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Steve E. Phurrough, MD,MPA Acting Director, Coverage and Analysis Group Office of Clinical Standards and Quality Chief Medical Officer, Centers for Medicare & Medicaid Services Director, Division of Medical & Surgical Services 7500 Security Blvd. Baltimore, MD21244

Dear Dr. Phurrough:

I have enclosed a new and more restricted coverage request for the use of Positron Emission Tomography (PET) for assisting physicians in the diagnosis of mild to moderate Alzheimer's Disease, than submitted to CMS on October 12,2001.Well-defined patient selection criteria are included along with the evidence to support this request. The patient selection criteria have been developed from a consensus of some of the country's leading experts in the care and research associated with Alzheimer's Disease.

The request is being submitted by a broad ran e of professionals involved in clinical care and researc1devoted to the welfare of patients with Alzheimer's disease and related dementias. These individuals come from a wide variety of clinical care environments, research settings, educational institutions, and professional organizations. These individuals and their affiliations are listed at the bottom of the coverage request.

We appreciate your review and decision on this request.

Warm regards,

cc: Dr. Sean Tunis, Medical Director, CMS The Honorable Tommy Thompson, Secretary, Health 6r Human Services

12 August 2003

Coverage request for positron emission tomography (PET) used in the evaluation of Alzheimer's disease and related dementias

This coverage request represents a more restricted and defined coverage request than submitted to CMS on October 12, 2001, that we believe is well supported by the evidence provided in this proposal.

The signatories below -- representing a broad range of professionals involved in clinical care and research devoted to the welfare of patients with Alzheimer's disease and related dementias, operating in a wide variety of clinical and care environments, research settings, educational institutions, and professional organizations - submit this request in unanimous support for coverage of the use of PET for the evaluation of dementia under the explicitly defined conditions listed below. A summary of the scientific literature most pertinent to the request and its supporting rationale follows.

Request for coverage

Medicare Coverage is requested to include reimbursement for brain positron emission tomography (PET) performed with the radiopharmaceutical **[F-18]fluorodeoxyglucose** (FDG) to distinguish patients with Alzheimer's disease (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 (e.g., AD and frontotemporal dementia), in cases for which the referring physician's medical record documents that all of the following criteria have been met:

1) patient has A) gradually progressive decline in one or more cognitive domains, and/or B) cognitive impairment representing a change from patient's normal level of functioning which includes: (i) memory loss, (ii) other cognitive impairment, and (iii) functional impairment;

2) patient has undergone comprehensive history and physical including neurological examination (per American Academy of Neurology guidelines; Knopman et al., 2001), common screening laboratory tests, and if indicated, structural imaging with CT or MRI, which does not provide explanation for cognitive impairment or symptoms, or which has not resulted in treatment of potentially reversible cause(s) of dementia that has restored patient to normal state of cognition;

3) As determined by a structured assessment of mental status, patient is documented to not suffer from severe dementia at the time of PET scan (such as an MMSE score of not less than or equal to lo), but is impaired sufficiently to warrant a neuroimaging evaluation, meeting criteria set forth in sub-clause 1);

4) brain SPECT scan has not been obtained for same indication, after the date of the CMS coverage decision for PET and AD;

5) diagnosis of dementia will have a specific impact on the care of patient and on major life planning decisions for patient, as made by patient, family or caregiver; and

6) physician has evidence from a collateral source or a serial examination that cognitive impairment has been present for six months prior to ordering a PET scan.

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