative effectiveness reports, pharmacoeconomic studies and outcomes data;
- FDA-approved prescribing information and related FDA information including safety data;
- Relevant information on use of medications by patients and experience with specific medications;
- Current therapeutic use and access guidelines and the need for revised or new guidelines;
- Economic data, such as total health care costs, including drug costs;
- Drug and other health care cost data (not all P&T committees review drug specific economic data); and
- Health care provider recommendations.

P&T committees compare medications by therapeutic classifications or upon similarities in clinical use. When two or more medications produce similar effectiveness and safety results in patients, then business elements like cost, supplier services, ease of delivery or other unique properties of the agents are considered when determining which agent to include on the formulary. In many organizations the P&T committee only performs clinical analyses; if two or more medications are determined to be clinically equivalent, then business elements will determine formulary inclusion or exclusion. The overall goal is to develop a list of the safest, most effective medications that will produce the desired goals of therapy at the most reasonable cost to the health care system.

¹ Academy of Managed Care Pharmacy. *Concepts in Managed Care Pharmacy Series – Prior Authorization and the Formulary Exception Process*. 2005. <http://www.amcp.org/amcp.ark?p=AAAC630C> (accessed September 7, 2009)

Formulary systems evolve as new information becomes available or resources are developed. Since formulary decisions rely on published clinical information to make those decisions, it is important to have as much quality information as is available. It is estimated that in the coming years, comparative effectiveness research (CER) and genetic-based medicine, also referred to as personalized medicine, will impact formulary systems. The information gained through CER methodology and outcomes will provide P&T committees additional resources to evaluate the use of medication versus alternative treatment options. Through diagnostic tests and targeted therapies, personalized medicine may add complexity to the P&T committee decision making process. P&T committees will have to develop policies and procedures for making individual decisions in addition to the traditional population-based decisions.

Recognized principles for the development and use of formularies can be found in the document, *Principles of a Sound Drug Formulary System*.²

Types of Formularies

Many managed care organizations use a “tiered” pharmacy benefit design. All medications and related products subject to clinical review are assigned to a formulary “tier.” The tier represents the level of coverage the health plan will provide. The most cost-effective agents (often generics) are usually assigned to the most preferred tier and have the lowest patient out-of-pocket costs. The least cost-effective agents are usually assigned to the least preferred tier and have the highest patient out-of-pocket costs or offer no coverage. The preferred tier(s) are commonly referred to as “formulary” and non-preferred tier(s) as “non-formulary.” In other cases, non-formulary drugs are not assigned a tier and are not listed on the formulary. A formulary may be published in a variety of ways including by tier status, by therapeutic class or alphabetically.

Formularies are used to make benefit coverage decisions and are categorized by type according to the benefit sponsors’ reimbursement structure goals. Factors such as the type of managed care plan, the size of the organization, its service objectives and drug benefit provisions, staff availability and resources to manage the formulary will determine which type of formularies best serves the needs of a health plan’s patients.

- **Open Formulary:** The payer may provide coverage for all formulary and non-formulary drugs. The payers include the health plan, the employer, or a PBM acting on behalf of the health plan or employer. However, some drug classes such as those for cosmetic use or over-the-counter drugs may be excluded from coverage. Physicians are encouraged to prescribe formulary agents. Patients may or may not incur additional out of pocket expenses for using non-formulary drugs.
- **Closed Formulary:** Non-formulary drugs are not reimbursed by the payer. Formulary exception policies allow patients and physicians reimbursement and access to non-formulary medications where medically appropriate.

² *Principles of a Sound Drug Formulary System*. Academy of Managed Care Pharmacy, Alliance of Community Health Plans, American Medical Association, American Society of Health-System Pharmacists, Department of Veterans Affairs, National Business Coalition on Health, U.S. Pharmacopeia. 2000. <http://www.amcp.org/amcp.ark?p=AA8CD7EC> (accessed on September 7, 2009)

Formularies developed for the Medicare Part D prescription drug benefit must adhere to specific rules established by the Centers for Medicare & Medicaid Services (CMS) as requirements for the prescription drug plan with which it contracts. For example, CMS regulations and guidances give specific instructions on the composition of P&T committees, the number of medications that must be included in each therapeutic classification, how soon new medications must be reviewed, prior authorization processes and on how information is communicated to beneficiaries.³

Formularies Complement Other Health Care Management Tools

A formulary is one component of health care management. It enhances other existing medication management practices designed to optimize patient care, including:

- Sound medical treatment and prescribing guidelines or protocols: Also called critical pathways or therapeutic guidelines, these recommended series of actions concerning a specific disease or condition involve drug therapy and all other aspects of patient care such as laboratory tests, x-rays and surgery. They enhance consistency, improve quality of care and improve outcomes for patients while reducing costs;
- Drug utilization review and drug use evaluation programs: These reviews of patient data evaluate the effectiveness, safety and appropriateness of medication use. They often alert clinicians about prescribing and drug regimen problems and about patients who may be inappropriately taking medications that can produce an undesirable reaction or create other medical complications;⁴ and
- Physician, pharmacist, and patient drug education programs: The success of the formulary system is largely dependent on its educational component. Physicians, pharmacists, patients and other health care professionals must understand the rationale behind formulary decisions. The formulary education process must continuously provide the following:
 - Drug information monographs, newsletters and in-service training to furnish physicians with information needed to provide a high standard of care;
 - Pharmacist education regarding changes in formulary content or policy, along with the rationale behind the formulary changes to ensure greater formulary compliance; and
 - Patient education, which explains how decisions are made, the role of the patient and the importance of formulary compliance to both the patient and managed health care system.

³ Centers for Medicare & Medicaid Services, Medicare Modernization Act 2007 Final Guidelines – Formularies: “CMS Strategy for Affordable Access to Comprehensive Drug Coverage.” <http://www.amcp.org/amcp.ark?pl=AB3C79C7> (accessed on May 5, 2009).

⁴ Academy of Managed Care Pharmacy. *Concepts in Managed Care Pharmacy Series – Drug Utilization Review*. 2009. <http://www.amcp.org/amcp.ark?p=AAAC630C> (accessed September 7, 2009)

The Role of the Health Care Practitioner

Health care practitioners serve many functions in the formulary management process. Pharmacists often lead formulary management initiatives, coordinate P&T committee tasks and make recommendations based on sound clinical evidence. To ensure the success of the formulary management process, pharmacists guide P&T committees through the drug product selection process. Pharmacists also develop benefit related policies, therapeutic guidelines and design utilization management strategies. Pharmacists and physicians also serve as voting members on P&T committees.

Health care practitioners may also serve to:

- Develop the formulary operational standards;
- Determine the P&T committee meeting agenda(s);
- Disseminate scientific, clinical and health economic information for P&T committee member review;
- Analyze economic factors, such as drug pricing, market share and manufacturer contracting strategies;
- Conduct follow-up research when necessary; and
- Communicate P&T committee decisions to health plan prescribers, other health care professionals and patients, as appropriate.

Importance of the Formulary Management Process

Providers and payers recognize a team approach involving physicians, pharmacists and other health care professionals working together to coordinate patient care produces the best clinical, humanistic and economic outcomes.⁵

Formulary decisions impact all aspects of health care management. In the face of the escalating number and complexity of drug products, rising drug prices and direct-to-consumer advertising, the formulary management process provides the managed health care system with the ability to objectively discriminate between superior and marginal medications. Such efficient and effective use of health care resources minimizes overall medical costs, improves patient access to more affordable care and provides an improved quality of life.

⁵ Academy of Managed Care Pharmacy. *Concepts in Managed Care Pharmacy Series – Disease Management*. 2008. <http://www.amcp.org/amcp.ark?p=AAAC630C> (accessed September 7, 2009)