



AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

September 17, 2004

Lynn Lang
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, Maryland 20852-1790

Re: Comments on the Draft Model Guidelines

Dear Ms. Lang:

The American College of Physicians (ACP), representing 116,000 internists and medical students, appreciates the opportunity to comment on the United States Pharmacopeia (USP) Draft Model Guidelines. ACP believes that the Draft Model Guidelines represent a reasonable attempt by USP to comply with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandate that it develop a list of categories and classes that may be used by prescription drug plans (PDPs). However, the Draft Model Guidelines need to be revised to address significant deficiencies—deficiencies that must be corrected to ensure beneficiaries have access to needed drugs under the MMA-established Medicare prescription drug benefit that becomes effective in 2006.

The main ACP concern is that the current USP Draft Model Guidelines' classification system is too restrictive. It is imperative that the Model Guidelines classification contain appropriate granularity to ensure beneficiary access to appropriate drugs because the MMA provides a safe harbor for PDPs in that the Secretary of Health and Human Services (HHS) "may not find that the design of categories and classes with a formulary discourages enrollment if the categories and classes are consistent with the USP Model Guidelines." Considering that the MMA only requires that PDPs cover at least two drugs for each category and class, it would be unwise to assume that PDPs will maintain formularies that routinely cover more drugs than would be required to comply with the USP Model Guidelines. This is especially true given the fact that compliance with the Model Guidelines affords a safe harbor exempting PDPs from CMS review to determine whether their formularies discourage beneficiary enrollment.

Accordingly, the USP Model Guidelines should be expanded. **ACP recommends that USP add needed granularity to the Model Guidelines by making inclusion of the "Recommended Subdivisions", Column 3 in the Model Guidelines Table, mandatory for safe harbor consideration.**

Specific Comments/Recommendations for USP Consideration

The current USP list of categories and classes would enable PDPs to comply with the Model Guidelines without covering common drugs, potentially denying beneficiaries' access to many valuable therapeutic agents. Under the USP's proposed classification, a PDP potentially could exclude entire classes of drugs currently listed as "Recommended Subdivisions" such as:

- HMG CoA Reductase Inhibitors (i.e., statins), the most widely used drugs to treat hypercholesterolemia;
- The thiazolidinedione class (i.e., glitazones) or other classes of drugs necessary to treat type II diabetes;
- Selective serotonin reuptake inhibitors (SSRIs), the primary drugs for treating depression;
- Angiotensin II receptor blockers (ARBs), an important class of well-tolerated and effective antihypertensives;
- Proton pump inhibitors (PPIs), the most effective drugs for gastroesophageal reflux disease (GERD);
- Bisphosphonates, unique and important drugs in the treatment of osteoporosis;
- Cyclooxygenase-2 inhibitors (COX-2s), a class of non-steroidal anti-inflammatory drugs (NSAIDs) used to treat joint inflammation that have a reduced risk for causing gastric ulceration and bleeding; silent NSAID-induced GI bleeding is a significant cause of morbidity and mortality in the elderly;
- Nonsedating antihistamines, which may be especially useful in elderly patients prone to falls and skeletal fractures; and
- One or more classes of beta blockers (BBs), calcium channel blockers (CCBs), antiarrhythmics, and diuretics, all important drugs for cardiovascular diseases, as well as other conditions common in the elderly.

The ACP recommends that USP correct all such improper class exclusions, using the above-cited examples as guidance.

Further, the USP should revise the Model Guidelines to address the following:

- The Pharmacologic Class of Opioid Analgesics should be further divided into long- and short-acting;
- The Therapeutic Category of Antiemetics should include a Pharmacologic Class for ondansetron hydrochloride (i.e., Zofran[®]) because, although more costly, it has special uses such as chemotherapy and hyperemesis gravidum;
- The Therapeutic Category of Antigout Agents should include a Pharmacologic Class for colchicine;
- The Therapeutic Category of Antihistamines should include a Pharmacologic Class for leukotrienes or nasal sprays for allergic rhinitis;
- The Therapeutic Category of Antimigraine Agents should include discrete Pharmacologic Classes for CCBs for prevention, valproic acid, and divalproex sodium (i.e., Depakote[®]);
- In the Therapeutic Category of Antineoplastics, clarify where imatinib mesylate (i.e., Gleevec[®]), taxol, and rituximab (i.e., Rituxan[®]) belong;

- The Therapeutic Category of Antipsychotics should be reviewed to ensure proper designation of Pharmacologic Classes, thereby providing coverage of all appropriate drugs;
- In the Therapeutic Category of Cardiovascular Medications:
 - Discrete Pharmacologic Classes should be included for angiotensin-converting enzyme inhibitors (ACEIs), ARBs, and aldosterone antagonists (AAs); and
 - The CCB Pharmacologic Class should include subdivisions for dihydropyridines and non-dihydropyridines, with non-dihydropyridines being divided into short- and long-acting, as the short-acting have a higher risk profile yet are inexpensive;
- The Pharmacologic Class of Sex Hormones should be divided into Oral, Transdermal, and Vaginal because estrogens have multiple delivery systems and drugs.

Restrictive Model Guidelines Unnecessary to Control Costs

ACP believes that the more comprehensive Model Guidelines list required to ensure beneficiary access to drugs can still serve the need to control costs. Proponents of restrictive Model Guidelines argue that maintaining a limited number of classes affords PDPs more leverage in negotiating drug prices with pharmaceutical manufacturers. The experience of the Medicare discount card program, which began in May 2004 and requires coverage of a broader array of drug classes than the USP Draft Model Guidelines, refutes this argument. CMS and the Kaiser Family Foundation report that drug card sponsors already have been able to negotiate very significant price concessions under this program, with discounts of more than 20 percent to most patients.

Furthermore, the MMA provides substantial leeway to PDPs to implement various utilization management strategies, such as tiered co-pays, prior authorization, and step therapies. Given the availability of these other utilization management strategies, as well as the safe harbor given to PDPs by adherence to the USP Model Guidelines, it is prudent that the number of classes mandated under the USP Model Guidelines be broadened to ensure that Medicare beneficiaries will have access to necessary drug therapies.

Areas that Need Clarification

ACP requests that USP clarify how off-label use of drugs, i.e., use for treatment in indications not approved by the Food and Drug Administration (FDA), and drugs that can appropriately be included in multiple categories/classes will be treated in the context of the Model Guidelines.

Future USP Involvement

USP should publish its plan for updating the Model Guidelines. The USP's cooperative agreement with CMS recognizes the need to revise the Model Guidelines based on new information (i.e., additional therapeutic uses) about existing drugs and FDA approval of new drugs. The agreement also requires USP to submit a plan to CMS. Soliciting public comment on its update plan would enable USP to strengthen its proposal to CMS.

Although USP's involvement beyond the terms of its cooperative agreement with CMS is unclear, ACP offers to assist USP and CMS as they work to refine the Model Guidelines, update them, and monitor their use by PDPs. PDPs must implement their formularies in a manner that minimizes the administrative burden on physicians who prescribe drugs to beneficiaries based on their knowledge of the patient.

Sincerely,

Joseph W. Stubbs, MD, FACP
Chair, Medical Service Committee