FEP 6.01.06 Miscellaneous (Noncardiac, Nononcologic) Applications of Fluorine 18 Fluorodeoxyglucose Positron Emission Tomography

Effective Date: January 15, 2019

Related Policies:
- 6.01.20 Cardiac Applications of Positron Emission Tomography Scanning
- 6.01.26 Oncologic Applications of Positron Emission Tomography Scanning
- 6.01.51 Interim Positron Emission Tomography Scanning in Oncology to Detect Early Response During Treatment
- 6.01.55 β-Amyloid Imaging With Positron Emission Tomography for Alzheimer Disease

Description

Positron emission tomography (PET) images biochemical and physiologic functions by measuring concentrations of radioactive chemicals that have been partially metabolized in a particular region of the body. Radiopharmaceuticals used for PET are generated in a cyclotron (nuclear generator) and then introduced into the body by intravenous injection or respiration.

Positron emission tomography (PET) scans coupled positron-emitting radionuclide tracers to other molecules, such as glucose, ammonia, or water. The radionuclide tracers simultaneously emit 2 high-energy photons in opposite directions that can be simultaneously detected (referred to as coincidence detection) by a PET scanner, which comprises multiple stationary detectors that encircle the region of interest.

A variety of tracers are used for PET scanning, including oxygen 15, nitrogen 13, carbon 11, and fluorine 18. The radiotracer most commonly used in oncology imaging has been fluorine 18, coupled with fluorodeoxyglucose (FDG), which has a metabolism related to glucose metabolism. While FDG has traditionally been used in cancer imaging, it potentially has many other applications.

OBJECTIVE

The objective of this evidence review is to determine whether use of fluorine 18 fluorodeoxyglucose positron emission tomography improves the net health outcome in individuals with epilepsy, suspected chronic osteomyelitis, suspected Alzheimer disease, suspected large vessel vasculitis, and other noncardiac and nononcologic conditions (eg, central nervous system, pulmonary, and musculoskeletal diseases).
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POLICY STATEMENT

Positron emission tomography (PET) using 2-[fluorine-18]-fluoro-2-deoxy-D-glucose (FDG) may be considered medically necessary in:

1. the assessment of select patients with epileptic seizures who are candidates for surgery (see Policy Guidelines section)
2. the diagnosis of chronic osteomyelitis.

The use of FDG-PET for all other miscellaneous indications is investigational, including, but not limited to:

- **Central Nervous System Diseases**
  - Autoimmune disorders with central nervous system manifestations, including:
    - Behçet syndrome
    - lupus erythematosus
  - Cerebrovascular diseases, including:
    - arterial occlusive disease (arteriosclerosis, atherosclerosis)
    - carotid artery disease
    - cerebral aneurysm
    - cerebrovascular malformations (arteriovenous malformation and Moya-Moya disease)
    - hemorrhage
    - infarct
    - ischemia
  - Degenerative motor neuron diseases, including:
    - amyotrophic lateral sclerosis
    - Friedreich ataxia
    - olivopontocerebellar atrophy
    - Parkinson disease
    - progressive supranuclear palsy
    - Shy-Drager syndrome
    - spinocerebellar degeneration
    - Steele-Richardson-Olszewski syndrome
    - Tourette syndrome
  - Dementias, including:
    - Alzheimer disease
    - multi-infarct dementia
    - Pick disease
    - frontotemporal dementia
    - dementia with Lewy bodies
    - presenile dementia
  - Demyelinating diseases, such as multiple sclerosis
  - Developmental, congenital, or inherited disorders, including:
    - adrenoleukodystrophy
    - Down syndrome
    - Huntington chorea
    - kinky-hair disease (Menkes disease)
    - Sturge-Weber syndrome (encephalofacial angiomatosis) and the phakomatoses
  - Miscellaneous
    - chronic fatigue syndrome
    - sick building syndrome
    - posttraumatic stress disorder
  - Nutritional or metabolic diseases and disorders, including:

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• acanthocytosis
• hepatic encephalopathy
• hepatolenticular degeneration
• metachromatic leukodystrophy
• mitochondrial disease
• subacute necrotizing encephalomyelopathy
  o Psychiatric diseases and disorders, including:
    ▪ affective disorders
    ▪ depression
    ▪ obsessive-compulsive disorder
    ▪ psychomotor disorders
    ▪ schizophrenia
  o Pyogenic infections, including:
    ▪ aspergillosis
    ▪ encephalitis
  o Substance abuse, including the central nervous system effects of alcohol, cocaine, and heroin
  o Trauma, including brain injury and carbon monoxide poisoning
  o Viral infections, including:
    ▪ HIV/AIDS
    ▪ AIDS dementia complex
    ▪ Creutzfeldt-Jakob disease
    ▪ progressive multifocal leukoencephalopathy
    ▪ progressive rubella encephalopathy
    ▪ subacute sclerosing panencephalitis
  o Mycobacterium infection
  o Migraine
  o Anorexia nervosa
  o Assessment of cerebral blood flow in newborns
    ▪ Vegetative vs locked-in syndrome
• Pulmonary Diseases
  o Adult respiratory distress syndrome
  o Diffuse panbronchiolitis
  o Emphysema
  o Obstructive lung disease
  o Pneumonia
• Musculoskeletal Diseases
  o Spondylodiscitis
  o Joint replacement follow-up
• Other
  o Giant cell arteritis
  o Vasculitis
  o Vascular prosthetic graft infection
  o Inflammatory bowel disease
  o Sarcoidosis
  o Fever of unknown origin
  o Inflammation of unknown origin.

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POLICY GUIDELINES

In patients with epileptic seizures, appropriate candidates are patients with complex partial seizures who have failed to respond to medical therapy and have been advised to have a resection of a suspected epileptogenic focus located in a region of the brain accessible to surgery. Further, for the purposes of this review, conventional noninvasive techniques for seizure localization must have been tried with results suggesting a seizure focus but not sufficiently conclusive to permit surgery. The purpose of the positron emission tomography (PET) examination should be to avoid subjecting the patient to extended preoperative electroencephalographic recording with implanted electrodes, or to help localize and minimize the number of sites for implanted electrodes to reduce the morbidity of that procedure.

A PET scan involves 3 separate activities: (1) manufacture of the radiopharmaceutical, which may be manufactured on site or at a regional center with delivery to the institution performing PET; (2) actual performance of the PET scan; and (3) interpretation of the results.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

Following the U.S. Food and Drug Administration’s (FDA) approval of the Penn-PET in 1989, a number of PET scan platforms have been cleared by FDA through the 510(k) process. These systems are intended to aid in detecting, localizing, diagnosing, staging and restaging of lesions, tumors, disease and organ function for the evaluation of diseases, and disorders such as, but not limited to, cardiovascular disease, neurologic disorders, and cancer. The images produced by the system can aid in radiotherapy treatment planning and interventional radiology procedures.

PET radiopharmaceuticals have been evaluated and approved as drugs by FDA for use as diagnostic imaging agents. These radiopharmaceuticals are approved for specific conditions.

In December 2009, FDA issued guidance for Current Good Manufacturing Practice for PET drug manufacturers and, in August 2011, issued similar Current Good Manufacturing Practice guidance for small businesses compounding radiopharmaceuticals. An additional final guidance document, issued in December 2012, required all PET drug manufacturers and compounders to operate under an approved new drug application (NDA) or abbreviated NDA, or investigational new drug application, by December 12, 2015.

In 1994, the FDG radiotracer was originally approved by FDA through the NDA (20-306) process. The original indication was for “the identification of regions of abnormal glucose metabolism associated with foci of epileptic seizures.” Added indications in 2000 were for “Assessment of glucose metabolism to assist in the evaluation of malignancy...” and “Assessment of patients with coronary artery disease and left ventricular dysfunction....”

Multiple manufacturers have approved NDAs for FDG.

See related evidence reviews 6.01.26 and 6.01.51 for oncologic indications and 6.01.20 for cardiac indications for FDG.

RATIONALE

Summary of Evidence

For individuals who have epileptic seizures who are candidates for surgery who have FDG-PET, the evidence includes systematic reviews (following the publication of 3 TEC Assessments). Relevant outcomes are symptoms, change in disease status, functional outcomes, health status measures, quality...
of life, hospitalizations, medication use, and resource utilization. The TEC Assessments and Program in Evidence-based Care PET recommendation report all concluded that FDG-PET accurately localizes the seizure focus compared with appropriate reference standards. A recent systematic review suggested it was difficult to discern the incremental value of FDG-PET in patients who have foci well localized by ictal scalp electroencephalography and magnetic resonance imaging. The evidence on whether FDG-PET has a predictive value for a good surgical outcome is mixed. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have suspected chronic osteomyelitis who receive FDG-PET, the evidence includes meta-analyses and a prospective study published after the meta-analyses. Relevant outcomes are test accuracy and validity, other test performance measures, change in disease status, functional outcomes, quality of life, and hospitalizations. One systematic review and meta-analysis from 2013 of 9 studies revealed that FDG-PET and FDG-PET plus computed tomography were useful for diagnosing suspected osteomyelitis in the foot of patients with diabetes. The results of another meta-analysis (2005) showed that FDG-PET was the most accurate mode (pooled sensitivity, 96%; pooled specificity, 91%) for diagnosing chronic osteomyelitis. The results appear to be robust across fairly diverse clinical populations, which strengthen the conclusions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have suspected Alzheimer disease who receive FDG-PET, the evidence includes 5 systematic reviews of observational studies and a retrospective study assessing clinical utility. Relevant outcomes are test accuracy and validity, other test performance measures, symptoms, quality of life, and hospitalizations. The studies included in the reviews were generally of poor quality. There is no standard cutoff for PET positivity for diagnosing Alzheimer disease, and many studies have not included postmortem confirmation of Alzheimer disease as the reference standard, leading to uncertainty about estimates of performance characteristics. FDG-PET may have high sensitivity and specificity for diagnosing Alzheimer disease, but there is little evidence comparing the performance characteristics of clinical diagnosis using PET with the clinical diagnosis not using PET; therefore, the incremental value of adding PET to the standard clinical diagnosis is unclear. No studies have reported on clinical outcomes of patients diagnosed with and without FDG-PET. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have suspected large vessel vasculitis who receive FDG-PET, the evidence includes 5 systematic reviews of observational studies. Relevant outcomes are test accuracy and validity, other test performance measures, symptoms, morbid events, quality of life, hospitalizations, and treatment-related morbidity. Most studies included in the reviews were small and lacked controls. The reported performance characteristics were heterogeneous, but reviewers were unable to determine the source of heterogeneity. Studies comparing PET with the true reference standard of biopsy or angiography are rare. There are no consensus criteria to define the presence of vascular inflammation by FDG-PET in large vessel vasculitis, and different parameters with visual and semiquantitative methods have been reported. Studies demonstrating changes in management based on PET results or improvements in clinical outcomes are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have diverse noncardiac or nononcologic conditions (eg, central nervous system, pulmonary, and musculoskeletal diseases) who receive FDG-PET, the evidence includes a few systematic reviews. Relevant outcomes are overall survival, symptoms, change in disease status, functional outcomes, health status measures, quality of life, hospitalizations, medication use, and resource utilization. Many studies cited in the reviews were small, retrospective, and published in the 1990s to early 2000s; further, many studies did not directly compare a modality with another in the same patient group—nor did they correlate PET results in individual patients with improved clinical outcomes. Additional studies are needed to demonstrate FDG-PET results can change management, and therefore...
improve patient outcomes to support the utility of FDG-PET. The evidence is insufficient to determine the effect of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Academy of Neurology
Evidence-based practice parameters from the American Academy of Neurology are summarized in Table 1.

<table>
<thead>
<tr>
<th>Practice Parameter</th>
<th>Date</th>
<th>PET Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis of dementia</td>
<td>2004: reaffirmed</td>
<td>PET imaging not recommended for routine use in diagnostic evaluation of dementia (LOR: moderate clinical certainty)</td>
</tr>
<tr>
<td>Early detection of dementia</td>
<td>2003: reaffirmed</td>
<td>Not addressed</td>
</tr>
<tr>
<td>Diagnosis of new-onset PD</td>
<td>2006: reaffirmed 2013; retired 2016</td>
<td>Evidence insufficient to support or refute FDG-PET as a means of distinguishing PD from other parkinsonian syndromes</td>
</tr>
<tr>
<td>Evaluation of depression, psychosis, and dementia in PD</td>
<td>2006; retired 2018</td>
<td>Not addressed</td>
</tr>
<tr>
<td>Mild cognitive impairment</td>
<td>2001; 2017</td>
<td>Not addressed</td>
</tr>
</tbody>
</table>

FDG: fluorine 18 fluorodeoxyglucose; LOR: level of recommendation; PD: Parkinson disease; PET: positron emission tomography.

American Academy of Orthopaedic Surgeons
The American Academy of Orthopaedic Surgeons (2010) published evidence-based, consensus guidelines. Fluorine 18 fluorodeoxyglucose positron emission tomography (FDG-PET) was considered:

“an option in patients in whom diagnosis of periprosthetic joint infection has not been established and are not scheduled for reoperation. (Strength of recommendation: limited [quality of the supporting evidence is unconvincing, or well-conducted studies show little clear advantage of one approach over another])”

American College of Radiology
Evidence- and consensus-based appropriateness criteria from the American College of Radiology are summarized in Table 2.

<table>
<thead>
<tr>
<th>Appropriateness Criteria</th>
<th>Last Reviewed</th>
<th>FDG-PET/CT Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suspected osteomyelitis, septic arthritis, or soft tissue infection (excluding spine and diabetic foot)</td>
<td>2017</td>
<td>Usually not appropriate for: (1) suspected osteomyelitis with soft tissue or juxta-articular swelling with cellulitis and a skin lesion, injury, wound, ulcer, or blister; or (2) suspected osteomyelitis with pain and swelling or cellulitis associated with site of previous nonarthroplasty hardware. Usually not appropriate for suspected osteomyelitis with soft-tissue or juxta-articular swelling with a history of surgery, though “this is promising new technology but data are limited.”</td>
</tr>
<tr>
<td>Diagnosis of dementia</td>
<td>2001, reaffirmed 2004</td>
<td>PET imaging not recommended for routine use in diagnostic evaluation of dementia (LOR: moderate clinical certainty)</td>
</tr>
<tr>
<td>Early detection of dementia</td>
<td>2001, reaffirmed 2003, 2015</td>
<td>Not addressed</td>
</tr>
<tr>
<td>Diagnosis of new onset-PD</td>
<td>2006: reaffirmed 2013; retired 2016</td>
<td>Evidence insufficient to support or refute FDG-PET as a means of distinguishing PD from other parkinsonian syndromes</td>
</tr>
<tr>
<td>Evaluation of depression, psychosis, and dementia in PD</td>
<td>2006</td>
<td>Not addressed</td>
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<table>
<thead>
<tr>
<th>PD</th>
<th>Effective Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dementia and movement disorders</td>
<td>2016</td>
<td>May be appropriate in patients with possible or probable AD and to differentiate suspected FTD, LBD, CJD, or vascular dementia; usually not appropriate in patients with suspected HD, clinical features of PD or hemochromatosis, or motoneuron disease</td>
</tr>
<tr>
<td>Imaging after total knee arthroplasty</td>
<td>2017</td>
<td>Usually not appropriate for routine follow-up of asymptomatic patient, in work-up for suspected periprosthetic infection, or for evaluation of prosthetic loosening</td>
</tr>
<tr>
<td>Seizures and epilepsy</td>
<td>2014</td>
<td>Usually appropriate for surgical planning in medically refractory epilepsy; may be appropriate for new-onset seizure unrelated to trauma in adults (age ≥18 y) and for posttraumatic (subacute or chronic), new-onset seizure; otherwise, usually not appropriate for new-onset seizure</td>
</tr>
<tr>
<td>Crohn disease</td>
<td>2014</td>
<td>Usually not appropriate</td>
</tr>
<tr>
<td>Fever without source – child</td>
<td>2015</td>
<td>May be appropriate. This procedure should not be used as the initial study. Consider if extensive clinical and imaging work-up is negative.</td>
</tr>
<tr>
<td>Suspected osteomyelitis of the foot in patients with DM</td>
<td>2012</td>
<td>Usually not appropriate</td>
</tr>
</tbody>
</table>

AD: Alzheimer disease; CJD: Creutzfeldt-Jakob disease; CT: computed tomography; DM: diabetes mellitus; FDG: fluorine 18 fluorodeoxyglucose; FTD: frontotemporal dementia; HD: Huntington disease; LBD: Lewy body disease; LOR: level of recommendation; PD: Parkinson disease; PET: positron emission tomography.

Infectious Diseases Society of America

The Infectious Diseases Society of America (IDSA; 2015) published evidence-based, consensus guidelines on the diagnosis and treatment of native vertebral osteomyelitis in adults. The guidelines stated that PET “is highly sensitive for detecting chronic osteomyelitis. A negative PET scan excludes the diagnosis of osteomyelitis, including native vertebral osteomyelitis, as the sensitivity of the test is expected to be very high in view of the high concentration of red marrow in the axial skeleton.”

IDSA (2013) published evidence-based, consensus guidelines on the diagnosis and management of prosthetic joint infections. The guidelines concluded that PET should not be routinely used to diagnose prosthetic joint infection (strength of recommendation: B [based on moderate evidence]; quality of evidence: III [expert opinion and descriptive studies]).

IDSA (2012) published evidence-based, consensus guidelines on the diagnosis and treatment of diabetic foot infections. The guidelines concluded that the role of FDG-PET in evaluating a diabetic foot infection has not been established.

IDSA (2018) will be publishing guidelines on the diagnosis and management of bone and joint infections in children.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

In 2004, the Centers for Medicare & Medicaid Services (CMS) released a national coverage decision for a subset of patients “with a recent diagnosis of dementia and documented cognitive decline of at least 6 months, who meet diagnostic criteria for both Alzheimer disease and frontotemporal dementia, who have been evaluated for specific alternative neurodegenerative diseases or causative factors, and for whom the cause of the clinical symptoms remains uncertain.”

The national coverage determination for FDG-PET for dementia and neurodegenerative diseases (220.6.13) states that:

“Medicare covers FDG Positron Emission Tomography (PET) scans for either the differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer’s disease (AD) under specific requirements; OR, its use in a Centers for Medicare & Medicaid Services (CMS)-approved practical

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clinical trial focused on the utility of FDG PET in the diagnosis or treatment of dementing neurodegenerative diseases. 86

Specific requirements for each indication are clarified in the document.

The national coverage determination for FDG-PET for infection and inflammation (220.6.16) states that:

“The CMS is continuing its national noncoverage of FDG PET for the requested indications. Based on our review, CMS has determined that the evidence is inadequate to conclude that FDG PET for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin improves health outcomes in the Medicare populations, and therefore has determined that FDG PET for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin is not reasonable....” 87

REFERENCES


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POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2012</td>
<td>New Policy</td>
<td>Policy updated with literature search; Sarcoidosis added as not medically necessary indication, no other changes to policy statement.</td>
</tr>
<tr>
<td>June 2013</td>
<td>Update Policy</td>
<td>Policy update with literature review. Reference 12 added; no changes to policy statement.</td>
</tr>
<tr>
<td>June 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 1-15, 19-21, 32, 39, 44, and 58 added. Policy statements unchanged. Added “Fluorodeoxyglucose F 18” to the title and “FDG” to the investigational statement.</td>
</tr>
<tr>
<td>December 2017</td>
<td>Update Policy</td>
<td>Policy updated with literature review through July 10, 2018; references 28 and 72 added; reference 18 updated. Policy statements unchanged.</td>
</tr>
</tbody>
</table>

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