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Billing Requirements for Positron Emission Tomography (PET) Scans for Dementia and Neurodegenerative Diseases

Note: This article was revised on March 25, 2014, to add a reference to MLN Matters® article MM8526 (<http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/MM8526.pdf>) to alert providers to a new NCD that affects PET A β scans. Effective for claims with dates of service beginning September 27, 2013, CMS will only allow coverage for PET A β imaging (one PET A β scan per patient) through coverage with evidence development to: (1) develop better treatment or prevention strategies for Alzheimer's Disease (AD) or as a strategy to identify subpopulations at risk for developing AD or (2) to resolve clinically difficult differential diagnoses when the use of PET A β imaging appears to improve health outcomes when the patient is enrolled in an approved clinical study under CED. All other information is unchanged

Provider Types Affected

Physicians and providers

Provider Action Needed

This instruction notifies physicians and providers that Medicare will provide coverage for 2-deoxy-2- [F-18] fluoro-D-glucose (FDG)-PET scans for beneficiaries with a recent diagnosis of dementia and documented cognitive decline of at least 6 months duration. This service may be covered:

- When the patient meets diagnostic criteria for both fronto-temporal dementia (FTD) and Alzheimer's disease (AD) under specific requirements; **or**
- For 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.

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Background

Effective for dates of service on or after September 15, 2004, Medicare will provide coverage for FDG Positron Emission Tomography PET for one of the following:

- When the patient meets diagnostic criteria for both fronto-temporal dementia (FTD) and Alzheimer's disease; **or**
- When used in a CMS-approved practical neurodegenerative disease clinical trial.

Clinical trial results are expected to help in determining if PET scans contribute to the effective diagnosis and treatment of Medicare beneficiaries with mild cognitive impairment or early dementia, and add information that will help monitor, evaluate, and improve clinical outcomes of patients with this disease.

Refer to the *Medicare Claims Processing Manual*, Publication 100-04, Chapter 13, Section 60, for general Medicare coverage and billing requirements for PET scans for dementia and neurodegenerative diseases.

Also, refer to the *Medicare National Coverage Determinations (NCD) Manual*, Publication 100-03, Section 220.6 for complete coverage policy and clinical trial requirements. The revision to the *NCD Manual*, Section 220.6 is an 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 Code of Federal Regulations (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.)

Key portions of these revised manuals are as follows:

FDG-PET Requirements for Use in the Differential Diagnosis of AD and FTD

According to the NCD on this issue, Medicare covers FDG-PET scans for either a) the differential diagnosis of both FTD and Alzheimer's disease AD under specific requirements **or**, b) 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.

For use in the differential diagnosis of FTD and AD, an FDG-PET scan is considered reasonable and necessary for 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 alternative neurodegenerative diseases or causative factors, but the cause of the clinical symptoms remains uncertain.

The following additional conditions must be met before an FDG-PET scan can be ordered:

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- 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;
- 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. 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 1 year has passed from the time the first SPECT or FDG-PET scan was performed.

- 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);

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- 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 services should be billed with HCPCS code of G0336 (Pet imaging, brain imaging for the differential diagnosis of Alzheimer's disease with aberrant features vs. FTD).

FDG-PET Requirements for Use in the Context of a CMS-Approved Neurodegenerative Disease Practical Clinical Trial Utilizing Specific Protocol

With regard to use of the FDG-PET in the context of a CMS-approved clinical trial, the clinical trial must compare patients who do and those who 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.

Physicians should note that a **QV** modifier must be used when billing Medicare carriers for a CMS-approved neurodegenerative disease practical clinical trial. In addition, on such claims from trials that are billed to Medicare intermediaries, a second diagnosis code (**ICD-9**) of **V70, 7**, along with the appropriate principal diagnosis code and **HCPCS code G0336** must be entered on the CMS-1450 or its electronic equivalent. There will be a link on the cms.hhs.gov/coverage website that will have a list of all the participating trial facilities once they have been selected.

Additional Information

As previously mentioned, the *Medicare Claims Processing Manual* (Publication 100-04), Chapter 13 (Radiology Services), Section 60 (Positron Emission Tomography (PET) Scans), is being updated by this instruction. It includes billing and claims processing requirements for PET Scans for beneficiaries with a recent diagnosis of dementia and documented cognitive decline of at least six months duration who meet diagnostic criteria

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for both FTD and AD, 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.

In addition, the “*Medicare NCD Manual*” (Publications 100-03), Chapter 1 (Coverage Determinations) Section 220 (Radiology), Subsection 6 (Positron Emission Tomography (PET)) Scans, is being updated by this instruction to include complete coverage policy and requirements for related clinical trials.

These updated manual instructions are included in the official instruction issued to your carrier/intermediary, which can be found by going to <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R310CP.pdf> on the CMS website.

If you have questions, please contact your intermediary at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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