CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

January 6, 2006

Filed Electronically

Roger Williams
Executive Vice President and CEO
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, Maryland 20852-1790

Dear Mr. Williams:

The undersigned organizations, representing cancer patients, physicians, and researchers, recommend modifications of the draft Model Guidelines for 2007 and also urge an extension of the comment period to permit a more meaningful response to these important guidelines.

Comment Period

We appreciate the decision by United States Pharmacopeia (USP) to extend the comment period on the draft Model Guidelines until Friday, January 6, 2006. However, because the draft Model Guidelines did not become available for public review until the second week of December 2005, the comment period is only slightly longer than three weeks. This period of time hardly provides an adequate opportunity to develop and submit comments on such an important document. In addition, the comment period coincides with two of the most widely observed national holidays, further undermining the public's meaningful opportunity to comment.

Although we are submitting brief comments on several key issues, we urge an extension of the comment period until the end of January 2006 to permit thoughtful consideration of the draft by interested parties. We appreciate that prescription drug plan sponsors require significant advance notice of revised guidelines to adjust their formularies accordingly, but extending the comment period one month should not hamper their ability to respond to revisions of the Model Guidelines by January 2007.

Therapeutic Category of Antineoplastics

The treatment of antineoplastics in the draft Model Guidelines for 2007 represents an improvement over the treatment of these agents in the 2006 guidance. The draft document adds a number of pharmacological classes in the antineoplastic category, to clarify that there may be clinical distinctions or to establish that Part B or Part D coverage may be applicable, depending

on setting and route of administration. The draft also amends the 2006 document to include formulary key drug types (FKDTs), a modification that will provide important guidance to drug plan sponsors.

We recommend that the pharmacologic class of sex hormones/modifiers, included in the draft in the therapeutic category of hormonal agents/suppressants, be included instead as a pharmacological class in the therapeutic category of antineoplastics. Despite their unique mechanism of action, these agents fundamentally function to inhibit or prevent the growth of cancer cells. For breast and prostate cancer patients, these agents are critical elements of anticancer therapy. Inclusion of these agents as antineoplastic agents would be a more accurate clinical classification and would be consistent with their usage in cancer care.

Antiemetics

The therapeutic category of antiemetics includes no pharmacologic classes but does list two formulary key drug types: 5-HT3 antagonists and non-5-HT3 antagonists. Control of nausea and vomiting is critical to maintaining the quality of life for patients in active treatment and also to ensuring that side effects do not disrupt treatment. Because cancer patients may have variable responses to different categories of antiemetics, the greatest possible degree of flexibility in management of nausea and vomiting is necessary.

We commend USP for distinguishing the 5-HT3 antagonists from the older classes of drugs that were used for management of chemotherapy-induced nausea. However, the draft guidelines do not include a key drug type, the NK1 antagonist, a new class of drugs that has a different mechanism of action from the older drugs or 5-HT3 antagonists and is important for control of nausea and vomiting in response to moderately and highly emetogenic chemotherapy. We recommend, for the purpose of appropriate clinical distinctions and for clarification of Part B or Part D coverage, that three pharmacologic classes be included in the antiemetic category: 5-HT3 antagonists, NK1 antagonists, and other antiemetics (non-5-HT3 antagonists and non-NK1 antagonists).

Smoking Cessation Drugs

The current draft does not identify a category or class of drugs that would include prescription smoking cessation agents. In its March 2005 decision memorandum providing Medicare coverage for smoking and tobacco use cessation counseling, the Centers for Medicare & Medicaid Services (CMS) cited as support for its coverage decision the 2000 Public Health Service guidelines on smoking cessation that recommend that smokers utilize counseling and behavioral therapies as well as pharmacotherapies to improve their chances of permanent cessation of smoking. In subsequent materials describing Medicare smoking cessation benefits, the agency has detailed Medicare coverage of counseling services along with coverage of smoking cessation drugs prescribed by a physician, which it describes as being covered under Part D beginning in January 2006.

We strongly urge the revision of the guidelines to include a therapeutic category of "antismoking agents." This would ensure that Medicare beneficiaries have access to the most effective smoking cessation program, which may combine counseling with pharmacotherapy. This would be consistent with the intent of Congress and CMS to provide Medicare beneficiaries the best available tools to quit smoking.

Process for Updating the Model Guidelines

We urge USP to develop a process for regular and timely updates of its model classification system. Such updates will guarantee the proper classification of novel therapies. We are optimistic that several new cancer therapies will be approved before the next annual review of the guidelines, and the USP guidelines should be regularly updated to reflect such treatment advances. Without such a process, patients will be left to rely on timely review of new therapies by plans' pharmacy and therapeutics committees or to depend on their ability to utilize the exceptions process to obtain access to a new drug not included on a formulary. For many cancer patients, reliance on these strategies for obtaining access to drugs may result in harmful delays in care.

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We urge your careful consideration of these comments.

Sincerely,

Cancer Leadership Council

American Cancer Society
American Society of Clinical Oncology
American Society for Therapeutic Radiology & Oncology
C3: Colorectal Cancer Coalition
Cancer Care
Cancer Research and Prevention Foundation
The Children's Cause for Cancer Advocacy
International Myeloma Foundation
Kidney Cancer Association
Lance Armstrong Foundation
The Lung Cancer Alliance
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
National Prostate Cancer Coalition
North American Brain Tumor Coalition
Ovarian Cancer National Alliance
Sarcoma Foundation of America
The Susan G. Komen Breast Cancer Foundation
Us TOO International Prostate Cancer Education and Support Network
Y-ME National Breast Cancer Organization