
CMS Manual System

Pub. 100-03 Medicare National Coverage Determinations

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 24

Date: OCTOBER 1, 2004

CHANGE REQUEST 3426

NOTE: This transmittal replaces Transmittal 20, dated August 13, 2004.

SUBJECT: Update to Chapter 1, Section 220.6 - Dementia and Neurodegenerative Diseases (Effective September 15, 2004)

I. SUMMARY OF CHANGES: CMS covers the use of FDG-PET Scans for the differential diagnosis of fronto-temporal dementia and Alzheimer's disease under specific requirements; OR its use in a CMS-approved practical clinical trial focused on the utility of FDG-PET in the diagnosis or treatment of dementing neurodegenerative diseases.

(This revision to §220.6, Pub. 100-03, is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans. Under 42 CFR 422.256(b), an NCD that expands coverage is also binding on Medicare Advantage Organizations. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

NEW/REVISED MATERIAL - EFFECTIVE DATE: September 15, 2004
***IMPLEMENTATION DATE: October 4, 2004**

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	1/Table of Contents
R	1/220.6/Dementia and Neurodegenerative Diseases (Eff: September 15, 2004)

***III. FUNDING:**

These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Medicare contractors only**

Medicare National Coverage Determinations Manual

Chapter 1 - Coverage Determinations

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(Rev. 24, 10-01-04)

220.6 - Dementia and Neurodegenerative Diseases (Effective September 15, 2004)

220.6 - Dementia and Neurodegenerative Diseases (Effective September 15, 2004)

(Rev. 24, Issued: 10-01-04, Effective: 09-15-04, Implementation: 10-04-2004)

A. General

Medicare covers FDG-PET scans for either the differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer's disease (AD) under specific requirements; OR, its use in a Centers for Medicare & Medicaid Services (CMS)-approved practical clinical trial focused on the utility of FDG-PET in the diagnosis or treatment of dementing neurodegenerative diseases. Specific requirements for each indication are clarified below:

B. Nationally Covered Indications

1. FDG-PET Requirements for Coverage in the Differential Diagnosis of AD and FTD:

An FDG-PET scan is considered reasonable and necessary in patients with a recent diagnosis of dementia and documented cognitive decline of at least 6 months, who meet diagnostic criteria for both AD and FTD. These patients have been evaluated for specific alternate neurodegenerative diseases or other causative factors, but the cause of the clinical symptoms remains uncertain.

The following additional conditions must be met before an FDG-PET scan will be covered:

- a. The patient's onset, clinical presentation, or course of cognitive impairment is such that FTD is suspected as an alternative neurodegenerative cause of the cognitive decline. Specifically, symptoms such as social disinhibition, awkwardness, difficulties with language, or loss of executive function are more prominent early in the course of FTD than the memory loss typical of AD;***
- b. The patient has had a comprehensive clinical evaluation (as defined by the American Academy of Neurology (AAN)) encompassing a medical history from the patient and a well-acquainted informant (including assessment of activities of daily living), physical and mental status examination (including formal documentation of cognitive decline occurring over at least 6 months) aided by cognitive scales or neuropsychological testing, laboratory tests, and structural imaging such as magnetic resonance imaging (MRI) or computed tomography (CT);***
- c. The evaluation of the patient has been conducted by a physician experienced in the diagnosis and assessment of dementia;***
- d. The evaluation of the patient did not clearly determine a specific neurodegenerative disease or other cause for the clinical symptoms, and information***

available through FDG-PET is reasonably expected to help clarify the diagnosis between FTD and AD and help guide future treatment;

e. The FDG-PET scan is performed in a facility that has all the accreditation necessary to operate nuclear medicine equipment. The reading of the scan should be done by an expert in nuclear medicine, radiology, neurology, or psychiatry, with experience interpreting such scans in the presence of dementia;

f. A brain single photon emission computed tomography (SPECT) or FDG-PET scan has not been obtained for the same indication.

(The indication can be considered to be different in patients who exhibit important changes in scope or severity of cognitive decline, and meet all other qualifying criteria listed above and below (including the judgment that the likely diagnosis remains uncertain). The results of a prior SPECT or FDG-PET scan must have been inconclusive or, in the case of SPECT, difficult to interpret due to immature or inadequate technology. In these instances, an FDG-PET scan may be covered after one year has passed from the time the first SPECT or FDG-PET scan was performed.)

g. The referring and billing provider(s) have documented the appropriate evaluation of the Medicare beneficiary. Providers should establish the medical necessity of an FDG-PET scan by ensuring that the following information has been collected and is maintained in the beneficiary medical record:

- Date of onset of symptoms;*
- Diagnosis of clinical syndrome (normal aging; mild cognitive impairment or MCI; mild, moderate or severe dementia);*
- Mini mental status exam (MMSE) or similar test score;*
- Presumptive cause (possible, probable, uncertain AD);*
- Any neuropsychological testing performed;*
- Results of any structural imaging (MRI or CT) performed;*
- Relevant laboratory tests (B12, thyroid hormone); and,*
- Number and name of prescribed medications.*

The billing provider must furnish a copy of the FDG-PET scan result for use by CMS and its contractors upon request. These verification requirements are consistent with federal requirements set forth in 42 Code of Federal Regulations section 410.32 generally for diagnostic x-ray tests, diagnostic laboratory tests, and other tests. In summary, section 410.32 requires the billing physician and the referring physician to maintain information in the medical record of each patient to demonstrate medical necessity [410.32(d) (2)] and submit the information demonstrating medical necessity to CMS and/or its agents upon request [410.32(d)(3)(I)] (OMB number 0938-0685).

2. FDG-PET Requirements for Coverage in the Context of a CMS-approved Practical Clinical Trial Utilizing a Specific Protocol to Demonstrate the Utility of FDG-PET in the Diagnosis, and Treatment of Neurodegenerative Dementing Diseases

An FDG-PET scan is considered reasonable and necessary in patients with mild cognitive impairment or early dementia (in clinical circumstances other than those specified in subparagraph 1) only in the context of an approved clinical trial that contains patient safeguards and protections to ensure proper administration, use and evaluation of the FDG-PET scan.

The clinical trial must compare patients who do and do not receive an FDG-PET scan and have as its goal to monitor, evaluate, and improve clinical outcomes. In addition, it must meet the following basic criteria:

- a. Written protocol on file;*
- b. Institutional Review Board review and approval;*
- c. Scientific review and approval by two or more qualified individuals who are not part of the research team; and,*
- d. Certification that investigators have not been disqualified.*

C. Nationally Noncovered Indications

All other uses of FDG-PET for patients with a presumptive diagnosis of dementia-causing neurodegenerative disease (e.g., possible or probable AD, clinically typical FTD, dementia of Lewy bodies, or Creutzfeld-Jacob disease) for which CMS has not specifically indicated coverage continue to be noncovered.

D. Other

Not applicable.

(This NCD last reviewed September 2004.)