### Description

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

### Related Policies

- Cardiac Applications of Positron Emission Tomography Scanning
- Oncologic Applications of PET Scanning

### Policy

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

- The assessment of selected patients with epileptic seizures who are candidates for surgery (see Policy Guidelines)
- The diagnosis of chronic osteomyelitis

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

**Central Nervous System Diseases**

- Autoimmune disorders with central nervous system (CNS) manifestations, including:
  - Behçet syndrome
  - Lupus erythematosus
- Cerebrovascular diseases, including:
  - Arterial occlusive disease (arteriosclerosis, atherosclerosis)
  - Carotid artery disease
  - Cerebral aneurysm
  - Cerebrovascular malformations (AVM and Moya-Moya disease)
  - Hemorrhage
  - Infarct
• Ischemia

• Degenerative motor neuron diseases, including:
  o Amyotrophic lateral sclerosis
  o Friedreich ataxia
  o Olivopontocerebellar atrophy
  o Parkinson disease
  o Progressive supranuclear palsy
  o Shy-Drager syndrome
  o Spinocerebellar degeneration
  o Steele-Richardson-Olszewski disease
  o Tourette syndrome

• Dementias, including:
  o Alzheimer disease
  o Multi-infarct dementia
  o Pick disease
  o Frontotemporal dementia
  o Dementia with Lewy bodies
  o Presenile dementia

• Demyelinating diseases, such as multiple sclerosis

• Developmental, congenital, or inherited disorders, including:
  o Adrenoleukodystrophy
  o Down syndrome
  o Huntington’s chorea
  o Kinky-hair disease (Menkes disease)
  o Sturge-Weber syndrome (encephalo facial angiomatosis) and the phakomatoses

• Miscellaneous
  o Chronic fatigue syndrome
  o Sick building syndrome
  o Posttraumatic stress disorder

• Nutritional or metabolic diseases and disorders, including:
  o Acanthocytes
  o Hepatic encephalopathy
  o Hepatolenticular degeneration
  o Metachromatic leukodystrophy
  o Mitochondrial disease
• Subacute necrotizing encephalomyelopathy

Psychiatric diseases and disorders, including:
• Affective disorders
• Depression
• Obsessive-compulsive disorder
• Psychomotor disorders
• Schizophrenia

Pyogenic infections, including:
• Aspergillosis
• Encephalitis

Substance abuse, including the CNS effects of alcohol, cocaine, and heroin

Trauma, including brain injury and carbon monoxide poisoning

Viral infections, including:
• Acquired immune deficiency syndrome (AIDS)
• AIDS dementia complex
• Creutzfeldt-Jakob syndrome
• Progressive multifocal leukoencephalopathy
• Progressive rubella encephalopathy
• Subacute sclerosing panencephalitis

Mycobacterium infection

Migraine

Anorexia nervosa

Cerebral blood flow in newborns

Vegetative versus "locked-in" state

Pulmonary Diseases
• Adult respiratory distress syndrome
• Diffuse panbronchiolitis
• Emphysema
• Obstructive lung disease
• Pneumonia

Musculoskeletal Diseases
• Spondylodiscitis
• Joint replacement follow-up

Other
• Giant cell arteritis
Medical Policy

- Vasculitis
- Inflammatory bowel disease
- Sarcoidosis

Policy Guidelines

In patients with epileptic seizures, appropriate candidates are patients with complex partial seizures that have failed to respond to medical therapy and who have been advised to have a resection of a suspected epileptogenic focus located in a region of the brain accessible to surgery. Conventional techniques for seizure localization must have been tried and provide data that suggested a seizure focus but were not sufficiently conclusive to permit surgery. In addition, the purpose of the 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.

Coding

A PET scan essentially involves 3 separate activities:

- Manufacture of the radiopharmaceutical, which may be manufactured on site, or manufactured at a regional delivery center with delivery to the institution performing PET
- Actual performance of the PET scan
- Interpretation of the results. The following CPT codes may be used.

CPT Codes:

- **78608**: Brain imaging, positron emission tomography (PET); metabolic evaluation
- **78609**: Brain imaging, positron emission tomography (PET); perfusion evaluation
- **78811**: Positron emission tomography (PET) imaging; limited area (e.g., chest, head/neck)
- **78812**: Positron emission tomography (PET) imaging; skull base to mid-thigh
- **78813**: Positron emission tomography (PET) imaging; whole body
- **78814**: Positron emission tomography (PET) imaging with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (e.g., chest, head/neck)
- **78815**: Positron emission tomography (PET) imaging with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
- **78816**: Positron emission tomography (PET) imaging with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body

HCPCS Codes:

There are HCPCS codes specific to the following radiotracers:

- **A9526**: Nitrogen N-13 ammonia, diagnostic, per study dose, up to 40 millicuries
• **A9552**: Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose, up to 45 millicuries

• **A9580**: Sodium fluoride F-18, diagnostic, per study dose, up to 30 millicuries

### Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

### Rationale

#### Background

A variety of positron emission tomography (PET) radiopharmaceuticals have been investigated; however, only a few have received approval by the U.S. Food and Drug Administration (FDA) for clinical use (see Regulatory Status). The scanners used for PET imaging are somewhat similar to those used for radiograph computed tomography (CT), but PET requires complicated technology and computerized mathematical models of physiologic functions and tracer kinetics for the generation of images.

**Note:** This policy only addresses the use of radiotracers detected with the use of dedicated full-ring PET scanners. Radiotracers such as fluorodeoxyglucose (FDG) may be detected using single-photon emission computed tomography (SPECT) cameras, a hybrid PET/SPECT procedure that may be referred to as FDG-SPECT or molecular coincidence detection.

#### Regulatory Status

The 1997 FDA Modernization Act (FDAMA) established FDA authority over the safety and effectiveness of locally manufactured radiotracers and developed streamlined regulations for good manufacturing practices (GMP) with which each PET facility must comply.

The following radiotracers have been approved by the FDA:

- $^{18}$F-FDG for evaluation of glucose metabolism in oncology
- $^{18}$F-FDG for evaluation of myocardial hibernation
- $^{13}$N-ammonia for evaluation of myocardial blood flow
- 82-rubidium chloride injection (NDA-19-414) was approved in 1989 “for assessing regional myocardial perfusion in the diagnosis and localization of myocardial infarction.”
- $^{18}$F FDG (NDA 20-306) was approved in 1994 for “the identification of regions of abnormal glucose metabolism associated with foci of epileptic seizures.”
• ¹⁸F sodium fluoride injection (NDA 17-042) was approved in 1972 for “injection as a bone imaging agent to define areas of altered osteogenic activity.” The original company ceased making this drug product in 1975, and it is now being marketed again by PETNET Solutions (a Siemens company).

In September 2005, the FDA issued a draft rule and draft guidance on current good manufacturing practice (CGMP) for PET drug products. The final CGMP regulation for the production of PET drugs was issued on December 9, 2009 and took effect on December 12, 2011. More detailed information is available online at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm085783.htm.

Literature Review

Policies on positron emission tomography (PET) were originally based on 4 TEC Assessments that addressed various applications of PET.(1-4) The key literature identified in updated literature searches is described next.

Epilepsy

A 2007 meta-analysis on the use of fluorodeoxyglucose (FDG)-PET for preoperative evaluation of patients with temporal lobe epilepsy found that ipsilateral PET hypometabolism had a predictive value for a good outcome of 86%. The authors note, however, the difficulty of the analysis because of differences in study design and lack of precise patient data, which made the incremental value of PET unclear. PET may not add value for patients well-localized by ictal scalp electroencephalography and magnetic resonance imaging (MRI).(5) A meta-analysis on predictors of long-term seizure freedom after surgery for frontal lobe epilepsy found that PET findings did not predict seizure freedom.(6)

Chronic Osteomyelitis

In 2005, Termaat et al published a systematic review and meta-analysis of diagnostic imaging to assess chronic osteomyelitis.(7) The authors reviewed studies on 6 imaging approaches to chronic osteomyelitis, including FDG-PET and concluded that PET is the most accurate mode (pooled sensitivity, 96%; 95% confidence interval [CI], 88% to 99%; pooled specificity, 91% 95% CI, 81% to 95%) for diagnosing chronic osteomyelitis. Leukocyte scintigraphy was adequate in the peripheral skeleton (sensitivity, 84% 95% CI, 72% to 91%; specificity, 80% 95% CI, 61% to 91%) but was inferior in the axial skeleton (sensitivity, 21% 95% CI, 11% to 38%; specificity, 60% 95% CI, 39% to 78%). The assessment of PET was based on 4 prospective, European studies published between 1998 and 2003, with a total of 1660 patients. However, the study populations varied and included the following: (1) 57 patients with suspected spinal infection referred for FDG-PET and who had previous spinal surgery but not “recently”(8); (2) 22 trauma patients scheduled for surgery who had suspected metallic implant-associated infection(9); (3) 51 patients with recurrent osteomyelitis or osteomyelitis symptoms for more than 6 weeks, 36 in the peripheral skeleton and 15 in the central skeleton(10); and (4) 30 consecutive nondiabetic patients referred for possible chronic osteomyelitis.(11) The results appeared to be robust across fairly diverse clinical populations, which strengthen the conclusions.

In a 2013 systematic review and meta-analysis of 9 studies, FDG-PET and PET/computed tomography (CT) was found to be useful for suspected osteomyelitis in the foot of patients with diabetes.(12) A meta-analysis of 4 studies found the sensitivity was 74% (95% CI, 60% to 85%), specificity 91% (95% CI, 85% to 96%), positive likelihood ratio 5.56 (95% CI, 2.02 to 15.27), negative likelihood ratio 0.37 (95% CI, 0.10 to 1.35), and diagnostic
odds ratio 16.96 (95% CI, 2.06 to 139.66). The area under the summary receiver operating characteristic (ROC) curve was 0.874.

**Alzheimer's Disease and Dementia**

The Centers for Medicare and Medicaid Services (CMS) issued a decision memorandum on April 16, 2003, that would not support coverage of FDG-PET in Alzheimer's disease (AD) because the evidence did not demonstrate its use for improved patient outcomes. This decision was based, in part, on a technology assessment conducted at Duke University through the Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Center. This assessment used decision-analysis modeling to examine whether the use of FDG-PET would improve health outcomes when used for diagnosis of AD in 3 clinical populations: patients with dementia, patients with mild cognitive impairment, or subjects with no symptoms but a first-degree relative with AD. PET was considered to have an 88% sensitivity (95% CI, 79% to 94%) and 87% specificity (95% CI, 77% to 93%) for diagnosing AD. The report concluded that outcomes for all 3 groups of patients were better if all patients were treated with agents such as cholinesterase inhibitors rather than using FDG-PET to select patients for treatment based on PET results, because the complications of treatment were relatively mild, and treatment was considered to have some degree of efficacy in delaying the progression of AD. Thus, the adverse effect of not treating subjects with AD who had false negative PET results was influential in this analysis. However, this conclusion was sensitive to the toxicity associated with treatment.

In October 2003, CMS agreed to reconsider its policy on PET for AD and dementia. On September 15, 2004, Medicare made public its final decision memorandum announcing a positive 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 AD and fronto-temporal dementia (FTD), who have been evaluated for specific alternative neurodegenerative diseases or causative factors, and for whom the cause of the clinical symptoms remains uncertain.” For its reconsideration, CMS requested an update of the original AHRQ assessment which concluded that no new publications provided direct evidence to evaluate the use of PET to either differentiate among different types of dementia or to identify those patients with mild cognitive impairment who were at greatest risk to progress to AD. In addition, Medicare considered a consensus report by the Neuroimaging Work Group of the Alzheimer's Association and proceedings of an expert panel discussion of neuroimaging in AD, convened by the National Institute of Aging and Medicare.

In 2005, a meta-analysis compared the ability of FDG-PET, single-photon emission computed tomography (SPECT), and structural MRI to predict patients' conversion from mild cognitive impairment to AD. Using 24 articles identified among studies published between 1990 to April 2008 (6 on FDG-PET, published 2001-2005), the authors found no statistically significant difference among the 3 modalities in pooled sensitivity, pooled specificity, or negative likelihood ratio, FDG-PET had the highest odds ratio and positive likelihood ratio. However, there was strong evidence of between-study heterogeneity and marked asymmetry in the funnel plot (with studies missing from the bottom left quadrant), reducing confidence in the results. Efforts to identify sources of heterogeneity (e.g., publication year, age, male-female ratio, follow-up interval, years of education, mean Mini-Mental State Examination [MMSE] score at baseline) yielded no significant results; only the imaging technique was associated with the log odds ratio. (In an apparent error, the article states that “[N]o statistically significant difference was found (p>.05) for each technique in pooled sensitivity and LR.” [emphasis added]. Also, in Table...
5, the odds ratio for FDG-PET is reported as 40.146, 95% CI, 18.53 ~ 6.97. The last number appears to be incorrect.

Research continues on efforts to use PET to identify AD and differentiate it from other types of dementia. For example, a 2008 multicenter, international study with 548 patients, including normal patients and those with mild cognitive impairment, AD, frontotemporal dementia, and dementia with Lewy bodies, used Neurological Statistical Image Analysis (Neurostat, University of Washington) to process the results. Excluding the patients with mild cognitive impairment, the sample was split in half, with key PET findings identified on half of the data set and validated on the second half of the data set. The disease-specific PET patterns correctly classified 94% normal patients, 95% AD, 92% dementia with Lewy bodies, 94% frontotemporal dementia (p<0.001). The PET patterns were also 98% sensitive and 92% specific (p<0.001) in distinguishing mild cognitive impairment from normal patients. While interesting, these findings need to be replicated on a less selected sample (i.e., one in which mild cognitive impairment (MCI) patients are included in the mix). Also, the reference standard used was clinical diagnosis, so the incremental value, if any, of PET imaging over clinical judgment alone could not be determined. More generally, evidence of clinical utility would require demonstrating that PET improved diagnostic accuracy and that earlier or more accurate diagnosis led to treatment changes that improved health outcomes.

One of the challenges in evaluating the use of PET to distinguish among dementias is to identify what serves as the reference standard. Durand-Martel et al noted in 2010 that the sensitivity of clinical diagnosis for AD varies between 75% and 98%, with an average of 82% (19). Therefore, comparing PET results with clinical diagnosis can be confounded by the fact that the clinical diagnosis itself may not be accurate. Durand-Martel et al asserted that autopsy results should serve as the reference standard in studies on the use of FDG-PET for dementia; they identified only 5 studies with 20 patients or more in which results of both FDG-PET imaging and autopsy were presented.

There is also research on alternative radiotracers to FDG in identifying AD. In particular, there is interest in amyloid PET tracers, because beta amyloid is the principal component of AD plaques in the brain. (20) (See Blue Shield of California Medical Policy: Beta Amyloid Imaging with Positron Emission Tomography [PET] for Alzheimer’s Disease.)

Another recent research interest is the potential use of PET scan results as a biomarker for progression to AD. It is difficult to evaluate treatments that may prevent or delay the onset of dementia in individuals with MCI because a relatively small number of study participants will progress to AD during the follow-up period. A 2011 study by Herholz et al in the U.K. used a quantitative PET score previously devised by this research group to evaluate disease progression; a software program was available to calculate the score. (21) The prospective study included 94 patients with MCI, 40 patients with mild AD, and 44 healthy controls. Participants received 4 PET scans and clinical assessments over 2 years. By the 2-year follow-up, 30 of 94 (32%) had progressed to MCI, 7 (7%) reverted to normal cognitive function, and 57 (61%) remained MCI. Two of 44 (4.5%) healthy controls had progressed to MCI. All of the individuals with AD at baseline remained in that category. The proportion of patients with abnormal PET scores at baseline was 85% in the AD group, 40% in the MCI group, and 11% in the control group. An abnormal PET score at baseline had a sensitivity to predict disease progression of 0.57 and a specificity of 0.67. The area under the ROC curve was 0.75 for PET scores. Areas under the ROC curve for predicting disease progression for the outcome measures MMSE and the Alzheimer’s Disease Assessment Scale-Cognitive, were 0.66 and 0.68, respectively. Conclusions about the utility of using this PET score in clinical practice cannot be drawn from the Herholz
study; additional research is needed that evaluates whether patient management decisions using the PET score results in improved health outcomes.

A meta-analysis(22) pooled 7 studies of FDG PET and 6 studies of PET with carbon-11 Pittsburgh Compound B (PIB) for prediction of conversion to AD among patients with MCI. Areas under the ROC curve were 0.88 for FDG PET and 0.85 for PIB PET. This report lacks comparisons with other means of predicting conversion from MCI to AD. It also lacks a discussion of how PET might influence treatment decisions and whether use of PET improves health outcomes.

It should be noted that much of the present interest in detecting AD early is to develop and test treatments that might affect the progression of the disease. This is clearly an important goal, but several important challenges must be overcome before PET imaging is routinely used in clinical practice to detect preclinical AD, so that treatment can be started. At the same time, other methods of diagnosing AD that do not involve imaging are also being explored.

Due to the lack of direct evidence that this imaging technique will result in a change in management that will improve patient outcomes, PET for AD and dementia is considered investigational.

**Vasculitis**

A systematic review of literature on PET and PET/CT in patients with large-vessel vasculitis was published in 2011 by Treglia et al.(23) The investigators identified 32 studies with a total of 604 vasculitis patients. The authors did not pool findings of the studies. They concluded that PET and PET/CT may be useful for initial diagnosis and assessment of severity of disease and that the role of these imaging methods in monitoring treatment response is unclear. They also concluded that “given the heterogeneity between studies with regard to PET analysis and diagnostic criteria, a standardization of the technique is needed.” The studies cited in support of using PET for diagnosing large vessel vasculitis had small sample sizes; 1 study included 25 vasculitis patients and 44 controls; the others had total sample sizes of fewer than 20 patients.

Lehmann et al in Germany published a study after the Treglia review.(24) PET scans of 20 patients with giant cell arthritis or Takayasu arthritis, and 20 healthy controls were retrospectively reviewed by 2 experienced nuclear medicine experts on a blinded basis. PET was found to have a sensitivity of 65% and a specificity of 80% for identifying patients with a known large vessel vasculitis diagnosis. The 2 reviewers agreed on the diagnosis in 34 of 40 (85%) scans; the interrater agreement (Cohen kappa) was 0.70. The authors concluded that, due to the low sensitivity and specificity, the diagnosis of large vessel vasculitis should not be based solely on PET findings. Study limitations include being retrospective and not including individuals with suspected, rather than established, large vessel vasculitis.

**Other Indications**

Review articles on the use of PET with spinal infections(25,26); inflammatory diseases more generally(27); fever of unknown origin (28,29); hyperinsulinemic hypoglycemia(30,31); mycobacterium infection(32); inflammatory bowel disease(33); and multiple sclerosis(34) indicate insufficient evidence on the benefit of PET for these indications. Many of the studies cited in the reviews were small, retrospective, published in the 1990s to early 2000s and/or many studies did not directly compare 1 modality with another in the same patient group or connect the PET results in individual patients to improved clinical outcomes.
A 2008 meta-analysis on using FDG-PET to diagnose prosthetic joint infection following hip or knee replacement reported pooled estimates of the sensitivity of PET in detecting infection of 82.1% (95% CI, 68.0% to 90.8%) and a pooled specificity of 86.6% (95% CI, 79.7% to 91.4%). The authors note, however, that the results should be interpreted with caution because of significant heterogeneity identified among the 11 studies included (which confers substantial uncertainty on the pooled estimates). Efforts to identify sources of heterogeneity were mostly unsuccessful; there were differences in performance based on location of prostheses (hip vs knee) and whether filtered back projection or iterative reconstruction was used. The authors stated that a large, multicenter trial is needed to evaluate the use of FDG-PET for identifying infection around joint prostheses. Both this study and another study on the same clinical issue found that the specificity of PET was significantly greater for hip prostheses than for knee prostheses. The articles also noted that these studies were based on the use of PET alone. CT is generally not useful in evaluating potential infections around joint prostheses because of the artifacts caused by the metallic implants, so additional research would be needed on combined PET/CT. The second study compared the accuracy of PET with a triple-phase scan and with white blood cell imaging. The authors concluded that the latter is the most accurate but also the most complex and time-consuming, while the former is readily available and the easiest to perform. However, these comparisons are open to question because the methods were poorly described and the authors appeared to mix together results from single-arm studies on 1 modality with comparative studies.

A 2011 systematic review addressed use of PET in evaluating disease activity in patients with sarcoidosis. The report does not include quality assessment of individual studies, a critical feature of a well-conducted systematic review. Only 3 small studies of 9 reviewed included data from a comparator imaging modality, thus conclusions about comparative diagnostic performance cannot be reached.

**Ongoing Clinical Trials**

A search of online site ClinicalTrials.gov on January 24, 2014, identified 2 phase 3 studies evaluating PET for miscellaneous applications. Metabolic cerebral imaging in incipient dementia (NCT00329706) is a randomized controlled trial evaluating whether PET scanning can distinguish between patients with early Alzheimer changes in their brains from patients with other types of cognitive impairment. All participants (estimated enrollment is n=710) will undergo scanning with FDG-PET. They will be randomized to immediate release of the PET report or a 2-year delay in the release of the report. Outcomes include change in cognitive function, utilization of health resources, and prescriptions for Alzheimer-specific therapies. The expected study completion date is January 2016. PET will be used to determine Parkinson from other movement disorders in an open label multicenter study (NCT01550484).

**Summary**

Positron emission tomography (PET) for selected patients with epilepsy and patients with chronic osteomyelitis may be considered medically necessary. There is insufficient evidence on the value of PET for other miscellaneous (noncardiac, nononcologic) indications. Studies are needed that demonstrate that PET will result in a change in management that will improve patient outcomes to determine that it is a clinically useful test.

**Practice Guidelines and Position Statements**

A 2006 Guideline practice parameter from the Quality Standards Subcommittee of the American Academy of Neurology states, in part:
“There is insufficient evidence to support or refute the following as a means of distinguishing PD from other parkinsonian syndromes: urodynamics, autonomic testing, urethral or anal electromyography (EMG), MRI, brain parenchyma sonography, and 18F fluorodeoxyglucose positron emission tomography.”(38)

**Medicare National Coverage**

National Coverage Determination (NCD) for FDG-PET for Dementia and Neurodegenerative Diseases (220.6.13): “Medicare covers FDG-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 clinical trial focused on the utility of FDG-PET in the diagnosis or treatment of dementing neurodegenerative diseases”. Specific requirements for each indication are clarified in the document.(13)

National Coverage Determination (NCD) for FDG-PET for Infection and Inflammation (220.6.16)

“The CMS is continuing its national noncoverage of FDG-PET for the requested indications. Based upon 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 and necessary under section 1862(a)(1)(A) of the Social Security Act.”(39)

**References**

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Positron emission tomography for assessment of myocardial viability TEC Assessments 1994; Volume 9, Tab 29.
4. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). FDG positron emission tomography for non-CNS cancers. TEC Assessments 1997; Volume 12, Tab 2.


Documentation Required for Clinical Review

- History and physical and/or consultation notes including:
  - Indication for PET scan
  - Previous treatment and response
- Previous Imaging reports (e.g., CT, MRI, SPECT)
- Pathology reports (if applicable)

Post Service
- PET report

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following service/procedure may be considered medically necessary in certain instances and investigational in others. Services may be medically necessary when policy criteria are met. Services are considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>78608</td>
<td>Brain imaging, positron emission tomography (PET); metabolic evaluation</td>
</tr>
<tr>
<td></td>
<td>78609</td>
<td>Brain imaging, positron emission tomography (PET); perfusion evaluation</td>
</tr>
<tr>
<td></td>
<td>78811</td>
<td>Positron emission tomography (PET) imaging; limited area (e.g., chest, head/neck)</td>
</tr>
<tr>
<td></td>
<td>78812</td>
<td>Positron emission tomography (PET) imaging; skull base to mid-thigh</td>
</tr>
<tr>
<td></td>
<td>78813</td>
<td>Positron emission tomography (PET) imaging; whole body</td>
</tr>
<tr>
<td>CPT®</td>
<td>78814</td>
<td>Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization</td>
</tr>
<tr>
<td>HCPCS</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>---------</td>
<td>-----------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>78815</td>
<td>Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh</td>
<td></td>
</tr>
<tr>
<td>78816</td>
<td>Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body</td>
<td></td>
</tr>
<tr>
<td>A9526</td>
<td>Nitrogen n-13 ammonia, diagnostic, per study dose, up to 40 millicuries</td>
<td></td>
</tr>
<tr>
<td>A9552</td>
<td>Fluorodeoxyglucose f-18 FDG, diagnostic, per study dose, up to 45 millicuries</td>
<td></td>
</tr>
<tr>
<td>A9580</td>
<td>Sodium fluoride f-18, diagnostic, per study dose, up to 30 millicuries</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-9 Procedure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>92.01</td>
<td>Thyroid scan and radioisotope function studies</td>
</tr>
<tr>
<td>92.02</td>
<td>Liver scan and radioisotope function study</td>
</tr>
<tr>
<td>92.03</td>
<td>Renal scan and radioisotope function study</td>
</tr>
<tr>
<td>92.04</td>
<td>Gastrointestinal scan and radioisotope function study</td>
</tr>
<tr>
<td>92.05</td>
<td>Cardiovascular and hematopoietic scan and radioisotope function study</td>
</tr>
<tr>
<td>92.09</td>
<td>Other radioisotope function studies</td>
</tr>
<tr>
<td>92.11</td>
<td>Cerebral scan</td>
</tr>
<tr>
<td>92.12</td>
<td>Scan of other sites of head</td>
</tr>
<tr>
<td>92.13</td>
<td>Parathyroid scan</td>
</tr>
<tr>
<td>92.14</td>
<td>Bone scan</td>
</tr>
<tr>
<td>92.15</td>
<td>Pulmonary scan</td>
</tr>
<tr>
<td>92.16</td>
<td>Scan of lymphatic system</td>
</tr>
<tr>
<td>92.17</td>
<td>Placental scan</td>
</tr>
<tr>
<td>92.18</td>
<td>Total body scan</td>
</tr>
<tr>
<td>92.19</td>
<td>Scan of other sites</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Procedure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C030BZZ</td>
<td>Positron Emission Tomographic (PET) Imaging of Brain using Carbon 11 (C-11)</td>
</tr>
<tr>
<td>C030KZZ</td>
<td>Positron Emission Tomographic (PET) Imaging of Brain using Fluorine 18 (F-18)</td>
</tr>
<tr>
<td>C030MZZ</td>
<td>Positron Emission Tomographic (PET) Imaging of Brain using Oxygen 15 (O-15)</td>
</tr>
<tr>
<td>C030YZZ</td>
<td>Positron Emission Tomographic (PET) Imaging of Brain using Other Radionuclide</td>
</tr>
<tr>
<td>CP211ZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Skull using Technetium 99m (Tc-99m)</td>
</tr>
<tr>
<td>CP211ZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Skull using Other Radionuclide</td>
</tr>
<tr>
<td>CP221ZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Cervical Spine using Technetium 99m (Tc-99m)</td>
</tr>
<tr>
<td>CP22YZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Cervical Spine using Other Radionuclide</td>
</tr>
<tr>
<td>CP231ZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Skull and Cervical Spine using Technetium 99m (Tc-</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>CP23YZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Skull and Cervical Spine using Other Radionuclide</td>
</tr>
<tr>
<td>CP241ZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Thorax using Technetium 99m (Tc-99m)</td>
</tr>
<tr>
<td>CP24YZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Thorax using Other Radionuclide</td>
</tr>
<tr>
<td>CP261ZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Pelvis using Technetium 99m (Tc-99m)</td>
</tr>
<tr>
<td>CP26YZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Pelvis using Other Radionuclide</td>
</tr>
<tr>
<td>CP271ZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Spine and Pelvis using Technetium 99m (Tc-99m)</td>
</tr>
<tr>
<td>CP27YZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Spine and Pelvis using Other Radionuclide</td>
</tr>
<tr>
<td>CP281ZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Right Upper Extremity using Technetium 99m (Tc-99m)</td>
</tr>
<tr>
<td>CP28YZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Right Upper Extremity using Other Radionuclide</td>
</tr>
<tr>
<td>CP291ZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Left Upper Extremity using Technetium 99m (Tc-99m)</td>
</tr>
<tr>
<td>CP29YZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Left Upper Extremity using Other Radionuclide</td>
</tr>
<tr>
<td>CP2B1ZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Bilateral Upper Extremities using Technetium 99m (Tc-99m)</td>
</tr>
<tr>
<td>CP2BYZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Bilateral Upper Extremities using Other Radionuclide</td>
</tr>
<tr>
<td>CP2C1ZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Right Lower Extremity using Technetium 99m (Tc-99m)</td>
</tr>
<tr>
<td>CP2CYZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Right Lower Extremity using Other Radionuclide</td>
</tr>
<tr>
<td>CP2D1ZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Left Lower Extremity using Technetium 99m (Tc-99m)</td>
</tr>
<tr>
<td>CP2DYZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Left Lower Extremity using Other Radionuclide</td>
</tr>
<tr>
<td>CP2F1ZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Bilateral Lower Extremities using Technetium 99m (Tc-99m)</td>
</tr>
<tr>
<td>CP2FYZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Bilateral Lower Extremities using Other Radionuclide</td>
</tr>
<tr>
<td>CP2G1ZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Thoracic Spine using Technetium 99m (Tc-99m)</td>
</tr>
<tr>
<td>CP2GYZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Thoracic Spine using Other Radionuclide</td>
</tr>
<tr>
<td>CP2H1ZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Lumbar Spine using Technetium 99m (Tc-99m)</td>
</tr>
<tr>
<td>CP2HYZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Lumbar Spine using Other Radionuclide</td>
</tr>
<tr>
<td>CP2J1ZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Thoracolumbar Spine using Technetium 99m (Tc-99m)</td>
</tr>
</tbody>
</table>
Medical Policy

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CP2jYZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Thoracolumbar Spine using Other Radionuclide</td>
</tr>
<tr>
<td>CP2YZZZ</td>
<td>Tomographic (Tomo) Nuclear Medicine Imaging of Musculoskeletal System, Other using Other Radionuclide</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-9 Diagnosis</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Diagnoses</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Diagnosis</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>For dates of service on or after 10/01/2015</td>
<td>All Diagnoses</td>
</tr>
</tbody>
</table>

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/15/2014</td>
<td>Policy title change from Positron Emission Tomography (PET)</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td></td>
<td>Policy revision with position change</td>
<td></td>
</tr>
</tbody>
</table>

Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the
right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.