



# Triad Isotopes

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Coverage criteria for approved PET indications

Refer to Pub. 100-03, NCD Manual, section 220.6.13

Effective for dates of service on or after September 15, 2004, Medicare will cover FDG PET scans for a differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer's disease.

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.

- 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.
- 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);
- The evaluation of the patient has been conducted by a physician experienced in the diagnosis and assessment of dementia;
- 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;
- 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;
- A brain single photon emission computed tomography (SPECT) or FDG-PET scan has not been obtained for the same indication; and,
- 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
  - Mini mental status exam (MMSE) or similar test score
  - Presumptive cause (e.g. possible, probable, uncertain AD)
  - Any neuropsychological testing performed
  - Results of any structural imaging performed MRI , CT
  - Relevant laboratory tests (B12, thyroid hormone)
  - Number and name of prescribed medications

A recent edit allowed to be billed no more than once in a beneficiary's lifetime has now **been removed**, effective 4/4/2005.

**CMS has added requirements for specifying the following ICD.9 diagnosis codes.**

**(Otherwise the claim will be denied)**

- 290.0 Senile dementia - uncomplicated
- 290.10 Presenile dementia - uncomplicated
- 290.11 Presenile dementia w/delirium
- 290.12 Presenile dementia w/delusional features
- 290.13 Presenile dementia w/depressive features
- 290.20 Senile dementia w/delusional features
- 290.21 Senile dementia w/depressive features
- 290.3 Senile dementia w/delirium
- 331.0 Alzheimer's disease
- 331.11 Pick's disease
- 331.19 Other frontotemporal dementia
- 331.2 Senile degeneration of brain
- 331.9 Cerebral degeneration, unspecified
- 780.93 Memory loss

*Medicare contractors shall instruct providers to issue an Advanced Beneficiary Notice to beneficiaries advising them of potential financial liability prior to delivering the service if one of the appropriate diagnosis codes will not be present on the claim.*

Sources: [www.cms.hhs.gov/coverage/](http://www.cms.hhs.gov/coverage/) & [www.ama-assn.org](http://www.ama-assn.org)

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## Medicare Coverage for PET

### AMA CPT® Codes Imaging

78608 Brain imaging, PET; metabolic evaluation.

HCPCS Code	APC Code	REV Code	SI	Product	Radiopharmaceutical Description
A9552	1651	0343	H	[ <sup>18</sup> F]FDG	Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose, up to 45 millicuries

Refer to Pub. 100-03, NCD Manual, section 220.6.13

**Use in a CMS-approved practical clinical trial focused on the utility of FDG-PET in the diagnosis or treatment of dementing neurodegenerative diseases.**

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:

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

### Carrier and Fiscal Intermediary Billing Requirements for FDG-PET Scans Claims for CMS-approved Neurodegenerative Disease Practical Clinical Trials

#### Carriers and Fiscal Intermediaries

Contractors should not receive claims for this service until the clinical trial centers have been identified. Once these centers are identified, CMS will list the centers on the CMS web site.

##### Carriers Only

- Carriers shall pay claims for PET scans for beneficiaries participating in a CMS-approved clinical trial submitted with the QV modifier.

##### Fiscal Intermediaries Only

- In order to pay claims for PET scans on behalf of beneficiaries participating in a CMS-approved clinical trial, FIs require providers to submit claims with ICD-9 codeV70.7 in the second diagnosis position on the Form CMS-1450 (UB-92), or the electronic equivalent, with the appropriate principal diagnosis code and an appropriate CPT code from section 60.3.1.

#### Other Clinical Applications in Neurology:

- Medically Intractable Epilepsy
- Alzheimer and other Dementias
- Movement Disorders
- Stroke
- Radiation Necrosis vs. Recurrent Brain Tumors Evaluation of Tumor Response to therapy

### General Information

The provider of the PET scan should maintain the file of the doctor's referral and documentation.

The ordering physician is responsible for documenting the medical necessity of the study.

The beneficiary's medical record should contain documentation to support the PET referral.

Alzheimer's Disease Meta-Analysis Summary		
	Sensitivity	Specificity
PET	86%-95%	86%-95%
Conventional Imaging	76%-93%	72%-93%

Radiology 2004; Patwardhan MB, et al. Alzheimer disease: operating characteristics of PET- a meta-analysis. 231: 73-80.