



Medicare: Today's Issue

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BETTER BENEFITS – MORE CHOICES

Good News about the Medicare Prescription Drug, Improvement and Modernization Act of 2003!

Medicare Proposes Expanded Coverage and New Studies of FDG-PET for the Diagnosis of Alzheimer's Disease

CMS Released the Following Information in a Press Release Yesterday

- ❖ The Centers for Medicare & Medicaid Services (CMS) announced today that it intends to expand Medicare coverage of positron emission tomography (PET) to include some Medicare beneficiaries with suspected Alzheimer's disease. CMS will accept public comments on the draft decision memorandum for 30 days, and will make the decision final within 90 days.
- ❖ "This new Medicare coverage will improve care for Americans living with suspected Alzheimer's disease," said Health and Human Services Secretary Tommy G. Thompson. "It is one of the many ways we're working to help our Medicare beneficiaries with cognitive impairment get the best possible care based on the best scientific evidence."
- ❖ With input from independent experts, including the National Institute on Aging and the Alzheimer's Association, CMS completed an exhaustive review of the evidence regarding the use of PET for diagnosis of Alzheimer's disease after receiving a request to reconsider its previous non-coverage decision. Based on this 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.
- ❖ To increase access of Medicare beneficiaries to innovative technology that will improve health outcomes, the best and latest clinical evidence will be used in coverage decisions and efforts will be made to improve the evidence when important questions remain. In addition to expanding PET coverage today, Medicare will collaborate with the National Institutes of Health (NIH) to develop needed evidence on the role of PET scans in guiding treatment and predicting the course of Alzheimer's disease.
- ❖ Alzheimer's disease is an age-related and irreversible brain disorder that occurs gradually and results in memory loss, behavior and personality changes, and a decline in thinking abilities. It is the most common cause of dementia, representing approximately two-thirds of cases.
- ❖ CMS used a consultative process with independent experts to analyze the clinical and scientific evidence on the diagnosis of AD. The expert input included an updated Technology Assessment produced by the Agency for Healthcare Research and Quality, the views of an expert panel convened by the National Institute on Aging (NIA), and the expert

recommendations of the Alzheimer's Association and medical professional organizations. Today's draft decision is based on a thorough review of all of this information.

- ❖ Input from the NIA expert panel suggested that the clinical evidence warrants reimbursement of PET in cases where patients have had thorough workups but the diagnosis remains uncertain. However, the expert panel also indicated that the evidence on the value of PET in early diagnostic evaluation of cognitive impairment is limited, and consequently expressed concerns about potential overuse leading to misdiagnosis, unnecessary radiation exposure, and avoidable medical costs.
- ❖ Consequently, the experts also recommended that CMS support a community-based, practical clinical trial that will help determine if a PET scan contributes to the effective diagnosis and management of Medicare beneficiaries with early dementia, or adds information that will help patients and their families in managing this debilitating disease. CMS is now working with the NIA, AHRQ and Alzheimer's experts to encourage the development and implementation of such a trial.
- ❖ Extensive consultations have taken place with clinical experts on Alzheimer's Disease and cognitive impairment in the elderly as a basis for this decision.
- ❖ CMS is publishing its draft decision memorandum today in accordance with the coverage decision timeline mandated by the Medicare Modernization Act of 2003 (MMA). The draft decision memorandum appears on the CMS on its web site at <http://www.cms.hhs.gov/coverage>.
- ❖ CMS invites public comments on 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.

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