



Association of American Cancer Institutes
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Pittsburgh, PA 15213



American Society of Clinical Oncology
1900 Duke Street, Suite 200
Alexandria, VA 22314

August 17, 2007

Leslye K. Fitterman, PhD
Lead Analyst
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mail Stop C1-09-06
Baltimore, MD 21244-1850

Re: Proposed Decision Memo for Clinical Trial Policy (CAG-00071R2)

Dear Dr. Fitterman,

The American Society of Clinical Oncology (ASCO) is the leading medical society for physicians involved in cancer treatment and clinical research. The Association of American Cancer Institutes (AACI) is comprised of 89 of the nation's leading academic and freestanding cancer research centers that are the nexus of both basic cancer research and clinical investigations. Members of ASCO and AACI conduct the overwhelming majority of cancer clinical trials in the United States. We regard the 2000 Clinical Trial Policy as central to our general shared mission of progress against cancer through clinical research, as well as to our more specific challenge of increasing participation by Medicare beneficiaries in cancer clinical trials. In our view, the proposed changes in the Medicare policy will be devastating not just to Medicare cancer patients but also to the cancer research enterprise generally.

The 2000 Medicare Clinical Trial Policy Has Been a Great Success.

ASCO, AACI, and others in the cancer community uniformly welcomed the 2000 Clinical Trial Policy with its generous scope of coverage and its relative ease of administration, relying on oversight judgments by the National Institutes of Health (NIH) and other federal funding agencies or by the Food and Drug Administration (FDA) for products within its jurisdiction. Medicare officials wisely declined to embark on an independent review of the validity of the thousands of clinical trials underway at any given time, but rather deferred to the expertise of federal funding agencies and FDA as the premier science-based health regulatory agency in the federal government, finding those trials to be "deemed" covered. We are aware of no questions that have been raised regarding the cost of the policy or the quality of patient care.

In fact, there are persuasive data suggesting that the 2000 Clinical Trial Policy exerted a measurable positive impact on participation in clinical trials by Medicare beneficiaries. A study by the Southwest Oncology Group found that Medicare participation rates in cancer clinical trials rose from 25 to 38 percent following adoption of the 2000 Clinical Trial Policy, at least for those with supplemental insurance.¹ The cancer community has pursued a variety of strategies to encourage

¹ "Impact of the Year 2000 Medicare Policy Change on Older Patient Enrollment to Cancer Clinical Trials," *Journal of Clinical Oncology*, vol. 24, pp. 141-144 (Jan. 1, 2006).

participation in clinical trials by Medicare beneficiaries, but none has been as successful in a relatively short period of time as the initiation of the 2000 Clinical Trial Policy. Given that record of achievement through the current policy, it is extremely puzzling that the Center for Medicare & Medicaid Services (CMS) would seek to deconstruct that policy in favor of an alternative that is not only completely untested but also was a target for elimination in the April 10, 2007 proposed decision memorandum.

There is No Reason to Deviate from the Current Clinical Trial Policy.

CMS has offered various explanations for its plan to amend the 2000 Clinical Trial Policy, but none of them withstands scrutiny. The 2000 policy was absolutely clear that coverage extended not just to federally funded trials but also to privately sponsored clinical trials of drugs or biologics under the purview of FDA. If there is confusion at this point, it may be because of the proposal made by CMS in the April 10, 2007 national coverage decision to eliminate coverage of one category of FDA trials: the so-called IND-exempt trials. We believe that IND-exempt trials should continue to be covered as they have been since initiation of the policy in 2000.

The only significant category of clinical trials not covered by the 2000 policy would be studies of surgical procedures that are not federally funded or not emanating from a cancer center or cooperative group under NIH auspices. All privately funded drug or biologic trials would be covered as either under an IND or as IND-exempt, and medical devices have their own separate coverage policy for investigational devices. If CMS wishes to employ self-certification for surgical trials that could not otherwise qualify for coverage, that would be a reasonable solution to ensure quality in such studies that might otherwise not be adequately monitored.

Use of Self-Certification for Trials Previously “Deemed” Covered Will Deter Participation by Medicare Beneficiaries.

CMS proposes that coverage should be available only for those sponsors or principal investigators who have self-certified as to 13 different criteria. There are numerous problems with the criteria, including their subjectivity, their tendency to duplicate information already provided elsewhere, and their potential inconsistency with existing requirements. The overarching issue, however, is the reasonable fear of retrospective reviews of compliance with the self-certification. Institutions are already burdened with a multiplicity of paperwork and other regulatory demands, any one of which can turn into a compliance situation; as a result, institutional counsel are understandably risk-averse in undertaking additional commitments of the sort suggested by the 13-point self-certification. Many institutions will no doubt conclude that this exercise, which contributes little if anything to the research effort, is not worth the trouble and the risk. Thus, Medicare beneficiaries will once again be systematically under-represented in cancer clinical trials.

The Clinical Research Enterprise Will Suffer if Coverage Policy is Unclear, Inconsistent, or Not Based on Science.

The Medicare Clinical Trial Policy was unchanged for more than five years, during which period participation in research studies by Medicare beneficiaries climbed significantly. CMS injected a considerable degree of uncertainty into the process by its initiation of a “reconsideration” of the policy in July 2006. Then CMS further stimulated concerns when, in April 2007, it proposed to eliminate from coverage the IND-exempt trials, which likely number in the thousands and thus have

a substantial impact on access for Medicare beneficiaries. Now, without responding to the many comments objecting to the move against IND-exempt trials, CMS has proposed eliminating the entire superstructure of the 2000 Clinical Trial Policy and replacing it with a complex, burdensome, and untested self-certification process.

In the April 2007 proposed decision memorandum, CMS also rejected out of hand the concept of self-certification as a meaningful oversight measure. As CMS stated at that time:

“While we wish to encourage participation in high quality studies by Medicare beneficiaries, we do not believe self-certification is sufficient. We propose deletion of the self-certification in the new policy.”

Now, the previously rejected self-certification process has become the only option. It is extremely difficult for institutions, or even individual providers, to make decisions about investment of personnel and other resources in a context where the standards are (and have been in recent history) very changeable, with, at this point, little confidence about the future direction of policy.

Conclusion

The 2000 Clinical Trials Policy has worked well since its inception, as demonstrated by increased rates of participation in cancer clinical trials by Medicare beneficiaries. It should be reaffirmed without significant change.

Sincerely,

American Society of Clinical Oncology
Association of American Cancer Institutes
Abramson Cancer Center of the University of Pennsylvania
Arizona Cancer Center
Barbara Ann Karmanos Cancer Institute
Cancer Research Center of Hawaii
Case Comprehensive Cancer Center and Ireland Cancer Center at University Hospitals of Cleveland
City of Hope National Medical Center and Beckman Research Institute
Cleveland Clinic Taussig Cancer Center
Dana-Farber Cancer Institute
Duke Comprehensive Cancer Center
Fox Chase Cancer Center
Fred Hutchinson Cancer Research Center
H. Lee Moffitt Cancer Center & Research Institute at the University of South Florida
Holden Comprehensive Cancer Center at the University of Iowa
Hollings Cancer Center at the Medical University of South Carolina
Huntsman Cancer Institute at the University of Utah
Kansas Masonic Cancer Research Institute
Lombardi Comprehensive Cancer Center at Georgetown University
Louisiana Cancer Research Consortium of New Orleans at the Tulane Cancer Center
Mary Babb Randolph Cancer Center at West Virginia University
Massey Cancer Center at Virginia Commonwealth University
Medical College of Wisconsin Cancer Center

Nevada Cancer Institute
Norris Cotton Cancer Center
Oregon Health and Sciences University Cancer Institute
Roswell Park Cancer Institute
Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University
SimmonsCooper Cancer Institute
Stanford University Comprehensive Cancer Center
The Alvin J. Siteman Cancer Center
The Barrett Cancer Center at University of Cincinnati
The Carole & Ray Neag Comprehensive Cancer Center
The Dan L. Duncan Cancer Center at Baylor College of Medicine
The Ohio State University Comprehensive Cancer Center
– James Cancer Hospitals & Solove Research Institute
UAB Comprehensive Cancer Center
UNC Lineberger Comprehensive Cancer Center
University of Chicago Cancer Research Center
University of Colorado Cancer Center
University of Miami Sylvester Comprehensive Cancer Center
University of Minnesota Cancer Center
University of New Mexico Cancer Center
University of Pittsburgh Cancer Institute
University of Virginia Cancer Center
University of Wisconsin Paul P. Carbone Comprehensive Cancer Center
UNMC Eppley Cancer Center
USC/Norris Comprehensive Cancer Center
Vanderbilt-Ingram Cancer Center