Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: FDG PET for Dementia and Neurodegenerative Diseases		
MNG #: 57	**☐SCO ☐One Care**	**Prior Authorization Needed? ☐Yes ☐No**
Clinical: ☐	**Operational: ☐**	**Informational: ☐**
Medicare Benefit: ☐Yes ☐No	**Approval Date: 2/4/2021**	**Effective Date:** 05/22/2021
Last Revised Date:	**Next Annual Review Date:** 02/04/2022	**Retire Date:**

OVERVIEW: Dementia is a disorder that is characterized by a decline in cognition involving one or more cognitive domains (1). The diagnosis of dementia disorders is multimodal, and advanced imaging may play a role in narrowing the differential diagnosis and driving therapy. This CCA Medical Necessity Guideline (MNG) outlines the criteria for medical necessity for FDG Positron Emission Tomography (PET) scans for the evaluation of dementia.

Clinical Coverage Criteria: In accordance with Medicare guidelines: In accordance with CMS regulations (2), CCA covers FDG PET scans for either of the following:

1. The differential diagnosis of frontotemporal dementia (FTD) and Alzheimer's disease (AD) under specific requirements as outlined below in Section A.
2. 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 as outlined below in Section B.

A. FDG PET Requirements for the Differential Diagnosis of AD and FTD: 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 **and** who meet diagnostic criteria for both AD and FTD. Specific alternate neurodegenerative diseases or other causative factors have been evaluated and ruled out, and the cause of the clinical symptoms remains uncertain.

All of the following conditions must be met and clinical documentation provided for a FDG PET scan to be approved for either AD or FTD evaluation:

1. 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;
2. 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);

3. The evaluation of the patient has been conducted by a physician experienced in the diagnosis and assessment of dementia;
4. 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;
5. 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;
6. 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.)
7. 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.

B. <u>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</u>

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:

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

LIMITATIONS/EXCLUSIONS:

1. 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 are not considered reasonable and necessary and are considered experimental as per CCA MNG 010 Experimental and Investigational Services.

RELATED REFERENCES:

1. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), American Psychiatric Association, Arlington 2013.
2. National Coverage Determination (NCD) for FDG PET for Dementia and Neurodegenerative Diseases (220.6.13). Publication 100-3, Manual Section Number 220.6.13, Version 3. Effective 4/3/2009.

ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	

REVISION LOG:

REVISION DATE	DESCRIPTION

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APPROVALS:

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