ALLIANCE OF DEDICATED CANCER CENTERS

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April 12, 2013

Submitted Online and Via E-mail

Submitted to:
Louis B. Jacques, MD
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Subject: Proposed Decision Memorandum for Positron Emission Tomography (FDG) for Solid Tumors (CAG-00181R4)

Dear Dr. Jacques:

The Alliance of Dedicated Cancer Centers (the "ADCC"), is comprised of eleven of the nation's premier cancer centers focusing exclusively on the care of cancer patients. Even before the National Cancer Act's enactment in 1971, our institutions played a pivotal role in the nation's cancer program to improve the detection, prevention, diagnosis, and treatment of cancer. We are singularly dedicated to deepening the understanding of the causes and cures for cancer, developing new treatments, and disseminating this knowledge to the provider community at-large. The ADCC's innovative therapies and research activities often offer the greatest possibilities for successful treatment of cancer patients. Our efforts have contributed to significantly increasing the number of surviving cancer patients, and resulted in countless individuals being able to return to productive lives.

As a group, we are concerned about CMS' Proposed Decision Memorandum for Positron Emission Tomography (FDG) for Solid Tumors (CAG-00181R4) and respectfully submit the comments below.

If you have any questions or require additional information, please contact me at (215) 266-3497 or our consultant on technical matters, Ms. Jugna Shah, at (215) 888-6037.

Sincerely,

R. Donald Leedy

R. Donald Leedy
Executive Director
Alliance of Dedicated Cancer Centers

The ADCC appreciates and supports CMS' proposal to end the Coverage with Evidence Development (CED) requirement for F^{18} fluorodeoxyglucose positron emission tomography (FDG PET) for oncologic indications, as described in section 220.6.17 of the Medicare *National Coverage Determinations Manual*.

We understand this proposal will end the requirement for prospective data collection by the National Oncologic PET Registry (NOPR), and we support this outcome. We appreciate CMS' conclusion there is adequate evidence to support the use of "*FDG-PET scans to guide physician management of subsequent anti-tumor treatment strategy in beneficiaries who have completed an initial treatment regimen the following types of solid tumors: brain, pancreas, prostate, soft tissue sarcoma, small cell (of lung), thyroid, testis, or for any other solid malignant tumor.*"

Our clinicians agree with CMS on these points. The science is clear: FDG PET is a reasonable and necessary tool for physicians to use in determining patients' optimal cancer treatment; the CED data collection process has been effective and can be ended at this time. Our clinical expertise supports CMS' finding that FDG PET diagnostic test results are vital components in determining optimal treatment approaches for cancer patients. These tests are necessary to guide anti-tumor strategies, and should be covered by Medicare.

FDG PET Scans are Critical to On-Going Cancer Treatment Determinations

We disagree, however, with CMS' proposal that national coverage be provided only for a single FDG PET scan after the patient has completed initial anti-cancer therapy. This proposal, if finalized, will create *significant* barriers to care for many beneficiaries. The ADCC appreciates CMS' concern about the risk of inappropriately using FDG PET scans for screening or surveillance purposes. Yet, experienced providers like the ADCC — which are at the leading edge of using new therapies and technologies to treat cancer — are fully aware that CMS only covers these scans when they are used for diagnostic purposes. We urge CMS *not* to create unnecessary barriers to the critical use of FDG PET scans in assessing cancer patients' response to treatment and identifying the presence (or absence) of active tumors.

Our physicians do not order FDG PET scans needlessly and are *very* cognizant of the high costs involved with this diagnostic tool. At our 11 institutions, multi-disciplinary teams monitor our cancer patients carefully and only use FDG PET for those who have complex cancers and a substantial probability of recurrence. These are the patients that are most likely to benefit from additional FDG PET scans to help determine the most appropriate and actionable therapeutic strategies for their specific conditions.

Cancer patients now live longer and have many more treatments available to them. For this reason, clinical decisions about managing a patient's on-going and evolving treatment are made at multiple times during the course of the individual's care. Sometimes, this involves the use of FDG PET scans at different times over the course of an individual's treatment, as his/her condition varies and the disease progresses and/or recurs. Hence, for many cancer patients, the gold standard of clinical care necessitates that they have more than one FDG PET scan as treatment progresses. This is often the case for patients who have cancers with multiple therapeutic possibilities to choose from when and if initial treatments are unsuccessful.

In addition, we note that CMS' proposal appears to be departure from existing coverage regulations, which allow for additional FDG PET scans in subsequent treatment strategy for specific cancers, when necessary. CMS has covered additional scans for lung, lymphoma, melanoma, and colorectal cancer since 1999; for head and neck carcinoma and esophageal cancer since 2001; and for breast cancer since 2002. In fact, CMS has *broadened* coverage for these cancers from initial staging and restaging to initial treatment strategy and subsequent treatment strategy (including monitoring the response to therapy).

A uniform restriction at the national level against covering more than one subsequent FDG PET scan contradicts current clinical practice and sound patient care and departs from existing coverage for many cancers. For this reason, the ADCC urges CMS *not* to limit national coverage to a baseline study and a single scan after the completion of initial therapy. We request that CMS maintain current coverage for subsequent FDG PET scans for the aforementioned malignancies, and allow coverage for additional scans for other malignancies, when medically necessary.

MAC Determination Will Hamper Beneficiary Access

The ADCC disagrees with the agency's proposal that coverage for additional FDG PET scans be left to local Medicare Administrative Contractors' (MACs) discretion. We believe this proposal is inappropriate for three reasons.

First, if CMS finalizes a national coverage policy establishing a standard of one FDG PET scan, it is very likely to lead the MACs to implement their own restrictive policies rather than keep an open mind about coverage decisions for specific patients. The agency's NCD essentially gives MACs marching orders to implement policies that deny coverage for subsequent FDG PET scans in most situations. This is inappropriate, because it will influence the MACs to make coverage decisions based on factors other than the best and most appropriate patient care.

Second, allowing MACs this level of discretion will result in increased costs and administrative burden for physicians, patients, hospitals and the government alike. For example, providers will spend scare time and resources requesting pre-authorizations for subsequent scans, appealing denials, and/or passing costs on to patients by issuing Advanced Beneficiary Notices (ABNs). These avenues are costly and unnecessary, given the importance of subsequent FDG PET scans to cancer patient care. For this reason, we do not support the agencies' implementation of a national coverage decision that will lead to increased administrative burden and healthcare system costs.

Third, allowing MACs this level of discretion will inevitably increase patients' uncertainty about whether their additional scans — which have been deemed to be medically necessary by their providers — will be covered. This uncertainty will impact delivery of cancer treatments and beneficiary access to timely and appropriate care. Patients will begin to receive ABNs for subsequent scans — despite the existing clinical evidence that for many malignancies indicating the medical necessity for these scans. Patients may not agree to sign the ABN in fear that the additional scans won't be covered and that they will be forced to pay high out-of-pocket costs. Some patients may place their treatment on hold (thereby jeopardizing their health), while others will assume the risk and face uncertainty about their total out-of-pocket liability.

The end result of the proposed MAC determination will be treatment delays, increased out-of-pocket patient costs, and widely varying levels of coverage across the country. We feel strongly that these outcomes are unfair and could be harmful to Medicare beneficiaries.

Conclusion

We are very concerned that, CMS' proposed decision will hamper cancer patient's ability to access the most beneficial care required to guide and manage their treatment. For this reason, the ADCC urges CMS to not restrict FDG PET national coverage to only a single scan after completion of initial anti-cancer therapy — particularly for all of the malignancies where no limits currently exist — and to further study the clinical literature before placing limits on other malignancies.

We urge CMS to allow the nation's expert clinicians, such as those at our institutions, to continue to deliver high-quality, clinically proven tests and services to our patients — including the medically necessary use of multiple FDG PET scans after completion of initial anti-cancer therapy.