

Formularies

The Academy of Managed Care Pharmacy (AMCP) supports the use of evidence-based formularies that enhance the quality of pharmaceutical care while lowering medication costs.

A drug formulary is a continually updated list of prescription medications that represent the current clinical judgment of providers who are experts in the diagnosis and treatment of disease. Formularies often contain additional prescribing and clinical information that assists health care professionals as they promote high quality, affordable care to patients. Formularies have existed for decades and are most commonly used by hospitals, health plans, pharmacy benefit management companies (PBMs), self-insured employers, and government agencies (including the Department of Veterans Affairs, Department of Defense, and many state Medicaid programs).

AMCP supports a well-designed, evidence-based formulary to assist in effectively managing a patient's total medical care regimen. A formulary enhances the quality of care by encouraging the use of those prescription medications that are demonstrated to be the safest, the most effective, and that produce positive patient outcomes.

A formulary may be used in many ways for the administration of a prescription benefit. Formularies may be used to recommend the most appropriate drug choice and assist in the determination of member cost share or drug coverage. The way a formulary will be utilized is based on many factors, including patient population and benefit design.

A formulary works best when it supports and operates in conjunction with other tools that promote quality and optimal results such as drug utilization review and medical treatment guidelines. In addition, the value of a formulary is maximized when it is part of an integrated patient care process that encourages physicians, pharmacists, and other caregivers to work together to ensure positive and cost-effective results.

The following elements should be considered when developing and operating a formulary:

- As part of the process by which a formulary is developed and maintained, a Pharmacy & Therapeutics Committee or equivalent entity should be established and meet regularly to review and evaluate the medical and clinical evidence from the literature, relevant patient utilization and experience, economic data, and provider recommendations to determine which drugs are the safest, most effective, and produce the best medical results.

The membership of a P&T Committee should include physicians, pharmacists, and other health care professionals and should, collectively, have current knowledge and expertise in clinical aspects of prescription drugs and drug use review, evidence-based decision making, evaluation, and intervention. AMCP supports the use of its *Format for Formulary Submissions*^[1] and the *Principles of a Sound Drug Formulary System*^[2] to ensure accuracy and completeness of the information reviewed.

- A formulary is a dynamic and continually revised document. The P&T Committee regularly evaluates the formulary and adjusts it to reflect the best medical practices and new clinical and economic evidence that may have an impact on which drugs are included or excluded.
- A formulary supports and maximizes the effectiveness of prescribing guidelines and protocols for physicians and other prescribers.
- Formulary decisions have an impact on all components of the health care delivery system. Studies show that choice of the most appropriate drug results in fewer treatment failures, reduced hospitalizations, better patient adherence to the treatment plan, fewer adverse side effects, and better overall outcomes. Such efficient and effective use of health care resources helps to keep overall medical costs down, improves the consumer's access to more affordable care, and provides the patient with an improved quality of life.
- The primary criteria for the formulary decision-making process should be centered on a drug's safety, efficacy, and effectiveness. A drug's clinical profile, rather than its costs, should be the primary factor in determining whether a drug is included or excluded from a formulary. Members of the P&T Committee should use evidence-based decision-making tools and models that relate key factors and probabilities to one another in order to determine the best drugs to have on the formulary. Inputs into this process include clinical trials, scientific studies, an evaluation of the drug's role in disease treatment guidelines, comparisons with other like products, and data that reflect the drug's actual or projected utilization in specific patient populations. In addition, the formulary review process has evolved from one requiring typical efficacy and safety data to one requiring data on health outcomes and actual effects and costs of a drug once it has been commercially released to the general population.
- For quality assurance purposes, health plans that use formularies should have policies in place to provide for a medical exceptions process. The medical exceptions process allows individuals to request:
 - coverage of a prescription drug that is not covered based on the formulary,
 - And continued coverage of a drug that has been removed from the formulary for reasons other than safety or because the drug cannot be supplied or has been withdrawn from the market.

Such exceptions should be based only on documented medical need.

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AMCP *Where We Stand* series: www.amcp.org/positionstatements.

^[1] Academy of Managed Care Pharmacy, *Format for Formulary Submissions: A Format for Submission of Clinical and Economic Data in support of Formulary Consideration by Health Care Systems in the United States* (Alexandria, VA: 2002).

^[2] *Principles of a Sound Drug Formulary System*, consensus document. October 2000. <http://www.amcp.org>.