

THE AMERICAN GERIATRICS SOCIETY

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LINDA HIDDEMEN BARONDESS
Executive Vice President

September 15, 2004

United States Pharmacopeia
Attn: Ms. Lynn Lang
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Dear Ms. Lang;

The American Geriatrics Society (AGS), an organization of nearly 7,000 geriatricians and other health care professionals who are specially trained in the management of care for frail, chronically ill older patients, appreciates the opportunity to submit comments on the USP draft therapeutic categories for the Medicare Part D drug benefit.

General Comments

In the Medicare Modernization Act, Congress charged the United States Pharmacopoeia (USP) with creation of a list of therapeutic categories and classes to serve as a framework for formulary development by the Prescription Drug Plans (PDPs) that are expected to provide a drug benefit for Medicare beneficiaries under Medicare Part D. PDPs with formularies that are consistent with USP's model guidelines are deemed to be in compliance with the requirement that PDPs do not discourage enrollment by beneficiaries.

The fundamental purpose of the USP Model Guidelines, therefore, appears to be protection of Medicare beneficiaries. The Guidelines, then, should be of sufficient breadth and granularity to assure that the standard established by Congress is met. That is, the Model Guidelines should accomplish the purpose of ensuring that Medicare beneficiaries, or certain categories of beneficiaries, are not discouraged from enrolling because of the nature of the formulary of the PDP.

The Centers for Medicare & Medicaid Services (CMS) has proposed, in draft regulations, that a minimum of two medications will be required in each of the drug classes established in the USP Model Guidelines. Medications not included on the formulary of

the PDP will be denied to the beneficiary, or will require the imposition of special procedures for access by the beneficiary and/or physician.

While all Medicare beneficiaries are at risk from restricted access to medications, those beneficiaries at the greatest risk are the 6 million dual eligibles (those with both Medicare and Medicaid coverage), the 4 million frail elderly (those age 85 and over), and residents of nursing homes and assisted living communities, numbering approximately 3 and one-half million. These individuals frequently take eight or more medications and have multiple chronic conditions. For these patients, selecting an appropriate therapeutic agent requires careful consideration of:

- Drug side effects and specifically the capacity of the drug to cause or worsen geriatric conditions, including falls, urinary incontinence, mental confusion, and delirium.
- Drug contraindications with co-morbid conditions
- Kidney and liver function of the patient
- Drug interactions
- Appropriate dosage form, such as liquids for those who have difficulty swallowing
- And a number of other factors

Frail elderly individuals and long-term care residents need access to a wide variety of medications and dosage forms to appropriately manage their multiple chronic conditions and medical problems. AGS believes that if seniors do not have access to the most commonly utilized medications that seniors will be forced to change to inappropriate medications resulting in costly adverse effects. **The AGS is concerned that the medications needed to appropriately treat these populations (1) will not be included in the proposed formulary and (2) will not be readily available through the formulary over-ride process.** In addition, the proposed guidelines reliance on the ICD-9 code approach does not adequately capture common geriatric syndromes. In fact, we would instead model the guidelines on the WHO essential medicines list and utilize their approach where common conditions are listed and necessary drugs are as well.

For these reasons, we provide specific comments on the proposed guidelines below.

Specific Comments on USP Model Guidelines

1. AGS is concerned that the USP Model Guidelines is based on a faulted assumption; that being that all medications work on the basis of **class effect**. For instance, recent studies of Cox-2 medications demonstrated that these medications are not necessarily equivalent. Another example is the current classes of vaccines and electrolytes – clearly medications within this class have different indications and mechanisms of action.

A final example is in the anticonvulsant therapeutic category (#14) where five subdivisions are recommended by USP. However, anticonvulsant medications are not interchangeable. Alternatively, we recommend that all anticonvulsants be included on all PDP formularies.

2. AGS is concerned that the draft Model Guidelines lump many types of medications that are commonly used in the elderly with older medications that are either less effective or have serious side effects in the elderly. This could result in loss of access or diminished access to many medications that are essential for appropriate pharmacotherapy in the elderly. Clearly there are certain **medications that are contraindicated for seniors**. By using the Beers' criteria these medications should be excluded from inclusion in the USP Model Guidelines.
3. The USP Model Guidelines has chosen to include some **medications, which are excluded from Part D coverage**; AGS supports the continued inclusion of these medications. Barbituric acid derivatives and benzodiazepine derivatives are specifically excluded from coverage under Medicare Part D although they are currently included in the USP Model Guidelines. Many seniors currently utilize these medications and their continued coverage should be provided.
4. The USP Model Guidelines as they are currently defined would result in an inordinately restrictive list of medications for seniors. This restrictive list could result in seniors being forced to change from the medications they are currently using (pre-Part D) to successfully manage their illnesses or conditions to a medication on their PDP's formulary (Part D) which they may not tolerate or it may not work as effectively. The USP Model Guidelines needs to have a significant **expansion of its 146 unique therapeutic categories and pharmacologic classes**. Below are specific suggestions for the USP Model Guidelines.
 - A. In #6, Beta-lactam, Cephalosporins, all 23 cephalosporin antibiotics on the market are lumped into a single category. Formularies routinely divide the cephalosporins into four generations since each generation differs in its antibacterial coverage; even within a generation there are differences between cephalosporins. Furthermore, bacterial resistance patterns differ across the nation, regionally and locally, thus limiting any antibiotic class to two agents increases the risk for therapeutic failure. These medications are especially critical for the frail elderly and dual eligible populations. Intravenous or intramuscular therapy with various types of cephalosporin antibiotics is frequently used to treat pneumonia or other infections in the home or nursing facility environment. This is much more cost-effective than transferring these individuals to the hospital for treatment. The danger of lumping all these drugs together is that PDPs might offer only oral agents or only offer first- or second-generation cephalosporins on their formularies. The inevitable delay in access to injectable antibiotics

would mandate a trip to the emergency room or hospitalization to access these drugs. When needed, these drugs must be administered immediately, and then for several days or weeks afterwards. It is critical, therefore, that USP include each of the four generations of cephalosporins as individual classes in the Model Guidelines.

- B. In the antidepressant category (#15), the Reuptake Inhibitors includes SSRIs, SNRIs, and tricyclic antidepressants. This would allow PDPs to offer two medications total from these combined categories. Tricyclic medications are inexpensive and generically available, but have high anticholinergic properties. In the elderly, tricyclics often produce constipation, urinary retention, blurred vision, cognitive impairment, and other symptoms. Yet drug plans might choose to offer only two tricyclic antidepressants and deny access to the newer antidepressants that are generally safer and better tolerated in the elderly, but are more costly.

AGS recommends that SSRI, SNRI, and tricyclic antidepressant as well as another (to include agents that have a unique mechanism of action) should each be a separate pharmacologic class. This would help ensure that Medicare beneficiaries have access to the newer and safer antidepressant medications that are currently recommended as first line agents by the American Psychiatric Association as well as the Agency for Health Care Policy and Research Clinical Practice Guideline on the Treatment of Major Depression.

- C. In the antihistamine category (#28), the class of H1 blockers should be further subdivided to ensure that non-sedating antihistamines are available to Medicare beneficiaries. The traditional antihistamines, such as cyproheptadine and hydroxyzine, are highly anticholinergic and produce multiple side effects in the elderly. The nonsedating agents are safer and needed for this population.

We recommend that nonsedating and less sedating antihistamines be placed into a separate pharmacologic class, separate from the traditional (sedating) antihistamines.

- D. In the Anti-inflammatories category, the Nonsteroidals class contains both traditional NSAIDs and COX-2 inhibitors. This could permit PDPs to exclude COX-2 inhibitors from their formularies. Clinical practice guidelines for management of pain and arthritis generally recommend COX-2 agents as preferred agents for those age 65 and over, and those with certain chronic conditions (American Geriatrics – Management of Persistent Pain in Older Persons, American Medical Directors Association – Guidelines for the Management of Chronic Pain, American Pain Society, and the American College of Rheumatology). The vast majority of

Medicare beneficiaries would be candidates for the use of COX-2 inhibitors as first line agents.

In addition, recent research studies are showing that the COX-2 inhibitors are not interchangeable. Even lumping all the COX-2 inhibitors into a separate class may not be adequate to assure that Medicare beneficiaries have access to the safest and most appropriate agents for their needs. At a minimum, however, we recommend that COX-2 inhibitors be placed into a separate pharmacologic class.

- E. In the category of Blood Glucose Regulating Agents (#77), all insulins are lumped into a single pharmacologic class. A wide variety of insulin products are available, with very different onset and durations of action and applications. Especially useful are the newer rapid acting insulins that may be administered just before a meal, and insulins that deliver a consistent blood level over most of the day. Yet, because all insulins are lumped together, and since PDPs only have to offer two drugs from this class, the potential exists for Medicare beneficiaries to be denied access to newer insulin products that may be more appropriate for their conditions. Furthermore, many diabetics take two different insulins on a daily basis to control their blood glucose. Limiting a formulary to only 2 insulins could result in their loss of glucose control. The AGS recommends that each of the recommended subdivisions, such as rapid-, intermediate-, and long-acting, within the insulin class be moved to separate pharmacologic classes.

- F. In the Oral Hypoglycemics class of the same category, five subdivisions are recommended, but only two medications are required for the combined five subdivisions. One of the subdivisions is sulfonylureas, which contains mostly older medications. Again, PDPs could make these older drugs easily available because they are cheap, but restrict access to newer medications for diabetes that often provide valuable advantages but at a higher cost. Several of these older sulfonylureas have been associated with prolonged and severe hypoglycemia (too low a blood sugar) in older patients and interact with more medications than newer agents. Many individuals with diabetes require combination therapy for adequate management, an approach that would be difficult with limited drug availability.

We recommend making each of the five subdivisions a separate pharmacologic class, to help ensure access to newer medications and the ability to provide combination therapy as needed. Access of these medications is essential to proper glycemic control as outlined by the American Diabetes Association.

- G. In the Anticoagulants pharmacologic class (#82), all oral and parenteral anticoagulants are lumped together. These agents are very diverse. The AGS recommends that each of the six recommended subdivisions should be moved to individual pharmacologic classes to assure access to medications recommended by the American College of Chest Physicians through their guidelines.
- H. The class of antilipemic agents (#94) contains five recommended subdivisions, including HMG-CoA Reductase Inhibitors. With this framework, a PDP could assemble a formulary that does not include statin drugs, which are recommended first line agents by the National Institutes of Health – National Cholesterol Education Program (www.nhlbi.nih.gov/guidelines/cholesterol/atp3xsum.pdf). We recommend that HMG-CoA Reductase Inhibitors be moved to a separate pharmacologic category.
- I. The class of antiulcer agents (#109) lumps proton pump inhibitors with H2 blockers and protectants. Yet proton pump inhibitors are among the most widely used medications in older adults and carry the recommendation as first line agents by the American Gastroenterological Association (www.gastro.org/edu/GERDmonograph.pdf). The AGS recommends that this group of medications be moved to a separate pharmacologic class.
- J. The presence of dementia commonly forces prescribers to use drugs with less frequent dosing so that visiting nurses can oversee administration. If such longer-acting drugs are not available, adherence declines and outcomes suffer. The AGS recommends that USP include this group of medications in the guidelines.

Conclusion

It is difficult to see how the proposed USP Model Guidelines can help assure access to needed and appropriate medications by the sickest and oldest of Medicare beneficiaries. Prescription Drug Plans under Medicare Part D could easily be able to offer a drug benefit within these USP guidelines that could discourage enrollment in their plans by high risk or high cost individuals.

CMS has indicated their intention to review all formulary proposals submitted by a PDP, whether or not it follows the USP therapeutic category list. The nature and extent of this review, however, is unclear at this time. CMS plans to provide their standards and guidelines for formulary review at a later time. It is also unclear whether CMS will have the resources to thoroughly review several PDP formularies in up to 50 regions within the United States in time for the January 2006 launch of the Medicare Part D benefit. AGS also encourages USP and CMS to include a method to allow for expansion of the therapeutic categories and drug classes as new medications with unique mechanisms of action are developed and approved.

Providing a drug benefit to the frail elderly and dual eligible population requires special consideration in a number of areas. The draft USP Model Guidelines appears to be based on a standard managed care approach to drug benefits, rather than serving the special needs of the Medicare population.

We encourage USP and the Expert Committee, in the final version of the Model Guidelines, to provide changes and improvements for the vulnerable Medicare beneficiaries who depend upon medications to manage their chronic conditions and other medical problems.

Thank you for the opportunity to provide comments on this important issue. If you have questions or comments, please contact Susan Emmer in the AGS Washington office at 301-320-3873.

Sincerely,

A handwritten signature in black ink, appearing to read 'Meghan Gerety', written in a cursive style.

Meghan Gerety, MD
President
American Geriatrics Society