

# Evaluating Drugs for Formulary Inclusion: Evidence-Based Decision Making

*Terri L. Levien*

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## **Pharmacist's Role**

- Determine drugs to be presented or considered for formulary inclusion
- Prepare the drug evaluation monograph
- Make formulary recommendations
- Guide discussions back to objective data when discussion wanders into vague subjective areas (e.g., “in my experience”); difficult with many newer drugs for which very little published information is available

## **Drug Evaluation Monographs**

- Evaluate drugs in all aspects, in relation to all similar agents
- Consider need, effectiveness, risk, and cost
- ASHP guidelines regarding content, plus added content for some settings
- Tailor to setting—institution, clinic, managed care
- Pharmacy has few votes, but monograph often guides the evaluation process and is likely a major factor in the final decision

Information gathered primarily through search of the scientific literature and from the pharmaceutical manufacturer. Look for:

- A current review article on treatment of the disease state
- Pharmacokinetic studies
- Clinical trials—ideal large-scale, randomized, double-blind, controlled clinical trial often not available for new drugs
- Package insert

Monographs are commercially available that can be individually tailored to setting

## **Format**

### *Summary Page*

Summarizes the most important information—including how it compares to similar medications or other agents (or nondrug therapies) used for the same indication.

Limited to items for which one agent has distinct advantage or clinically significant differences.

Includes specific recommendation of the action to be taken on the product.

### *Institution Name*

### *Generic name:*

### *Trade name:*

### *Manufacturer:*

### *Classification:*

AHFS classification (from AHFS Drug Information) or other similar therapeutic classification

Status—prescription, nonprescription, and/or controlled substance

FDA classification (approval rating):

<b>FDA Classification System</b>	
<i>By Chemical Type</i>	
Type	Definition
1	New molecular entity not marketed in U.S.
2	New salt, ester, or other derivative of another drug marketed in the U.S.
3	New formulation of a drug marketed in U.S.
4	New combination of drugs already marketed in U.S.
5	New manufacturer of a drug product already marketed by another company
6	New indication for a product already marketed
<i>By Therapeutic Potential</i>	
Type	Definition
P	Priority handling by FDA
S	Standard handling by FDA

### Summary

Short summary of advantages and disadvantages, particularly in relation to other drugs or treatments used for each major indication.

### Recommendation

Once monograph written, then write summary page including the recommendation

- Must be supported by objective evidence; consider efficacy, safety, patient convenience, drug interactions, storage and handling. Does it offer any advantages in efficacy, safety, or patient convenience relative to other agents on formulary?
- Should be made in concert with appropriate physicians and pharmacists specializing in that area of therapy; need physician involvement and support
- Must address the needs of the institution, including medical staff needs, distribution concerns, and drug availability

ASHP guidelines for formulary status—

- Added for uncontrolled use by the entire medical staff
- Added for monitored use; no restrictions placed on use, but the drug will be monitored to determine appropriateness of use; this is a tie-in to the quality assurance/drug usage evaluation process
- Added with restrictions; drug is added to the formulary, but there are restrictions on who may prescribe it and/or how it may be used (specific indications, certain physicians or physician groups, certain policies to be followed, etc.)
- Conditional; available for use by the entire medical staff for a finite period of time; must specify time when will be reconsidered
- Not added or deleted from formulary

First and last recommendations are preferred; all but first and last increase pharmacy work.

Are restrictions or guidelines necessary? Considerations include toxicity of medication, rarity of condition, and potential for inappropriate use.

### **General Rule of Thumb**

- FDA classification 1P signifies an important advance and often justifies formulary inclusion depending on the patient population
- Less expensive or same price and more efficacious or safer—recommend addition
- Less expensive and no added therapeutic benefit—consider adding, consider other factors such as the costs associated with a switch (education, therapeutic substitution)
- More expensive and no added benefit—recommend not adding
- More expensive and more benefits—gray area. Will it improve quality of care? Will it reduce the overall health care costs?

### **Body of the Monograph**

- Must be prepared in order to compile the summary information that is most relevant and to form a recommendation, but often is not reviewed by the committee.
- Must compare the drug to other therapies (drug, surgical, radiation, etc.)
- Must address every item, even if to state information is not available or is not applicable, so it is apparent that each item was reviewed
- Must be referenced

### **Pharmacologic Data**

- Pharmacologic class
- Mechanism of action
- Identification of similar drugs
- How properties compare to other similar medications (e.g., bacterial spectrum)
- Brief unless unique or antibiotic where spectrum must be addressed

### **Therapeutic indications/efficacy**

- FDA approved versus non-FDA approved indications—differentiate between FDA approved, non-FDA approved but supported by the literature, and clearly investigational uses.
- Disease state information—description, epidemiology
- Clinical comparison—emphasize efficacy, incidence of treatment success, remission, sensitivity, ease of monitoring, and treatment periods required.
  - Include critical analysis of clinical studies with regard to patient population, methodology, statistics, and conclusions, including limitations and missing information.
  - One well conducted study is sufficient, with mention of other studies that support the use; reference all or several less well conducted studies. Ideally the one study should be a well-conducted comparative study with the standard therapy.
- Efficacy compared to active agents
- Efficacy compared to placebo

### **Pharmacokinetics**

- Absorption, bioavailability, extent and rate of absorption, factors affecting rate or extent of absorption,
- Distribution, protein binding, volume of distribution, cross blood-brain barrier
- Metabolism, sites, extent, activity of metabolites

- Excretion, routes of elimination
- Special populations, pediatrics, renal or hepatic insufficiency, geriatrics

### **Dosage forms**

- Forms and strengths
- Special handling or storage

### **Dosage range**

- Adults
- Pediatrics
- Elderly
- Renal or hepatic insufficiency
- Special administration requirements—time of day, with regard to meals or other medications

### **Adverse effects**

- List most frequent, most serious, and distinguishing adverse reactions
- Prevention

### **Contraindications**

### **Special warnings and precautions**

- Toxicities
- Pregnancy
- Lactation

### **Drug interactions**

- Drug-drug
- Drug-food
- Drug-laboratory
  - Include reported and theoretical
  - Include recommendations

### **Patient monitoring guidelines**

- Effectiveness
- Adverse effects
- Compliance

### **Patient information**

- Ambulatory setting may choose to add

### **Cost comparison**

- Compare to other therapies
- Cost impact—pharmacy budget vs. institution/system budget
  - Fewer than 50% of respondents in a 1995 survey of P&T committee members indicated savings outside pharmacy were considered when reviewing expensive medications

- Cost-effectiveness data rarely available at time medications are reviewed for formulary inclusion
- Decision analysis looks beyond the pharmacy budget, particularly useful when factors other than acquisition costs are important in determining overall treatment costs. Useful for comparing drug and non-drug therapies (e.g., angioplasty vs. thrombolysis).
- Value analysis useful for considering addition of “me-too” agents
- Cost per course or for a 30 day supply
  - Consider institution’s cost for the medication and the AWP (especially for medications patient will be discharged on and need to fill at a community pharmacy)
  - Consider differences in package size, frequency of administration
- Consider associated costs (drug preparation costs, administration costs, laboratory costs, monitoring requirements, changes in length of stay or therapy)

**Date presented and name and title of document author**

**References**

- Listed in the order they are cited
- For style see: International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. *Ann Intern Med* 1997;126:36-47.

**References**

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