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Subject: Positron Emission Tomography (PET) Miscellaneous Applications

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Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Positron emission tomography (PET) is an imaging technique that uses radioactive substances injected into individuals to provide images of the body using specialized scanners. These PET images provide information about the function and metabolism of the body's organs, in contrast to computed tomography (CT) or magnetic resonance imaging (MRI), which show the body's anatomy and structure. A variety of radiotracers are used for PET imaging, including oxygen-15, nitrogen-13, carbon-11, and fluorine-18.

Summary and Analysis of Evidence: A meta-analysis was conducted to estimate the clinical use value of ^{11}C-FMZ and ^{18}F-FDG in PET for the localization of epileptogenic zone and to provide evidence for practitioners' clinical decision-making. Studies utilizing FMZ or FDG-PET or FDG-PET/MRI used in patients with epilepsy, with EEG or surgical outcomes as the gold standard and corresponding outcomes such as concordance rates of PET or PET/MRI scan compared with reference standard, absolute numbers of participants with true-positive (TP), false-positive (FP), true-negative (TN), and false-negative (FN) results in FDG or FMZ PET. Pooled concordance rates, overall sensitivity, and specificity of ^{11}C-FMZ-PET and ^{18}F-FDG-PET were calculated. In total, 44 studies met the inclusion criteria. The pooled concordance rates of FDG-PET, FMZ-PET, and FDG-PET/MRI coregistration compared with reference standard were 0.67 (95% CI: 0.60-0.73), 0.75 (95% CI: 0.57-0.93), and 0.93 (95% CI: 0.89-0.97), respectively. The concordance rate of ^{18}F-FDG-PET in patients with temporal lobe epilepsy (TLE) was 0.79 (0.63; 0.92). The overall sensitivity and specificity of ^{18}F-FDG-PET were 0.66 (95% CI: 0.58-0.73) and 0.71 (95% CI: 0.63-0.78), respectively. ^{11}C-FMZ-PET displayed an overall sensitivity of 0.62 (95% CI: 0.49-0.73) and specificity of 0.73 (95% CI: 0.59-0.84). The authors concluded that both^{11}C-FMZ PET and ^{18}F-FDG PET are

the choice of modalities for the localization of epileptogenic zone, especially when coregistered with MRI (Niu et al, 2021).

Based on the results of a systematic review Llewellyn et al (2020) concluded that MRI and PET both reliably diagnose osteomyelitis in diabetic foot ulcer patients. SPECT may also have good diagnostic accuracy, although evidence is limited. This review confirms most current guidelines, showing that MRI may be the preferable test in most cases, given its wider availability and the lack of potentially harmful ionising radiation. The authors reviewed the evidence on the diagnostic accuracy of imaging tests to diagnose osteomyelitis in people with diabetic foot ulcers. Thirty-six studies were included in the meta-analysis. Eight studies were at high risk of bias MRI had high diagnostic accuracy (22 studies: 96.4 % sensitivity (95 % CI 90.7-98.7); 83.8 % specificity (76.0-89.5)). PET scans also had high accuracy (6 studies: 84.3 % sensitivity (52.8-96.3); 92.8 % specificity (75.7-98.2)), and possibly also SPECT, but with few studies (3 studies: 95.6 % sensitivity (76.0-99.3); 55.1 % specificity (19.3-86.3)). Scintigraphy (17 studies: 84.2 % sensitivity (76.8-89.6); 67.7 % specificity (56.2-77.4)), and X-rays (16 studies: 61.9 % sensitivity (50.5-72.1); 78.3 % specificity (62.9-88.5)) had generally inferior diagnostic accuracy.

An UpToDate review on Clinical features and diagnosis of Alzheimer disease (Wolk, Dickerson) “Alzheimer disease (AD) is a neurodegenerative disorder of uncertain cause and pathogenesis that primarily affects older adults and is the most common cause of dementia. The most essential and often earliest clinical manifestation of AD is selective memory impairment, although there are exceptions. While treatments are available that can ameliorate some symptoms of the illness, there is no cure and the disease inevitably progresses in all patients. The first approval by the US Food and Drug Administration (FDA) of a therapy that is potentially disease-modifying provides a mandate for a specific diagnosis of AD in patients with cognitive impairment and dementia. Amyloid PET tracers (florbetapir F-18, flutemetamol F-18, florbetaben F-18) measure amyloid lesion burden in the brain; these aid in the diagnosis of AD, differentiating AD from other causes of dementia. A large study of the use of amyloid PET imaging in clinical decision-making was completed in December 2017 (NCT02420756) and revealed that an amyloid PET result significantly impacted clinical management and etiologic diagnosis. At present, these scans are generally not covered by most health insurances plans in the United States. These tracers have been approved by regulatory agencies in the United States and elsewhere as qualitative assessments of beta-amyloid (Aβ) plaque density. Since there are issues with how much ligand binding to plaques constitutes a "positive" scan, the US Food and Drug Administration (FDA) approval specifies that an amyloid PET scan that is negative decreases the likelihood that a patient with dementia has AD. In a symptomatic dementia patient, a positive scan indicates that the person has amyloid plaque pathology, but such a finding does not rule out a coexisting pathology. Based on the FDA approval label, scans are determined positive or negative based on a radiologist's clinical read, although there are more quantitative approaches that are used in research and may complement such clinical assessments. A consensus opinion of the Amyloid Imaging Task Force, the Society of Nuclear Medicine, and the Alzheimer's Association concluded that amyloid imaging is not appropriate in patients who meet the core clinical criteria for probable AD and have a typical age of onset, and such a scan should not be used to determine dementia severity. These guidelines may be adjusted with the approval of aducanumab, for which a positive amyloid scan is generally believed to be a prerequisite.”

Alzheimer's disease (AD) is the most common cause of dementia. Neuropathological changes in AD patients occur up to 10-20 years before the emergence of clinical symptoms. Specific diagnosis and

appropriate intervention strategies are crucial during the phase of mild cognitive impairment (MCI) and AD. The detection of biomarkers has emerged as a promising tool for tracking the efficacy of potential therapies, making an early disease diagnosis, and prejudging treatment prognosis. Specifically, multiple neuroimaging modalities, including magnetic resonance imaging (MRI), positron emission tomography, optical imaging, and single photon emission-computed tomography, have provided a few potential biomarkers for clinical application.The authors note that MRI modalities, structural MRI, functional MRI, diffusion tensor imaging, magnetic resonance spectroscopy, and arterial spin labelling allows for the detection of presymptomatic diagnostic biomarkers in the brains of cognitively normal elderly people and might also be used to monitor AD disease progression after the onset of clinical symptoms. Further studies are necessary to explore more biomarkers and overcome the limitations of multiple neuroimaging modalities for inclusion in diagnostic criteria for AD (Dang et al 2023).

In a multicenter, randomized, controlled study, Pontecorvo et al (2017) evaluated the impact of amyloid PET imaging on diagnosis and patient management. Physicians identified patients seeking a diagnosis for mild cognitive impairment or dementia, possibly due to Alzheimer disease (AD), and recorded a working diagnosis and a management plan. The patients underwent florbetapir PET scanning and were randomized to either immediate or delayed (1-year) feedback regarding amyloid status. At the 3-month visit, the physician updated the diagnosis and recorded a summary of the actual patient management since the post-scan visit. The study examined the impact of immediate versus delayed feedback on patient diagnosis/management at 3 and 12 months. A total of 618 subjects were randomized (1:1) to immediate or delayed feedback arms, and 602 subjects completed the 3-month primary endpoint visit. A higher proportion of patients in the immediate feedback arm showed a change in diagnosis compared to the controls (32.6 vs. 6.4%; $p = 0.0001$). Similarly, a higher proportion of patients receiving immediate feedback had a change in management plan (68 vs. 55.5%; $p < 0.002$), mainly driven by changes in AD medication. Specifically, acetylcholinesterase inhibitors were prescribed to 67% of the amyloid-positive and 27% of the amyloid-negative subjects in the information group compared with 56 and 43%, respectively, in the control group ($p < 0.0001$). These between-group differences persisted until the 12-month visit. The authors concluded that Knowledge of the amyloid status affects the diagnosis and alters patient management.

The American College of Radiology (ACR) issued a practice parameter “ACR–ACNM–ASNR–SNMMI Practice Parameter for Brain PET-CT Imaging in Dementia (2020). This practice parameter was revised collaboratively by the American College of Radiology (ACR), the American College of Nuclear Medicine (ACNM), the American Society for Neuroradiology (ASNR), and the Society of Nuclear Medicine and Molecular Imaging (SNMMI). The ACR practice parameter is for both FDG and amyloid brain PET or PET/computed tomography (CT) for patients with cognitive decline. “The use of amyloid imaging is recommended to determine presence (or absence) of pathological fibrillar Aß-amyloid deposition in patients with progressive cognitive decline or dementia of uncertain etiology in whom AD is a possibility. Amyloid-PET studies should be performed at the request of physicians knowledgeable in clinical diagnosis and management of dementia and under circumstances in which the results of the examination are likely to impact patient care. Indications for amyloid-PET imaging in cognitive decline and dementia include, but are not limited to, the detection of amyloid plaques in cognitively impaired adults. Subjects with progressive cognitive decline who demonstrate features atypical of Alzheimer disease (AD) and suggestive of another neurodegenerative process, such as FTD (eg, early age of onset, prominent behavioral dysregulation, or primary progressive aphasia), may have atypical AD

presentations or may have frontotemporal dementia (FTD). Patients with FTD do not demonstrate abnormal levels of amyloid deposition at pathology evaluation and do not have increased binding of amyloid radiopharmaceuticals in PET imaging. A negative amyloid PET scan is inconsistent with Alzheimer pathology and suggests that AD does not account for symptoms and signs of progressive cognitive decline. Recently published primary analysis of the Imaging Dementia-Evidence for Amyloid Scanning (IDEAS) study included 11,409 participants with mild cognitive impairment (MCI) or dementia of uncertain cause. The patient management 90 days after amyloid PET changed (compared with the pre-PET plan) in 60.2% of patients with MCI and 63.5% of patients with dementia. Hence, amyloid PET was associated with changes in the subsequent management of diagnostically challenging patient cognitive disorders. At the present time, clinical amyloid-PET imaging has not been validated for screening asymptomatic subjects with genetic or other risk factors for developing AD or in subjects without a clinical diagnosis of a progressive cognitive decline or dementia as established by a clinician expert in the assessment and management of dementing disorders. In addition, amyloid PET cannot be used to establish the diagnosis of AD or monitor the response to therapy for AD in terms of disease progression or improvement, except as part of an approved clinical research trial of antiamyloid therapy. A negative amyloid-PET study indicates absence of significant ß-amyloid plaques at the time of the study and does not exclude the future development of these plaques."

A multicenter sudty (The Imaging Dementia-Evidence for Amyloid Scanning (IDEAS) study) was conducted to determine if amyloid PET is associated with subsequent changes in the management of patients with mild cognitive impairment (MCI) or dementia of uncertain etiology. The Imaging Dementia-Evidence for Amyloid Scanning (IDEAS) study was a single-group, multisite longitudinal study that assessed the association between amyloid PET and subsequent changes in clinical management for Medicare beneficiaries with mild cognitive impairment MCI or dementia. Participants were required to meet published appropriate use criteria stating that etiology of cognitive impairment was unknown, Alzheimer disease was a diagnostic consideration, and knowledge of PET results was expected to change diagnosis and management. A total of 946 dementia specialists at 595 US sites enrolled 16 008 patients between February 2016 and September 2017. Patients were followed up through January 2018. Dementia specialists documented their diagnosis and management plan before PET and again 90 (±30) days after PET. Participants underwent amyloid PET at 343 imaging centers. The primary end point was change in management between the pre- and post-PET visits, as assessed by a composite outcome that included Alzheimer disease drug therapy, other drug therapy, and counseling about safety and future planning. The study was powered to detect a 30% or greater change in the MCI and dementia groups. One of 2 secondary end points is reported: the proportion of changes in diagnosis (from Alzheimer disease to non-Alzheimer disease and vice versa) between pre- and post-PET visits. Among 16 008 registered participants, 11 409 (71.3%) completed study procedures and were included in the analysis (median age, 75 years [interquartile range, 71-80]; 50.9% women; 60.5% with MCI). Amyloid PET results were positive in 3817 patients with MCI (55.3%) and 3154 patients with dementia (70.1%). The composite end point changed in 4159 of 6905 patients with MCI (60.2% [95% CI, 59.1%-61.4%]) and 2859 of 4504 patients with dementia (63.5% [95% CI, 62.1%-64.9%]), significantly exceeding the 30% threshold in each group ($P < .001$, 1-sided). The etiologic diagnosis changed from Alzheimer disease to non-Alzheimer disease in 2860 of 11 409 patients (25.1% [95% CI, 24.3%-25.9%]) and from non-Alzheimer disease to Alzheimer disease in 1201 of 11 409 (10.5% [95% CI, 10.0%-11.1%]). The authors concluded that among Medicare beneficiaries with MCI or dementia of uncertain etiology evaluated by dementia specialists, the use of amyloid PET was associated with changes in clinical management within

90 days. Further research is needed to determine whether amyloid PET is associated with improved clinical outcomes (Rabinovici et al, 2019).

POSITION STATEMENT:

Epileptic Seizures

Positron emission tomography (PET) imaging using fluourodeoxyglucose (FDG) **meets the definition of medical necessity** to determine the operability of refractory seizures.

Chronic Osteomyelitis

Positron emission tomography (PET) using 2-[fluorine-18]-fluoro-2-deoxy-D-glucose (FDG) **meets the definition of medical necessity** in the diagnosis of chronic osteomyelitis.

Post-operative/procedureal evaluation

A follow-up study may be needed for evaluation of a member's progress after treatment, procedure, intervention or surgery. Documentation required.

Positron emission tomography (PET) imaging (amyloid, FDG-PET) **meets the definition of medical necessity** for members who are being considered for an anti-amyloid drug (e.g., Aducanumab (Aduhelm), Lecanemab-irmb (Leqembi)) or discontinuation of treatment.

Other Indications

The use of PET imaging for screening and **ALL** other indications is considered **experimental or investigational**. There is insufficient evidence to determine the role of PET imaging for screening and all other indications.

Radiopharmaceutical/Radiotracers

Radiopharmaceuticals or radiotracers for PET imaging **meets the definition of medical necessity** for the Food and Drug Administration (FDA) approved indication.

BILLING/CODING INFORMATION:

CPT Coding

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

HCPCS Coding

G0235	PET imaging, any site, not otherwise specified

LOINC Codes

The following information may be required documentation to support medical necessity: physician history and physical, physician progress notes, plan of treatment and reason for positron emission tomography (PET) imaging.

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Plan of treatment	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim

REIMBURSEMENT INFORMATION:

PET scans are performed using a camera that has either been approved or cleared for marketing by the Food and Drug Administration (FDA) to image positron annihilation gamma photons in the body.

PET scans are performed using FDA approved radiotracer or radiopharmaceutical. The radiopharmaceutical may be manufactured on site or manufactured at a regional delivery center with delivery to the institution performing the PET scan. When the radiopharmaceutical is provided by an outside distribution center, there may be a separate charge for both the radiopharmaceutical and transportation of the radiopharmaceutical.

PROGRAM EXCEPTIONS:

Federal Employee Plan (FEP): FEP is excluded from the National Imaging Associates (NIA) review; follow FEP guidelines.

Medicare Advantage products:

No Local Coverage Determination (LCD) was found at the time of the last guideline reviewed date.

The following National Coverage Determinations (NCDs) were reviewed on the last guideline reviewed date: PET Scans (220.6), FDG PET for Refractory Seizures (220.6.9), Dementia and Neurodegenerative Disease (220.6.13) and FDG PET for Infection and Inflammation (220.6.16) located at cms.gov.

DEFINITIONS:

Epilepsy: Any of a group of syndromes characterized by paroxysmal transient disturbances of the brain function that may be manifested as episodic impairment or loss of consciousness, abnormal motor phenomena, psychic or sensory disturbances, or perturbation of the autonomic nervous system.

RELATED GUIDELINES:

Positron Emission Tomography (PET) Cardiac Applications, 04-78000-16
Positron Emission Tomography (PET) Oncologic Applications, 04-78000-17

OTHER:

Other names used to report positron emission tomography (PET):

Positron emission transverse tomography (PETT)
Positron emission coincident imaging (PECI)

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2. Agency for Healthcare Research and Quality Technology Assessment Number 7 – Use of Positron Emission Tomography and other Neuro-imaging Techniques in the Diagnosis and Management of Alzheimer's Disease and Dementia, 12/14/01.
3. Blue Cross Blue Shield Association Evidence Positioning System®. 6.01.06 Miscellaneous (Noncardiac, Nonocologic) Applications of Fluorine 18 Fluorodeoxyglucose Positron Emission Tomography, 11/23.
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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 08/22/24.

GUIDELINE UPDATE INFORMATION:

10/15/03	Annual review. Developed separate policy for PET Miscellaneous Applications.
12/15/04	Reviewed; added musculoskeletal diseases (investigational) to when services are not covered. Added G0336 to HCPCS coding. Added G0336 to program exception for Medicare and coverage criteria for G0336 (PET imaging; brain imaging for the differential diagnosis of Alzheimer's disease with aberrant features vs. frontotemporal dementia), and updated references.
03/15/05	Added program exception for Health Options, Blue Care, and Medicare Advantage products.
01/01/06	Scheduled review. No change in coverage and investigational statements, and updated references. HCPCS update; added G0235.
03/15/06	HCPCS update, deleted G0229 and G0336. Revised Medicare Advantage products program exception.
06/15/06	Added A9552. Revised reimbursement information section. Updated references.
10/15/06	Added coverage statement for follow-up of known brain tumor to WHEN SERVICES ARE COVERED section. Revised Medicare Advantage products program exception, and updated references. Added statement regarding radiopharmaceutical.
07/01/07	Reformatted guideline. Maintain coverage statement for epileptic seizures and brain tumor. Maintain investigational statement for all other PET indications (CNS diseases, pulmonary diseases, musculoskeletal diseases), considered investigational. Revised

	reimbursement statement. Revised Medicare Advantage products program exception, and updated references.
01/21/08	Updated Program Exceptions.
07/15/08	Annual review. Added chronic osteomyelitis (meets the definition of medical necessity) and giant cell arteritis (considered experimental or investigational) to position statements. Added definition for giant cell arteritis to definitions section, and updated references.
05/21/09	Removed Federal Employee Plan (FEP) from BCBSF Radiology Management program exception statement. Added FEP program exception statement: FEP is excluded from the National Imaging Associates (NIA) review; follow FEP guidelines.
07/01/09	Updated BCBSF Radiology Management program exception; added BlueSelect. Added program exception for Medicare Advantage products for dementia (Alzheimer's disease and fronto-temporal dementia.
10/15/09	Updated description section. Added, "if the diagnosis cannot be determined by a bone scan" for chronic osteomyelitis, and updated references.
01/01/10	Revised BCBSF Radiology Management program exception section.
10/01/11	Revision; formatting changes.
10/15/11	Revision; formatting changes.
02/15/13	Scheduled review; added inflammatory bowel disease and mycobacterium infection (experimental or investigational). Added coverage statement for Medicare Advantage; FDG PET for: seizures and infection and inflammation. Updated references.
01/01/14	Annual HCPCS coding update; added A9599.
05/11/14	Revision: Program Exceptions section updated.
06/15/15	Revision; added "or Cancer to Brain Tumor, when used to differentiate between treatment induced (radiation) tumor necrosis and brain tumor recurrence, post-operative/procedureal evaluation (brain PET imaging), and dementia.
01/01/17	Annual HCPCS code update. Revised A9599 code descriptor.
04/15/17	Code update; deleted A9552, revised G0235 descriptor.
01/01/18	Annual HCPCS code update. Deleted A9599.
09/15/18	Revision; revised position statement. Updated references.
11/15/18	Revision; Added staging or restaging of brain cancer. Updated references.
03/15/20	Review/revision. Revised criteria for: epileptic seizures, brain tumor or cancer, dementia, chronic osteomyelitis and other indications. Deleted pre-operative evaluation. Revised position statement, definitions and format. Updated description and references.
05/15/22	Review/revision. Updated description. Revised criteria for mild cognitive impairment. Updated references.
07/08/23	Review: position statements and references updated.
09/15/24	Review; added statement for anti-amyloid drug. Updated references.