



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

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September 5, 2000

VIA ELECTRONIC MAIL

Nancy-Ann Min DeParle  
Administrator  
Health Care Financing Administration  
Department Health & Human Services  
200 Independence Ave., S.W.  
Room 314-G B HHH Bldg.  
Washington, D.C. 20201

RE: Medicare Coverage of Clinical Trials

Dear Ms. DeParle:

The Cancer Leadership Council (CLC) includes organizations representing cancer patients, providers and researchers. The CLC has been involved in advocacy for coverage of routine patient care costs in cancer clinical trials for many years and is now gratified that the Health Care Financing Administration (HCFA) has taken the bold and creative step of implementing such coverage through a National Coverage Decision (NCD). We believe that the NCD is relatively straightforward, thorough and persuasive in its rationale. There are, however, several points that we perceive as requiring clarification.

First, we are aware that the intent of the drafters was to extend “deemed” coverage status to privately sponsored trials conducted under an investigational new drug (IND) exemption from the Food and Drug Administration (FDA) as well as to federally funded trials. Unfortunately, however, this result is not consistently conveyed in the NCD. The initial discussion of the trials presumed to be covered leaves the impression that only federally funded trials are eligible for coverage:

“Trials funded by certain Federal agencies, as described below, will be automatically deemed to receive Medicare coverage of routine costs as soon as this NCD takes effect. Other types of trials will be included later as the principal investigators certify that the trials meet criteria developed by a Federal multi-agency group that are based on the desirable characteristics that follow.”

Subsequently, the NCD adds that “all trials of patients that are either conducted under an investigational new drug application (IND) or are exempt from having an IND under 21 CFR 312.2(b)(1) would have deemed status.”

While we have no doubt that so-called IND trials are intended to qualify automatically for coverage, the inconsistency between the two above statements could result in confusion. In fact, several trade press accounts of the NCD have focused on the initial statement and reported that coverage extends only to federally funded trials. The NCD should be clarified by noting in both instances that IND trials enjoy the same “deemed” coverage status as federally funded trials.

In addition, we have some concern that the NCD’s description of trials that are not considered covered may lead to questions about the status of phase I clinical trials in cancer and perhaps other life-threatening diseases. The NCD states, “Trials that are designed exclusively to test such things as toxicity or basic disease biology are excluded from coverage.” Because phase I trials are traditionally viewed as solely for the purpose of assessing toxicity by administering the drug to healthy volunteers, this statement could be interpreted as excluding all phase I trials. Such a result would be very problematic for Medicare beneficiaries diagnosed with cancer, as phase I trials are viewed as valid therapeutic options for some patients. (A review article on the “Critical Role of Phase I Clinical Trials in Cancer Treatment,” adopted by the American Society of Clinical Oncology and published in the Journal of Clinical Oncology, is attached.) Denying coverage for phase I clinical trials would be contrary to the intent and spirit of the NCD, and the language should be clarified to indicate specifically that phase I trials in cancer patients are to be covered.

Finally, we wish to commend HCFA for its attention to the issue of coverage for beneficiaries enrolled in Medicare+Choice plans. HCFA’s proposal is entirely appropriate, as Medicare+Choice enrollees deserve the same access to clinical trials as those enrolled in the traditional Medicare fee-for-service program.

Once again, we thank you and your staff for your efforts in reviewing this very important issue and arriving at a policy that will help to ensure quality cancer care for Medicare beneficiaries.

### **Cancer Leadership Council**

Alliance for Lung Cancer Advocacy, Support, and Education  
American Society of Clinical Oncology  
Association of American Cancer Institutes  
Cancer Care, Inc.  
Cancer Research Foundation of America  
The Children’s Cause, Inc.  
Coalition of National Cancer Cooperative Groups  
Colorectal Cancer Network  
Cure For Lymphoma Foundation  
International Myeloma Foundation  
Kidney Cancer Association  
The Leukemia & Lymphoma Society  
Multiple Myeloma Research Foundation  
National Coalition for Cancer Survivorship  
National Patient Advocate Foundation  
National Prostate Cancer Coalition  
North American Brain Tumor Coalition  
Oncology Nursing Society

Ovarian Cancer National Alliance  
Pancreatic Cancer Action Network  
The Susan G. Komen Breast Cancer Foundation  
US-TOO International, Inc.  
Y-ME National Breast Cancer Organization

Attachment

cc:

The Honorable William Jefferson Clinton, President of the U.S.  
The Honorable Albert Gore, Vice President of the U.S.  
The Honorable Donna Shalala, Secretary, HHS  
Ruth Kirschstein, M.D., Acting Director, NIH  
Jane E. Henney, M.D., Commissioner, FDA  
The Honorable Connie Mack  
The Honorable John D. Rockefeller  
The Honorable Nancy L. Johnson  
The Honorable Benjamin L. Cardin  
The Honorable Ken Bentsen  
The Honorable Henry A. Waxman