MedStar Health, Inc.
POLICY AND PROCEDURE MANUAL

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Last Review Date: 11/04/2016
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PA.137.MH – Imaging Dementia

This policy applies to the following lines of business:
- ✓ MedStar Employee (Select)
- ✓ MedStar MA – DSNP – CSNP
- ✓ MedStar CareFirst PPO

MedStar Health considers **Imaging Dementia** medically necessary for the following indications:

Fluoro-D-glucose (FDG) Positron Emission Tomography (PET) scan for the Differential Diagnosis of Alzheimer's Disease (AD) and Fronto-temporal dementia (FTD) is considered reasonable and medically 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 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 (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.

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 MCI 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:
    - 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.

Limitations: 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 non-covered.

Background

CMS defines Alzheimer's Disease (AD) as an age-related and irreversible brain disorder that occurs gradually and results in memory loss, behavior and personality changes, and a decline in thinking abilities. AD is the most common dementia of old age, representing approximately two-thirds of cases.

Frontotemporal dementia (FTD) is a dementia syndrome characterized histopathologically by the formation of microvacuoles, gliosis (i.e., excess of neuroglial cells) with or without inclusion bodies (Pick's bodies) and swollen neurons.

Positron emission tomography (PET) is a minimally invasive diagnostic imaging procedure used to evaluate glucose metabolism in normal tissue as well as in diseases such as cancer, ischemic heart disease, and certain neurological disorders.

Functional neuroimaging, such as FDG-PET, has been proposed for the evaluation of elderly patients who may have early dementia and for whom the differential diagnosis includes one or more kinds of neurodegenerative diseases. FDG-PET may be able to diagnose AD by identifying anatomical patterns of brain hypometabolism, which typically occur bilaterally in the temporal and parietal lobes. FDG-PET scans typical of AD may be differentiated by visual inspection from scans suggestive of vascular dementia (asymmetric and focal abnormalities) and scans indicative of FTD (marked hypometabolism of frontal or temporal lobes with sparing of parietal lobes). An accurate distinction, for instance between AD and FTD may prove helpful in patient management given the variation in the course of these two diseases.

Codes: CPT HCPCS

Code	Description
78608	Brain imaging, positron emission tomography (PET); metabolic evaluation
78609	perfusion evaluation

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References

1. Centers for Medicare and Medicaid Services. Decision Memo for Positron Emission Tomography (FDG) and Other Neuroimaging Devices for Suspected Dementia (CAG-00088R). https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=104
2. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for FDG PET for Dementia and Neurodegenerative Diseases (220.6.13). https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=288&ncdver=3&DocID=220.6.13&ncd_id=220.6.13&ncd_version=3&basket=ncd%25253A220%25252E6%25252E13%25253A3%25253AFDG+PET+for+Dementia+and+Neurodegenerative+Diseases&bc=gAAAAAgAAAAAAA%3d%3d&

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