APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

Clinical Coverage Guideline

BACKGROUND

Positron emission tomography (PET) is a three-dimensional (3D) nuclear imaging technique that measures the level of physiologic and biochemical activity or other organic function in an organ or tissue by reflecting the distribution of a radiotracer that has been administered to the patient. PET has been proposed as a method for diagnosing and predicting Alzheimer’s disease (AD) and for monitoring and predicting response to treatment for AD.¹

The Centers for Medicare & Medicaid Services (CMS) (2013) has determined that the evidence is insufficient to conclude that the use of positron emission tomography (PET) amyloid-beta (Aβ) imaging is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member for Medicare beneficiaries with dementia or neurodegenerative disease, and thus PET Aβ imaging is not covered under §1862(a)(1)(A) of the Social Security Act (“the Act”).²

However, there is sufficient evidence that the use of PET Aβ imaging is promising in two scenarios: (1) to exclude Alzheimer’s disease (AD) in narrowly defined and clinically difficult differential diagnoses, such as AD versus frontotemporal dementia (FTD); and (2) to enrich clinical trials seeking better treatments or prevention strategies for AD, by allowing for selection of patients on the basis of biological as well as clinical and epidemiological factors.³

POSITION STATEMENT

Applicable To:

☑ Medicaid – All Markets
☑ Medicare – All Markets

PET Scans for Dementia and Neurodegenerative Disease are considered medically necessary when one of the two (2) criteria below are met.

1) Diagnosis of Frontotemporal Dementia (FTD) (Source: CMS, 2013)

Coverage is limited to one (1) PET Aβ scan per member through coverage with evidence development (CED), under §1862(a)(1)(E) of the Social Security Act, when one of the criteria are met:

a. To exclude Alzheimer’s disease (AD) in narrowly defined and clinically difficult differential diagnoses, such as AD versus frontotemporal dementia (FTD);
   - Member has a recent diagnosis of dementia and documented cognitive decline of at least 6 months; AND,
   - Member meets diagnostic criteria for both FTD and AD; AND,
   - Member has been evaluated for specific alternate neurodegenerative diseases or other causative factors, but the cause of the clinical symptoms remain uncertain.

The following additional conditions must be met before a PET scan will be covered:

   - Member’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; AND,
• Member has had a comprehensive clinical evaluation (as defined by the American Academy of Neurology AAN)) encompassing a medical history from the member 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); AND,

• The evaluation of the member has been conducted by a physician experienced in the diagnosis and assessment of dementia; AND,

• The evaluation of the member did not clearly determine a specific neurodegenerative disease or other cause for the clinical symptoms, and information available through PET is reasonably expected to help clarify the diagnosis between FTD and AD and help guide future treatment; AND,

• The 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; AND,

• A brain single photon emission computed tomography (SPECT) or 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 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 PET scan may be covered after one year has passed from the time the first SPECT or PET scan was performed.); AND,

• The referring and billing provider(s) have documented the appropriate evaluation of the Medicare beneficiary. Providers should establish the medical necessity of an PET scan by ensuring that the ALL of 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 (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.

OR,

b. To enrich clinical trials seeking better treatments or prevention strategies for AD, by allowing for selection of patients on the basis of biological as well as clinical and epidemiological factors. For clinical trials, the following must be met:

• Clinical study objectives must be to: (1) develop better treatments or prevention strategies for AD, or, as a strategy to identify subpopulations at risk for developing AD, or (2) resolve clinically difficult differential diagnoses (e.g., frontotemporal dementia (FTD) versus AD) where the use of PET Aβ imaging appears to improve health outcomes. These may include short term outcomes related to changes in management as well as longer term dementia outcomes.

• Clinical studies must be approved by CMS, involve subjects from appropriate populations, and be comparative and longitudinal. Where appropriate, studies should be prospective, randomized, and use postmortem diagnosis as the endpoint. Radiopharmaceuticals used in the PET Aβ scans must be FDA approved. Approved studies must address one or more aspects of the following questions. For Medicare beneficiaries with cognitive impairment suspicious for AD, or who may be at risk for developing AD:
(1) Do the results of PET Aβ imaging lead to improved health outcomes? Meaningful health outcomes of interest include: avoidance of futile treatment or tests; improving, or slowing the decline of, quality of life; and survival.

(2) Are there specific subpopulations, patient characteristics or differential diagnoses that are predictive of improved health outcomes in patients whose management is guided by the PET Aβ imaging?

(3) Does using PET Aβ imaging in guiding patient management, to enrich clinical trials seeking better treatments or prevention strategies for AD, by selecting patients on the basis of biological as well as clinical and epidemiological factors, lead to improved health outcomes?

2) PET scans are considered medically necessary in members with mild cognitive impairment (MCI) or early dementia in the following circumstances:
   - The scan is performed in the context of an approved clinical trial that contains member safeguards and protections to ensure proper administration, use and evaluation of the PET scan; AND,
   - The clinical trial compares members who do and do not receive a PET scan and has as its goal to monitor, evaluate, and improve clinical outcomes.

In addition, ALL of the following criteria must be met:
   - Written protocol on file; AND,
   - Institutional Review Board (IRB) review and approval; AND,
   - 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.

3) All other uses of PET scans for members with 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 considered not medically necessary and non-covered.

**CODING**

**Covered CPT® Codes**

- 78608  Brain imaging, positron emission tomography (PET); metabolic evaluation

**Covered HCPCS Codes**

- A9552  Fluorodeoxyglucose (F-18 FDG), diagnostic, per study dose up to 45 millicuries

**ICD-9-CM Procedure Code**

- 92.11  Cerebral scan

**Covered 2015 ICD-10-PCS Codes**

- C030BZZ  Positron Emission Tomographic (PET) imaging of brain using Carbon 11 (C-11)
- C030KZZ  Positron Emission Tomographic (PET) imaging of brain using Flourine 18 (F-18)
- C030MZZ  Positron Emission Tomographic (PET) imaging of brain using Oxygen 15 (O-15)
- C030YZZ  Positron Emission Tomographic (PET) imaging of brain using other radionuclide

**Covered ICD-9-CM Diagnosis Codes**

- 290.0  Senile Dementia Uncomplicated
- 290.10 - 290.13  Presenile Dementia Uncomplicated ; Presenile Dementia with Depressive Features
- 290.20 - 290.21  Senile Dementia with Delusional Features; Senile Dementia with Depressive Features
- 290.3  Senile Dementia with Delirium
- 294.8  Other persistent mental disorders due to conditions classified elsewhere
- 331.0  Alzheimer's Disease
- 331.11  Pick’s Disease
- 331.19  Other Frontotemporal Dementia
PET (FDG) SCAN FOR DEMENTIA AND NEURODEGENERATIVE DISEASE

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331.2  Senile Degeneration of Brain
331.9  Cerebral Degeneration Unspecified
780.93  Memory Loss
790.97  Altered mental status
797  Senility without mention of psychosis

Covered 2015 ICD-10-CM Diagnosis Codes
F03.90 - F03.91  Unspecified dementia
F06.8  Other specified mental disorders due to known physiological condition
G30.0 - G30.9  Alzheimer’s disease
G31.01 - G31.09  Frontotemporal dementia
G31.1  Senile degeneration of brain, not elsewhere classified
G31.9  Degenerative disease of nervous system, unspecified
R41.81  Age related cognitive decline; senility
R41.82  Altered mental status, unspecified
R41.9  Unspecified symptoms and signs involving cognitive functions and awareness

Non-Covered ICD-9-CM Diagnosis Codes – (Presumptive, possible, or probable diagnoses)
046.11  Variant Creutzfeldt-Jakob disease
046.19  Other and unspecified Creutzfeldt-Jakob disease
331.0  Alzheimer’s Disease
331.82  Dementia with Lewy bodies
331.19  Other Frontotemporal Dementia

Non-Covered 2015 ICD-10-CM Diagnosis Codes – (Presumptive, possible, or probable diagnoses)
A81.01-A81.09  Creutzfeldt-Jackob disease
G30.0 - G30.9  Alzheimer’s disease
G31.01 - G31.09  Frontotemporal dementia
G31.83  Dementia with Lewy bodies


REFERENCES

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

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<tr>
<td>10/1/2015, 10/2/2014</td>
<td>Approved by MPC. No changes.</td>
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<tr>
<td>8/9/2013</td>
<td>Reinstated for markets where CareCore is not a vendor.</td>
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<tr>
<td>5/3/2012</td>
<td>Retired by MPC; covered by CareCore criteria.</td>
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<td>2/2/2012</td>
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