



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

Submitted Electronically

September 17, 2004

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

Re: Comments on the Draft Model Guidelines for the Medicare Prescription Drug Benefit

Dear Ms. Lang:

The undersigned organizations, representing cancer patients, physicians, and researchers, urge significant revision of the United States Pharmacopeia draft model guidelines for the Medicare prescription drug benefit. Our comments relate to the treatment of antineoplastics in the proposal.

Recommendation

The draft guidelines establish a single therapeutic category for antineoplastics, which would be divided into only nine pharmacologic classes (including one for "antineoplastics, other") that are based on mechanism of action. We believe the nine pharmacologic classes in the draft fail to capture the range of antineoplastic agents, especially when both injectable and oral anticancer agents are considered for Part D coverage. However, a further subdivision of this therapeutic category into additional pharmacologic classes will not transform the draft into an appropriate means of administering the Medicare Part D benefit. Guidelines that establish classes of drugs and permit a limited number of drugs to be listed in each class are inconsistent with the practice of oncology.

We recommend instead that the USP model guidelines include the single therapeutic category of “antineoplastics” and that **all** anticancer drugs should be included in this therapeutic category. Such a structure would reflect the manner in which cancer treatment is delivered and would ensure that cancer patients have access to appropriate therapies.

Discussion

Cancer care is protocol-driven, and the protocols that guide the delivery of care are based on specific drugs. A physician treating a cancer patient does not select a drug according to mechanism of action, as the draft guidelines suggest, but instead chooses the drug, or more likely the combination of drugs, determined to be effective in that patient’s specific form of cancer. The draft guidelines, which would permit the exclusion of certain drugs in a pharmacologic class, would force the substitution of cancer drugs, a practice that is at odds with cancer care protocols and that may result in a decline in the quality of cancer care. Establishing classes of drugs and allowing the inclusion of only some drugs in each class will violate current standards of cancer care.

For example, among the classes of antineoplastics included in the draft guidelines is the class of “molecular target inhibitors.” If these guidelines are adopted, it is possible that only one of the new targeted molecular therapies would be included for coverage through Part D. This action would undermine the value and benefits of the targeted therapies, which may be appropriate for use only in a narrowly defined population of cancer patients but which may be the best therapy for that population. The draft guidelines include a “recommended subdivision” of platinum coordination complexes, and under the standards for Part D, only one of the platinum-based antineoplastics might be listed on the formulary. These compounds are not interchangeable, although the proposed structure would suggest they are.

Comments to the Centers for Medicare & Medicaid Services

We will submit comments to the Centers for Medicare & Medicaid Services that will recommend an open formulary for the special population of cancer patients. This is the most appropriate means of ensuring that individuals with cancer have access to the antineoplastics that are appropriate for their diagnosis, as well as the supportive care drugs that are a necessary part of treatment. If an open formulary approach is not adopted for cancer patients, the model guidelines must be significantly revised in their treatment of antineoplastics.

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Conclusion

We appreciate the opportunity to comment on the draft guidelines and strongly urge that they be modified to reflect a single therapeutic category of antineoplastics, eliminate any classes within that category, and include all antineoplastics in the single therapeutic category.

Sincerely,

Cancer Leadership Council

American Cancer Society
American Society of Clinical Oncology
Cancer Care, Inc.
Cancer Research and Prevention Foundation
Fertile Hope
Kidney Cancer Association
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
Multiple Myeloma Research Foundation

National Coalition for Cancer Survivorship
National Patient Advocate Foundation
National Prostate Cancer Coalition
Pancreatic Cancer Action Network
Sarcoma Foundation of America
Susan G. Komen Breast Cancer Foundation
US Too International Prostate Cancer
Education and Support Network
The Wellness Community
Y-ME National Breast Cancer Organization