Questions for Public Input on PET for Alzheimer's

CMS is requesting input from the public regarding questions we have developed after reviewing the NCD request and the Alzheimer's Association statement. All comments received will be made public and will not be kept confidential. Responses requested by March 31, 2004.

After reviewing the questions, please send responses to Samantha Richardson at srichardson@cms.hhs.gov.

Questions on the use of PET scans in diagnosing Alzheimer's disease (AD)

CMS has opened an NCD in response to a request for coverage for a PET scan when:

- It is difficult 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 includes one or more kinds of neurodegenerative disease.

In addition, we have correspondence from the Alzheimer's Association that recommends coverage in the following circumstances:

a. Dementia diagnosis, or cause for progressive cognitive impairment, remains uncertain after a physician experienced in the diagnosis and assessment of dementia has conducted a comprehensive clinical evaluation. The evaluation should include review of the medical history, physical and neurological examinations, mental status testing, assessment of activities of daily living, laboratory tests, and structural imaging (MRI or CT); and
b. The information available through PET reasonably is expected to help clarify the diagnosis and/or help guide future treatment.

We are currently reviewing the evidence. We request public input on operational issues that might arise should the evidence support the request.

- What minimal services must be performed and documented as pre-requisites for ordering a PET scan?

- Is a medical history alone sufficient to ascertain six months of cognitive decline or is actual observation by a clinician necessary to assess and document a decline over such a period prior to ordering a PET scan?
- What qualifications must a practitioner have to be considered "experienced in the diagnosis and assessment of dementia"?

- What type of facility or setting is likely to offer the knowledgeable and experienced interdisciplinary staff needed to conduct a comprehensive assessment and render an accurate clinical diagnosis of dementia? Can a minimum set of facility criteria be identified that provide assurance that a

comprehensive assessment will be performed? What set of skills and professions must be assembled on the interdisciplinary team?

- A comprehensive workup utilizing the NINCDS-ADRDA criteria for clinical diagnosis of Alzheimer's disease qualifies the likelihood of Alzheimer's disease as "definite," "probable," "possible," or "uncertain". Should PET be ordered only when the comprehensive assessment results in an uncertain diagnosis?

- What are the key differential diagnoses among neurodegenerative causes of dementia (e.g., frontotemporal dementia vs. AD) that PET could reasonably be expected to help clarify after an experienced clinician or team has completed an assessment? What are those clinical situations for which other imaging or other tests would be better indicated (e.g., distinguishing AD from mixed AD- multi-infarct dementia)?

- What are the minimal educational requirements for staff performing and interpreting the PET scans? How should test performance and interpretation be standardized? What accreditation requirements must facilities performing PET scans for AD meet?