ASHP Guidelines on Formulary System Management

Preamble

The purposes of these guidelines are to

• Provide an outline of recommended techniques and processes for formulary system management.
• Define terms associated with formulary system management.
• Provide guidance and direction to pharmacists on how to apply the concepts of formulary system management within the context of the “ASHP Statement on the Formulary System.”
• Describe the pharmacist’s responsibility and leadership role, in partnership with the medical staff, in the management of the formulary system.

The formulary system, as defined in the “ASHP Statement on the Formulary System,” is a method for evaluating and selecting suitable drug products for the formulary of an organized health-care setting. Formulary system management is the application of various techniques to ensure high quality and cost-effective drug therapy through the formulary system.

The formulary of an organized health-care setting (e.g., a given hospital, managed care, or home-care operation) is a list of drugs (and associated information) that are considered by the professional staff in that setting to be the most useful in patient care.

Development, maintenance, and approval of the formulary are the responsibilities of the pharmacy and therapeutics (P&T) committee, or its equivalent, which exists as a committee of the medical staff. These responsibilities include oversight of the procedures used to carry out these formulary functions. The information a formulary should contain and the way a formulary should be organized are described in the “ASHP Technical Assistance Bulletin on Drug Formularies.”

Three key elements are important for the establishment and maintenance of a credible formulary. They are

1. A collaborative work relationship among health-care professionals, such as occurs in an organized health-care setting.
2. A defined medical staff (or physician-provider network) that practices within that health-care setting.
3. An interdisciplinary P&T committee as a committee of the medical staff.

Principles of Formulary System Management

The purpose for ongoing management of the formulary system is to optimize patient care through rational selection and use of drugs and drug products within the health-care setting. Pharmacists play a primary role in assessing the relative safety and efficacy of pharmaceuticals nominated for addition to or deletion from the formulary. Through the application of techniques of formulary system management and through reevaluation and improvement of these techniques as necessary, the effectiveness of the formulary system is continuously assessed, resulting in quality improvement of the overall drug use process. Both therapeutic outcomes and costs related to the drug use process can thus be optimized.

Prescriber acceptance of the formulary management process is essential to effect quality improvements through formulary system management. Pharmacists play a key leadership role in fostering this acceptance by clarifying and supporting the goals and processes of formulary system management. Restated, the goal of formulary system management should be sound therapeutics. To achieve this goal successfully, prescribers should be actively involved in developing the techniques used to manage the formulary system. Communication and understanding among pharmacists, prescribers, other health-care providers, and the P&T committee members should be timely and routine. Pharmacists should ensure that a balanced presentation of drug information is provided to prescribers.

Techniques of formulary system management fall into three general categories: (1) drug use evaluation, (2) formulary maintenance, and (3) drug product selection.

Drug Use Evaluation

Drug use evaluation is an ongoing, structured, organizationally authorized process designed to ensure that drugs are used appropriately, safely, and effectively. A well-designed drug use evaluation program applies continuous quality improvement methods to the drug use process. Drug use evaluation should be a part of the hospital’s overall quality-assurance program. The role and responsibilities of pharmacists in drug use evaluation are identified in the “ASHP Guidelines on the Pharmacist’s Role in Drug Use Evaluation.” Drug use evaluation is a quality-assurance activity, but it may also be considered a formulary system management technique. The P&T committee should be involved in the drug use evaluation process.

Effective drug use evaluation begins with drug use criteria or treatment guidelines approved by the P&T committee on behalf of the medical staff. Drug use evaluation should measure and compare the outcomes of patients whose treatment did, or did not, comply with approved criteria or guidelines. Based on this comparative information, criteria or guidelines can be revised, compliance can be encouraged, educational programs can be initiated, or changes can be made to the formulary system. Drug use evaluation programs should include provisions for periodic review of all components of the system.

Drug Use Criteria. In cases where a drug poses potential efficacy, toxicity, or utilization problems for the health-care setting, criteria may be established by the P&T committee to promote appropriate use. Drug use criteria are approved guidelines regarding how, or under what conditions, a drug is recommended for use. Preliminary drug use criteria should be developed at the time that a drug is proposed for addition to the formulary. Drug use criteria should be updated as needed over time. There are three general types of criteria: diagnosis
criteria, prescriber criteria, and drug-specific criteria. Criteria of any type can be used independently or in combination.

Diagnosis criteria identify indications that constitute acceptable uses for a formulary drug within the health-care setting. Protocols, if any, for restricting the use of a formulary drug to specific diagnoses or medical conditions should be established by the P&T committee. For instance, a particular colony-stimulating factor might be approved for use only as an adjunct to cancer chemotherapy. Use of this drug for other indications would then fall outside the approved diagnosis criteria.

Prescriber criteria identify prescribers approved to use specific formulary drugs or drug classes. Examples include limiting the use of specific injectable antibiotics to infectious disease specialists or establishing cardiologists or emergency room physicians as the only approved prescribers for thrombolytic drugs.

Drug-specific criteria identify approved doses, frequency of administration, duration of therapy, or other aspects that are specific to the use of a formulary drug. An example would be limiting the dosing of a long-acting injectable antibiotic to once every 24 hours. More frequent dosing regimens might require approval by an infectious disease specialist.

Treatment Guidelines. Treatment guidelines are similar to drug use criteria, except that treatment guidelines focus on disease-based drug therapy. Whereas drug use criteria relate to a specific drug, treatment guidelines outline a recommended therapeutic approach to specific diseases. This approach generally identifies the use of several different drugs, depending on disease severity or specific patient characteristics. A treatment guideline, for example, may outline a recommended approach to treating community-acquired pneumonia, reflux esophagitis, or otitis media, or it may list drugs to be used in bone marrow transplantation.

Treatment guidelines are typically developed and approved by P&T committees for high risk, high volume, or problem-prone diseases encountered in the health-care setting.

Formulary Maintenance

Formulary maintenance techniques include

- Therapeutic drug class review.
- Processes by which drug products are added to or deleted from the formulary.
- Use of nonformulary drugs in unique patient situations.

To be effective in improving the drug use process, pharmacists and medical staff must work collaboratively. The pharmacist should assume responsibility and a leadership role in the development and presentation of information required by the P&T committee for decisionmaking. The medical staff must understand and support the processes by which these techniques are applied, as well as participate in the development and review of information.

Therapeutic Drug Class Review. It is useful for the P&T committee to review the use and therapeutic effects of several classes of drug products every year. Examples of drug classes suitable for review are nonsteroidal anti-inflammatory agents, injectable cephalosporins, antihistamines, β-blockers, and neuromuscular blockers. These reviews can be prompted by criteria set by the P&T committee itself. For example, based on the number of adverse drug reaction reports, new information in the medical literature, or drug class expenditures, the committee can determine which classes of formulary drugs are worthy of reassessment.

The goal is to identify preferred agents based on effectiveness, toxicity, or cost differences within the same class. It is important that appropriate medical staff input, outside the committee, be solicited during these reviews. Outcomes of therapeutic class reviews can include development of new drug use criteria, new treatment guidelines, or changes to the formulary.

Formulary Addition or Deletion. To strengthen the ability of the P&T committee to make sound decisions on changes to the formulary, it is recommended that there be an approved policy and procedure for requesting changes to the formulary. This process typically involves submission of a request to the P&T committee by pharmacists or members of the medical staff.

Consideration of a drug for addition to the formulary should include a review of an evaluation report (monograph) prepared by the pharmacy. A recommendation on how to prepare and organize an evaluation report can be found in the “ASHP Technical Assistance Bulletin on the Evaluation of Drugs for Formularies.” In addition to monograph information, an impact statement describing the effects of the proposed change on the quality and cost of patient care and drug therapy should accompany each request for addition to or deletion from the formulary.

The use of predetermined decision-reassessment dates is advised (e.g., the drug is placed on the formulary for a 6-month evaluation) to allow the committee to review the actual impact of certain formulary decisions. Reassessment dates are especially useful in situations where the expected impact of the formulary decision on the quality or cost of drug therapy may be significant or uncertain.

Use of Nonformulary Drugs. In general, only formulary drugs are endorsed as appropriate for routine use within the organized health-care setting. The underlying principle for the existence of a process for approval of nonformulary drugs is that individual or unique patient needs can exist that may not be satisfied by the use of formulary drugs.

There should be an approved policy and procedure for obtaining approval for use of nonformulary drugs. This process should include the generation of information on the use of nonformulary drugs to enable the P&T committee to review trends in nonformulary drug use, which may influence formulary addition or deletion decisions. There should also be a process in place for obtaining nonformulary drugs in a timely manner.

In managed care settings, the decision to approve the use of nonformulary drugs is separate from the decision to grant payment coverage for a drug. Coverage decisions are governed by the patient’s contract with a specific health plan.

Drug Product Selection

Pharmacists and prescribers must understand the concept of therapeutic equivalence to ensure proper application of generic substitution and therapeutic interchange principles.
Pharmacists should assume a leadership role in drug product selection by proposing opportunities for drug product selection. This includes evaluation and assessment of bioequivalence data; storage, dispensing, and administration characteristics; cost; and other relevant product information. Pharmacists must also ensure that products of adequate quality are procured.

The application of generic substitution and therapeutic interchange principles may result in a drug product being dispensed to the patient that is different from the product originally prescribed. To ensure high quality drug therapy, therapeutic equivalence between the product dispensed and that prescribed must be ensured.

**Therapeutic Equivalence.** The 1991 edition of the Approved Drug Products with Therapeutic Equivalence Evaluations (FDA Orange Book) describes therapeutic equivalence as a guideline to assist in drug substitution between chemically identical products. Both generic substitution and therapeutic interchange, however, should be safe and effective if the therapeutic equivalence of products to be exchanged has been established. For the purpose of this document, drugs are considered therapeutically equivalent if they can be expected to produce essentially the same therapeutic outcome and toxicity.

The use of therapeutically equivalent products can contribute to improvement in the drug use process by maintaining a high quality of drug therapy in the most cost-effective manner.

**Generic Substitution.** For the purpose of this document, generic substitution is defined as the substitution of drug products that contain the same active ingredient(s) and are chemically identical in strength, concentration, dosage form, and route of administration to the drug product prescribed (i.e., these are “pharmaceutical equivalents” as defined in the FDA Orange Book). These products can also be termed “generic equivalents.” Logically, these products should display therapeutic equivalence.

The key word in this definition is “identical.” For example, the substitution of one brand of propranolol tablets for another represents the application of generic substitution if the strength of the active ingredients and the dosage form are identical. To ensure quality patient care, the two propranolol products must also be shown to achieve therapeutic equivalence as defined above. The substitution of purified pork insulin for human insulin is not generic substitution, because the products are not chemically identical. However, the interchangeability of these products may be acceptable under the principle of therapeutic interchange (discussed below), provided that therapeutic equivalence can be ensured.

Prescribers have the prerogative to override a generic substitution. In some cases, a patient preference may negate an otherwise acceptable generic substitution. The P&T committee is responsible for determining which drugs are acceptable for generic substitution and for developing guidelines for pharmacists who carry out this formulary system management activity. Typically, pharmacists determine which products are purchased and dispensed as generic substitutes. In most healthcare settings, prescribers prospectively authorize generic substitution during their credentialing process. Notification of generic substitution is generally not provided to the prescriber at the time that a generic equivalent is dispensed.

**Therapeutic Interchange.** Therapeutic interchange is defined, for the purpose of this document, as the interchange of various therapeutically equivalent drug products by pharmacists under arrangements between pharmacist(s) and authorized prescriber(s) who have previously established and jointly agreed on conditions for interchanges.

Therapeutic interchange occurs pursuant to development of agreements between pharmacists and prescribers and implies that there is appropriate and timely communication between them. Therapeutic interchange agreements can vary from simple understandings to complex protocols. For example, a therapeutic interchange agreement permitting interchange between cephradine and cephalixin may be a simple arrangement; the dose and dosage form of the two drugs are equivalent, and the drugs typically can be interchanged in the treatment of any disease for which the drugs are indicated. A therapeutic interchange agreement that permits the interchangeability of different colony-stimulating factors in treating a specific diagnosis pursuant to specific protocols might be more complex. In either case, the P&T committee acts on behalf of the medical staff to develop and approve these arrangements.

The approval of a therapeutic interchange arrangement is typically a separate decision by a P&T committee, unrelated to adding or deleting drugs from the formulary. In some settings, all drugs that may be therapeutically interchanged are acceptable to the formulary, and the pharmacy is authorized to purchase and dispense the most cost-effective products. In other settings, certain drug products are deemed interchangeable, but the P&T committee designates a preferred product and approves it for formulary addition. Then the other equivalent drugs or products are deleted from the formulary.

To remain effective over time, therapeutic interchange decisions should be routinely reviewed and revised as appropriate. Therapeutic interchange may not be appropriate for all patients. Professional judgment must be exercised by the pharmacist and the prescriber. Consultation with the prescriber and the patient may be necessary. Prescribers have the prerogative to override a therapeutic interchange. In some cases, a patient preference may negate an otherwise acceptable therapeutic interchange.

Pharmacists should strive for consistency of product use to avoid unnecessary switching of products dispensed to patients. When a change is made, the pharmacist should ensure that appropriate monitoring and followup are undertaken to identify and prevent any unexpected or untoward patient response. The pharmacist should provide appropriate notification and educational materials to prescribers, patients, and other health-care providers as needed regarding therapeutic interchange decisions.

**References**


Approved by the ASHP Board of Directors, November 20, 1991. Developed by the ASHP Council on Professional Affairs. Marvin A. Chamberlain developed the initial draft for council review.

Copyright © 1992, American Society of Hospital Pharmacists, Inc. All rights reserved.