

**CMS Discussion Paper:**  
**Role of USP Draft Model Guidelines for Formulary Classification  
in Determining Formulary Adequacy for the Medicare Drug Benefit**

The United States Pharmacopeia (USP) Model Guidelines for drug categories and classes provide a standard framework that may be used for the development of Medicare Prescription Drug Benefit formularies. The issuance of these guidelines is another step in the implementation of the Medicare Modernization Act (MMA). Section 1860D-4(b)(3)(C)(ii) of the MMA provides that the USP develop, in consultation with pharmaceutical benefit managers and other interested parties, and revise from time to time, a list of categories and classes that may be used by Prescription Drug Plans (PDP's) that offer a Medicare prescription drug benefit.

The Model Guidelines do not reflect a pure classification system, but rather a starting point for structuring formulary categories and classes. They are meant to balance the need to provide guidance for this comprehensive benefit with the need to allow plans flexibility to develop their own formularies to manage costs. Maintaining some breadth in how the categories and classes are described will provide plans with the ability to tailor their formularies, but P & T Committees must oversee their development and CMS will review formularies for adequacy and nondiscrimination according to publicly reviewed principles that will make sure patients have reasonable access to important drugs.

In practice, CMS will require formularies to provide a choice of drugs within each category and class that appropriately reflects current medical practice. In conjunction with reviewing formulary categories and classes, CMS will also review individual formularies to ensure the adequacy of the drug benefit offered and to prevent any discriminatory practices. Therefore, the Model Guidelines will help plans organize their formularies into appropriate, and commonly agreed upon clinical categories and can be used as a starting point for developing an adequate formulary for their Medicare Prescription Drug Benefit.

To provide appropriate guidance to plans and beneficiaries, CMS will develop explicit formulary review standards and criteria-driven processes and expects to share them for public comment this fall. While CMS encourages and appreciates the appropriate use of utilization management strategies, our goal is to ensure that all beneficiaries have access to medically necessary drug therapies available under this benefit at the lowest possible cost.

**Formulary Evaluation by CMS**

CMS realizes that pharmacy benefit management involves much more than categorizing and classifying drugs in a formulary. Regardless of formulary structure, utilization management strategies can significantly affect access to prescription drugs. Common strategies include tiered cost-sharing, step therapy and prior authorization requirements. While the Model Guidelines can provide an important first step, CMS intends to review formularies to rule out discriminatory exclusions, cost-sharing and/or administrative requirements.

Our formulary review standards and processes are under development and will be released in draft form in the Fall for public comment. We are seeking preliminary comments at this time on the factors to include in this guidance and on how our formulary assessments should interact with formulary classification systems.

Plan formularies must include drugs from each therapeutic category and class, and available drug choices must represent a full range of drug therapies necessary to adequately support current medical practice. This requirement could be satisfied with two drugs in some categories and classes, but the majority will need to include more drugs. CMS will evaluate formularies at a more granular level than described by the Model Guidelines to make sure they include sufficient choices of clinically significant drugs. (Granularity refers to the level of detail-- as an evaluation moves from the broader drug categories included in the USP Model Guidelines, such as cardiovascular drugs, to more specific drug classes such as beta-blockers, and then to an evaluation of individual drugs, it is said to become more granular.) This will likely include evaluating available formulary choices and conditions at the sub-class level.

CMS also will not allow plans to discourage enrollment by requiring higher levels of cost sharing on drugs that disproportionately affect specific groups of beneficiaries. For example, plans will not be allowed to price all antiretroviral drugs in the highest tier. However, this does not mean that these beneficiary groups cannot be subject to tiered cost sharing, just that such tiering cannot be designed to discourage enrollment of that specific beneficiary group.

Finally, CMS will review drug plan prior authorization requirements, exceptions criteria and appeal policies. We understand that prior authorization techniques include clinically appropriate step therapies or diagnosis-related restrictions. Nevertheless, our focus will be to determine if specific beneficiary groups are disproportionately affected by such requirements. CMS will examine the drugs that are subject to prior authorization and the associated criteria for obtaining approval.

### **USP Model Guidelines Compared to Existing Formulary Classification Systems**

The Medicare Modernization Act directed CMS to request the USP to develop Model Guidelines for categories and classes of drugs covered under the Medicare Prescription Drug Benefit. The statute does not specify the intent of the Model Guidelines other than to suggest that they may be used by drug plans for formulary development. However, since the statute also requires that a plan's formulary include multiple drugs in each therapeutic category and class of the formulary, it created a conflict between the use of a pure classification system and the use of a formulary.

Ideally, these Model Guidelines would provide a standard format to show that prescription drug plan sponsors and Medicare Advantage organizations utilizing formularies are offering comprehensive prescription drug benefits. However, since the classification system has been made to do the work of a formulary in determining the number of drugs offered in each class, it must be developed in such a way as to be compatible with formulary design. This dual nature of the USP Model Guidelines means that in some places the Model Guidelines will look more like a classification system (that is, with more comprehensive sub-classification, or "granularity",

within certain classes of drugs), and more like a formulary structure (that is, with less sub-classification) in others.

This dual approach allows prescription drug plans to negotiate best prices in classes within which a good deal of therapeutic substitution is clinically appropriate, while ensuring that there is less flexibility to substitute drugs in other classes, such as those classes of drugs used predominantly by special populations. For example, the Model Guidelines provide the opportunity for clinically appropriate therapeutic substitution with cardiovascular and gastrointestinal medication categories. Alternatively, anti-virals for HIV are divided into four separate classes, the anti-psychotic category contains three classes that differentiate between older and newer treatments, and memory enhancers include two distinct classes. This level of detail signals an increased sensitivity towards managing therapeutic options in these areas.

The Model Guidelines categorize and classify the universe of drugs covered under the Medicare Prescription Drug Benefit. This level of detail provides beneficiaries and providers with guidance about the types of drugs that will make up individual formularies. The Model Guidelines also allow prescription drug plan sponsors and Medicare Advantage organizations the flexibility to design their own formularies. This flexibility is necessary to increase competition and achieve optimal cost savings, which will allow plans to offer comprehensive benefits at reasonable prices. To allow appropriate use of formularies, a manageable number of drug categories and classes needs to encompass all drugs that will be available under the Medicare Prescription Drug Benefit. Therefore, practical considerations, in addition to the clinical justification, must be incorporated in the category and class determinations.

No universal method exists for categorizing and classifying drugs on a formulary. Commonly used approaches include categories and classes based on organ systems, therapeutic indications and pharmacologic activity. Most formularies utilize a combination of these criteria for determining specific categories and classes. The current draft of the USP Model Guidelines resemble similar formulary classification systems used in pharmacy benefit management today:

- The USP Model Guidelines list 43 major categories and 138 pharmacologic drug classes.
  - The Blue Cross/Blue Shield Federal Employee Health Plan (Basic Option) formulary lists 17 major categories and approximately 175 therapeutic drug classes. (Approximately 660 drug products are included on the formulary)
  - The Aetna Federal Employee Health Plan formulary lists 17 major categories and approximately 108 therapeutic drug classes. (Approximately 325 brand name drug products and most generically available covered prescription oral products are included on the formulary)
  - The Advance PCS 2004 formulary lists 17 major categories and approximately 95 therapeutic classes. (More than 900 drug products are listed on the formulary)

- The Caremark Preferred Drug List has 13 major categories and approximately 158 therapeutic classes. (Approximately 360 brand name drug products are listed and most generically available prescription drug products would be included)
- The Wellpoint formulary lists 26 major categories and approximately 99 therapeutic classes. (More than 650 drug products are listed on the formulary)