

## PUBLIC AFFAIRS UPDATE



### CMS Proposes Expanded Coverage for PET in Alzheimer's Disease

The Centers for Medicare & Medicaid Services (CMS) announced late on June 15 that it intends to expand Medicare coverage of PET to include some Medicare beneficiaries with suspected Alzheimer's disease (AD). CMS will accept public comments on the draft decision memorandum for 30 days and will make the decision final within 90 days.

The announcement came more than a week after the anticipated date of the decision and almost 6 weeks after the National Institute on Aging (NIA) and CMS convened an expert panel meeting in Rockville, MD, to "assess the value of neuroimaging technology including  $^{18}\text{F}$ -FDG PET scanning in the diagnosis and management of patients with dementia or mild cognitive impairment who have undergone a previous standard evaluation as described in the American Academy of Neurology guidelines." Based on its scientific review, CMS determined that use of PET for the diagnosis of suspected AD would be covered for patients when a specific diagnosis remains uncertain despite a thorough clinical evaluation. In addition, in view of indications of the potential benefit of PET, Medicare will also cover PET in other patients with early dementia or unexpected memory loss who are enrolled in clinical trials with certain safeguards for patients, including informed individualized analysis and evaluation of test results and health status.

Although the NIA experts endorsed reimbursement for PET in individuals who have undergone standard neurologic workups but whose diagnoses remain uncertain, the panel expressed concerns about a perceived lack of evidence supporting the value of PET in early diagnostic evaluation of cognitive impairment. As a result, these experts also recommended that CMS support a community-based, practical clinical trial to determine whether a PET scan contributes to the effective diagnosis and management of individuals with early dementia or adds information that will help patients and their families in managing the disease. According to the June 15 announcement, "CMS is now working with the NIA, the Agency for Health Research Quality [AHRQ] and Alzheimer's experts to encourage the development and implementation of such a trial."

This latest incremental approval of indications for PET technology came almost 1 year after CMS released a decision memorandum stating that it would retain its previous noncoverage decision for PET for AD. At that time, the agency's analysis concluded that "the addition of an FDG PET scan to the standard evaluation of AD

does not result in improved patient outcomes." On October 7, 2003, CMS accepted a request from nuclear medicine physicians from the University of California at Los Angeles School of Medicine for a more restrictive coverage determination for  $^{18}\text{F}$ -FDG PET to distinguish patients with AD from those with other causes of symptoms confounding the diagnosis of dementia or to assist with the diagnosis of early dementia in beneficiaries for whom the differential diagnosis included 1 or more kinds of neurodegenerative disease. The following month, CMS broadened the scope of the review to include PET imaging for suspected dementias.

As part of its standard review process, CMS requested input from the public on the proposed extension of coverage. The recent meeting with NIA included reviews of these comments as well as formal presentations and open group discussions among the participants, including practitioners, clinical researchers, methodologists, provider and patient advocates, and reimbursement specialists. On May 25, 2004, the final technology assessment on the request was submitted to CMS by the AHRQ (available at: [www.cms.hhs.gov/coverage/download/id104b.pdf](http://www.cms.hhs.gov/coverage/download/id104b.pdf)).

"To increase access of Medicare beneficiaries to innovative technology that will improve health outcomes, we will use the best and latest clinical evidence in our coverage decisions—and we will work to improve the evidence when important questions remain," said CMS Administrator Mark McClellan, MD, PhD. "In addition to expanding PET coverage today, Medicare will collaborate with the National Institutes of Health to develop needed evidence on the role of PET scans in guiding treatment and predicting the course of Alzheimer's disease."

The full text of the draft decision can be accessed at the CMS coverage site at [www.cms.hhs.gov/coverage](http://www.cms.hhs.gov/coverage).

CMS invites public comments on the draft and specifically on the clinical criteria proposed to identify patients eligible for coverage of a PET scan for suspected AD. CMS also is interested in suggestions about the design and implementation of a practical clinical trial to determine the value of PET for a broader patient population. Comments can be submitted until July 15 through the CMS Web site cited previously, by clicking on "NCAs Open for Public Comment" and then scrolling to "Positron Emission Tomography (FDG) and Other Neuroimaging Devices for Suspected Dementia." ❁