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February 5, 2009

Via Electronic Mail to CAGinquiries@cms.hhs.gov

Steve E. Phurrough, MD, MPA
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, Maryland 21244

Re: Proposed Decision Memo for Positron Emission Tomography (FDG) for Solid Tumors (CAG-00181R)

On behalf of the American Society of Clinical Oncology (ASCO), I am pleased to provide these comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed decision memorandum (CAG-00181R) involving the use of positron emission tomography (PET) for solid tumors.

ASCO is the leading medical society in the United States for physicians involved in providing clinical care to individuals with cancer and conducting research that leads to improved patient outcomes. We are committed to ensuring that evidence-based practices for the prevention, diagnosis and treatment of cancer are available to all Americans, including Medicare beneficiaries. We support continued access to PET scans for Medicare beneficiaries who have cancer and appreciate the opportunity to comment on CMS' proposed policy.

ASCO participated in development of the National Oncologic PET Registry (NOPR) and was pleased to publish the initial results from NOPR in our flagship journal, the *Journal of Clinical Oncology*.[1] As you know, study results showed that for initial staging, PET altered the planned intervention in 36% of the cases. We understand this information, as well as other data, provided the basis upon which CMS has proposed coverage of PET as part of initial treatment planning. ASCO supports this proposal.

For all cancers except breast cancer, CMS proposes to cover PET scans used for subsequent scans only under the coverage with evidence development (CED) policy. This proposal is based on the agency's determination that there is insufficient evidence to warrant coverage of these scans. However, we encourage CMS to review

[1] Hillner et al. Impact of Positron Emission Tomography/Computed Tomography and Positron Emission Tomography (PET) Alone on Expected Management of Patients With Cancer: Initial Results From the National Oncologic PET Registry. *Journal of Clinical Oncology*. May 1 2008: 2155-2161.

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additional published data on PET such as the recent article in *Cancer* that shows information from PET scans conducted for treatment monitoring altered treatment decisions in 49% of cases.[2] This is clearly comparable to the level of change reported following initial staging scans. In light of these newly published data, it seems inconsistent to judge initial PET scans worthy of coverage, but restrict subsequent scans to the CED framework as proposed.

If CMS ultimately determines that subsequent scans will continue to be covered only under the CED policy, then it is imperative that the final provisions are implemented in a manner that assures continuity of care—as well as coverage—for patients. Patient access to PET scans should be maintained throughout the transition to any new CED framework.

ASCO has serious concerns with the proposed provision that would impose thirteen criteria clinical trials involving PET. ASCO objects to imposition of these criteria and strongly recommends their deletion from this coverage policy. CMS proposed these same criteria in 2007 as part of its consideration of a new national coverage determination for all clinical trials. Based on comments received from the public, the agency excluded these provisions from its final policy (see Decision Memorandum for Clinical Trial Policy, CAG-00071R2). The rationale for their inclusion in the proposed coverage for PET scans is unclear.

We have attached the comments ASCO submitted in 2007 in response to the second reconsideration of the clinical trials policy (CAG-00071R2). Many other organizations submitted similar comments. The criteria are overwhelmingly subjective, are duplicative of many existing rules and regulations, and represent significant administrative burden. In short, they are unworkable in practice. Our earlier comments warned that adoption of these criteria would have an adverse impact on accrual of seniors to cancer clinical trials. Their inclusion in this proposed policy would, likewise, represent an unnecessary and adverse impact on accrual of Medicare beneficiaries to clinical trials involving CED for PET scans. We commend CMS for withdrawing the proposed 13 criteria from the national policy on clinical trials in 2007, and we strongly urge CMS to refrain from using these same criteria within the PET scan policy or any other CED policy.

We value our longstanding and collaborative relationship with CMS, and we hope that you and your colleagues at CMS and other federal agencies will continue to rely on ASCO as a resource for issues involving the interpretation of scientific data and the standards of clinical practice for preventing, diagnosing and treating cancer. Please contact Deborah Kamin, Ph.D., Senior Director of Cancer Policy and Clinical Affairs, at (571) 483-1610 or deborah.kamin@asco.org with questions or requests for information.

Sincerely,

Allen S. Lichter, MD
Chief Executive Officer

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[2] Hillner et al. Impact of Positon Emission Tomography on Expected Management During Cancer Treatment. *Cancer.* Jan 15 2009: 410-418.

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August 8, 2007

Leslye K. Fitterman, PhD
Centers for Medicare and Medicaid Services
7500 Security Blvd., Room C1-12-04
Mail Stop C1-09-06
Baltimore, MD 21244-1850

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

Dear Dr. Fitterman,

As the leading medical society for physicians involved in cancer treatment and research, the American Society of Clinical Oncology (ASCO) submits these comments in strong opposition to the proposed changes in the clinical trial policy of the Medicare program, now renamed the Clinical Research Policy. If adopted as proposed, the new policy will impose substantial impediments to research as well as needless additional expense for the research enterprise, in both the public and private sectors. The proposal represents a significant retreat from the enlightened policy developed by the Medicare program to implement President Clinton's June 2000 executive memorandum.

After six years of providing coverage of routine patient care costs in high quality clinical trials, as determined by the peer-review and oversight mechanisms of respected federal science agencies like the National Institutes of Health (NIH) and the Food and Drug Administration (FDA), the Centers for Medicare & Medicaid Services (CMS) now proposes to create a burdensome, duplicative and impractical bureaucratic scheme that will discourage provider participation in clinical research and greatly add to its cost, while providing no tangible benefit. It also will likely result in fewer Medicare beneficiaries participating in clinical trials – compromising the overarching goals of the clinical research policy that CMS reaffirmed in its July 2006 reconsideration announcement. The current policy has worked well, enhancing participation of Medicare beneficiaries in high quality clinical research without adding significantly to the cost of care or compromising in any way the quality of that care.

Origin of the Policy

Throughout the second half of the 1990's, ASCO and many other cancer-related organizations advocated for comprehensive policy to require third-party payers to cover patient care costs in clinical trials that met certain standards for peer review and oversight and general quality of the research. We argued, and a number of

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legislative proposals reflected, that the best way to determine the quality of clinical trials in an efficient manner—i.e., without individualized auditing and analysis of each trial and trial site—was to rely on the peer-review and oversight mechanisms already in place under the auspices of federal agencies like NIH and FDA.

Thus, when President Clinton issued his June 2000 executive memorandum requiring Medicare coverage of patient care costs in clinical trials, the Medicare program looked to its sister agencies to identify trials worthy of coverage. As a result, and in order to make the review process as straightforward as possible, Medicare "deemed" coverage for trials sponsored by federal funding agencies like NIH (as well as NIH-funded centers and cooperative groups) and for trials reviewed by FDA under an investigational new drug (IND) application or designated by FDA to be "IND-exempt."

The self-certification process which CMS now proposes to make the centerpiece of the policy was never implemented in the initial policy. In fact, CMS proposed eliminating the process in its July 2006 reconsideration announcement. The core of the original policy was coverage of the deemed trials overseen by NIH and FDA, and self-certification was reserved for the limited number of trials that did not qualify for deemed coverage. It is illogical, to say the least, that the cumbersome and untested self-certification process now proposed in the Clinical Research Policy would replace the policy of deemed coverage that has worked well for Medicare beneficiaries seeking treatment for their cancer in the context of a quality clinical trial.

Problems with the Proposed Policy

The proposal seems to abandon the deemed coverage of the original policy, replacing it with an untried self-certification process. In order to obtain Medicare coverage under the new policy, the sponsor or principal investigator must certify that each of 13 separate criteria has been satisfied. In contrast to the current policy, where any "deemed" trial is automatically covered with no further paperwork or other burden, the new policy will require specific review of each of the 13 criteria and "[d]iscussion as to how the study meets each of the standards in [the] policy." This approach poses a number of challenges to clinical researchers, including uncertainty regarding the intent of CMS with respect to subjective elements of the criteria; the quantum of justification required to satisfy

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CMS; and the consequences of failing, in a post-hoc analysis, to meet CMS's unspecified requirements.

Facing such uncertainty, there is a very real chance that institutions and investigators engaged in research in both the public and private sectors will eschew Medicare coverage, with the result that Medicare beneficiaries will once again be systematically excluded from participation in cancer clinical trials. Those sponsors and principal investigators who do not forsake Medicare coverage entirely will be subject to significant new and additional burdens that will substantially delay the initiation of clinical research studies. The paperwork imposed by the new policy is basically duplicative of what research institutions already must provide to other Federal agencies and institutional review boards (IRBs), so it adds no value, but the burden of complying with new Medicare requirements will be expensive and will contribute to delays in protocol activation and accrual. At both academic institutions and large pharmaceutical companies, compliance officials will be concerned about the prospect of false claims liability through retrospective claims review, prompting additional review and oversight beyond that envisioned by the proposed policy. All of this will occur in the context of woefully under-funded support for research sponsored by the NIH and its centers and cooperative groups, so that this public-sector research will be even more at risk than others.

The criteria themselves are unworkable. For example, by what standard or measure does an investigator determine, for the purpose of certifying compliance, that the study is "well-supported by availablc sciсntific and medical information" and that it "does not unjustifiably duplicate existing studies?" These are overwhelmingly subjective criteria that offer no useful information regarding a given clinical trial. At the same time, the proposed policy leaves unanswered or unclear certain issues of concern to cancer clinical researchers and cancer patients, including the coverage status of phase I trials. The ninth criteria—that the study "is not designed to exclusively test toxicity or disease pathology in healthy individuals" seems to be an obvious reference to phase I clinical trials, but they are not identified as such, contributing to general confusion.

Other criteria seem to have been selected without consideration of ongoing parallel initiatives regarding the same issues. For example, the very specific requirements for public release of all pre-specified outcomes do not take into account the current efforts by Congress to pass legislation requiring clinical trials registries, including reporting of results. The requirement that CMS seeks to

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impose here would, in some instances, be inconsistent with the pending legislative standards, which are more likely than not to become law. Moreover, the CMS criteria seem unmindful of confidentiality protections that FDA regulations afford to data supporting pending new drug applications.

The criteria seeking analysis of how subpopulations—presumably including not only Medicare patients but also racial and ethnic minorities—are or are not affected by the study protocol seem unnecessarily burdensome and also somewhat irrelevant. Most clinical trials protocols address these issues prior to, or as part of, the peer review process and review by IRBs. If CMS concludes, after approval of the protocol by NIH or FDA reviewers and by IRBs, that a research study does not adequately discuss these "subpopulation" issues, will CMS deny Medicare coverage? And how will CMS otherwise use the information provided in these self-certifications? It is somewhat ironic and troubling that CMS, ostensibly in support of Medicare beneficiaries' inclusion in clinical trials, would impose unneeded criteria that will in diminish the likelihood that beneficiaries will participate in such trials.

Consequences of a Policy Change

Establishment of the Medicare clinical trials policy in 2000 is a welcome example of a government initiative that can be shown to have made a measurable difference for patients. Prior to adoption of the coverage policy, a study by the Southwest Oncology Group found that Medicare-age patients were significantly under-represented in clinical trials—Mcdicare patients constituted 25% of the group's accrual to clinical trials, whereas they comprised 63% of the population of all cancer patients. After adoption of the Medicare clinical trials policy in 2000, participation by Medicare patients increased to 38%, at least for those with supplemental insurance.[1]

To the extent that the proposed policy rolls back the relatively straightforward qualification for Medicare coverage through "deemed" status and substitutes a burdensome, complex and uncertain procedure for self-certification, there will undoubtedly be fewer clinical trial opportunities for Medicare beneficiaries. This would be extremely unfortunate for cancer patients and detrimental to our ability to determine how best to treat cancer in the elderly. The 2000 clinical trials policy

[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).

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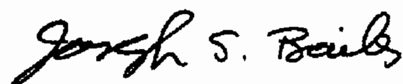
was one of the finest moments for the Medicare program, embodying a forward-looking and patient-friendly posture that the program does not often achieve. The proposed policy essentially reverses all that has been accomplished since adoption of the original policy in 2000 at a time when the prevalence of cancer in the Medicare population is rapidly increasing.

Conclusion

The current proposal should be withdrawn, and the original 2000 clinical trials policy, which has served cancer patients well, should be reaffirmed. Otherwise, Medicare beneficiary participation in clinical trials will inevitably suffer, together with progress against cancer.

Sincerely,



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