



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Positron Emission Tomography (PET)

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Hyperlink to Related Coverage Policies

Cardiac Nuclear Imaging

INSTRUCTIONS FOR USE

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Coverage Policy

ONCOLOGIC

CIGNA covers positron emission tomography (PET) or PET with concurrently acquired computed tomography (PET/CT) as medically necessary for any of the listed diagnoses when standard staging/restaging diagnostic and imaging studies are inconclusive AND further characterization is needed to make management decisions:

Occult Primary:

- when other imaging studies fail to identify the site of primary cancer

Bone Cancer for any of the following:

- Ewing's sarcoma family of tumors (ESFT)
- osteosarcoma
- suspected metastases to the bone

Brain Cancer:

- distinguishing recurrent tumor from radiation necrosis in an individual with a known anaplastic tumor of glial origin (e.g., glioblastoma, anaplastic astrocytoma, and anaplastic oligodendroglioma)

Breast Cancer for any of the following:

- staging evaluation of unresectable clinical Stage III and Stage IV disease including if needed to clarify positive findings on other studies
- documenting response to therapy for Stage IV disease
- detection and evaluation of metastatic disease

Cervical Cancer for either of the following when any of the associated criteria are met:

- Staging:
 - Stage IB1 or less to explain abnormal findings on other imaging studies
 - Stage IB2 or higher
 - incidental cervical cancer found in a hysterectomy specimen
- Restaging:
 - following radiation therapy (RT) when RT was the primary treatment therapy and if surgical salvage is an option

Colorectal Cancer for either of the following when any of the associated criteria are met:

- Staging:
 - when an abnormality on standard imaging suggests a possible solitary metastatic lesion amenable to resection
- Restaging:
 - when postoperative carcinoembryonic antigen (CEA) or liver function tests (LFTs) remain elevated and other attempts at imaging are negative
 - evaluation of a potentially resectable metastatic lesion in order to confirm that it is resectable and to confirm absence of other sites of disease
 - differentiating local tumor recurrence from postoperative and/or post- radiation scarring

Esophageal Cancer for either of the following:

- staging and restaging when the individual is a candidate for aggressive therapy
- clinical instance where an open biopsy is potentially high risk

Gastric Cancer:

- staging or restaging (exception: T1 gastric cancers)

Head and Neck Cancers for any of the following:

- staging including ruling out distant metastases (exception: T1 lesion in sites with low risk of nodal spread, such as the larynx, when there is no clinical evidence of adenopathy)
- directional assistance for biopsy in an individual who presents with a neck mass when initial attempts to find a primary source are unsuccessful/difficult
- restaging (exception: if surgery only was the primary treatment modality)

Hepatobiliary Cancers:

- detection of lymph node involvement and distant metastatic disease in gallbladder cancer in an individual with otherwise potentially resectable disease

Lung Cancer for any of the following:

- staging and restaging non-small cell lung cancer (NSCLC)
- initial staging small cell lung cancer (SCLC) when there is no obvious extensive disease
- pulmonary nodule(s) greater than or equal to 7 millimeters in size on computed tomography (CT) and/or magnetic resonance imaging (MRI) (exception: if lesions on previous CT appear ground-glass or pneumonic (pneumonia-like))

Lymphoma for either of the following:

- staging and restaging (exception: indolent non-Hodgkin lymphomas, including chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), gastric mucosa-associated lymphoid tissue (MALT) lymphomas, and low-grade follicular)
- diagnosis when biopsy of an inaccessible body region is contemplated

Malignant Pleural Mesothelioma:

- staging

Melanoma:

- Stage III or Stage IV only, to address specific signs and symptoms not explained by other imaging studies

Multiple Myeloma for either of the following:

- staging or restaging if standard imaging and lab tests cannot define extent of disease
- plasmacytoma

Neuroendocrine Tumors for either of the following:

- pheochromocytomas
- symptomatic neuroendocrine tumor following an apparently complete resection that fails to resolve secretion of pathologic levels of hormones or neurotransmitter compounds

Ovarian Cancer:

- restaging recurrence if symptomatic and other imaging is negative or inconclusive

Pancreatic Cancer for any of the following:

- clinical suspicion that a pancreatic malignancy is a possible metastasis from an unknown primary
- pre-operative staging
- post-radiation

Prostate Cancer:

- restaging following a progressive increase of prostate-specific antigen (PSA)

Renal Cancer for either of the following:

- when recurrence or metastatic disease is suspected
- when a positive PET will avoid an invasive biopsy

Soft Tissue Sarcoma for any of the following:

- when the grade of a unresectable tumor remains in doubt after biopsy
- when a solitary metastasis amenable to resection needs further assessment
- differentiation of suspected tumor from radiation or surgical fibrosis
- determination of response to therapy
- gastrointestinal stromal tumor (GIST) for initial staging and re-staging when there is documented recurrence

Testicular Cancer:

- seminoma - evaluation of a residual mass post-chemotherapy

Thyroid Cancer for any of the following when the associated criteria are met:

- diagnosis and staging of anaplastic thyroid cancer
- restaging and monitoring response to treatment of papillary, follicular and Hürthle cell thyroid cancer in an individual with ALL of the following:
 - previous treatment with both thyroidectomy and radioiodine ablation
 - serum thyroglobulin (Tg) >10 nanograms per milliliter (ng/ml)
 - negative iodine 131 (¹³¹I) whole body (scintigraphy) scan
- medullary thyroid cancer, when calcitonin levels are elevated post-operatively

SEIZURES

CIGNA covers metabolic brain PET as medically necessary for pre-surgical evaluation of refractory seizure activity

CARDIAC

CIGNA covers myocardial perfusion stress PET as medically necessary for EITHER of the following indications:

- inability to adequately exercise on a treadmill or similar device
- uninterpretable resting EKG for assessment of ischemia in a standard exercise stress test

When combined with ANY of the following indications:

- obesity (body mass index [BMI] over 35)
- woman with large breasts or implants that preclude an accurate myocardial perfusion imaging study
- inconclusive single-photon emission computed tomography (SPECT)

CIGNA covers myocardial viability (metabolic) PET as medically necessary for EITHER of the following indications:

- previous study has shown severe left ventricular dysfunction in an individual who is under consideration for a revascularization procedure and there is a need to determine myocardial viability
- identifying and monitoring response to therapy for cardiac sarcoidosis

NOT COVERED INDICATIONS

CIGNA does not cover PET for ANY of the following indications because it is considered experimental, investigational, or unproven (this list may not be all-inclusive):

Oncology:

- cancer screening
- routine monitoring of therapy unless otherwise specified above
- surveillance of an asymptomatic individual previously treated for a malignant disease
- adrenal carcinomas
- carcinoid tumors
- gastric cancer, T1 gastric cancers
- head and neck, imaging of a T1 lesion in any site with a low risk of nodal spread, such as the larynx, when there is no clinical evidence of adenopathy OR PET for restaging when the only primary treatment modality was surgery
- hepatocellular carcinoma
- lymphoma, indolent non-Hodgkin lymphomas, including chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), gastric mucosa-associated lymphoid tissue (MALT) lymphomas, and low-grade follicular
- non-seminomatous germ cell tumors, including mixed histology
- pulmonary nodules less than 7mm; or nodules that present on CT as a ground-glass or pneumonia-like appearance
- skin cancers, non-melanoma
- small cell carcinoma, except for initial staging of apparently limited disease
- urinary bladder cancer
- uterine/endometrial cancer

Non-Oncologic:

- Alzheimer's disease or dementia, including fronto-temporal dementia
- Huntington's disease
- psychiatric disorders
- Parkinsons disease
- stroke
- chronic osteomyelitis
- infection of hip arthroplasty
- fever of unknown origin

General Background

Positron emission tomography (PET) is a nuclear imaging examination showing molecular function and activity, and can often detect abnormalities before structural changes have occurred. Computed tomography (CT) and magnetic resonance imaging (MRI) provide morphological and structural information only. This is the primary difference between the CT and MRI scans, as compared to PET. In PET scans, subatomic particles are emitted from a radioactive substance given, usually with glucose, to the patient. Radioactive substance decay leads to the ejection of positive particles called positrons. Special crystals, called photomultiplier-scintillator detectors, within the PET scanner detect emitted gamma rays. Dedicated PET scanners consist of multiple detectors arranged in a full or partial ring around the patient. The camera records the millions of gamma rays being emitted, and a connected computer uses the information and algorithms to map an image of the area where the radioactive substance has accumulated. Different colors or degrees of brightness on a PET image represent different levels of tissue or organ function. For example, cancerous tissue, which uses more glucose than normal tissue, will absorb more of the substance and appear brighter than normal tissue on the PET images.

The primary radiopharmaceutical used in clinical PET for oncologic imaging is 2-deoxy-2-[F-18]fluoro-D-glucose (FDG). Images obtained with this tracer provide both qualitative and quantitative information about the regional distribution of glucose metabolism. Most malignancies have greater glucose utilization than do normal tissues and accordingly exhibit greater FDG uptake.

The American College of Radiology (ACR) defines the following:

- PET/CT fusion: The simultaneous display (superimposed or not) of registered PET and CT image sets. When superimposed, the image sets are typically displayed with the PET data color-coded onto the grayscale CT data.
- PET/CT registration: The process of taking PET and CT image sets that represent the same body volume and aligning them such that there is a voxel-by-voxel match for the purpose of combined image display (fusion) or image analysis.
- PET/CT scanner: A device that includes a single patient table for obtaining a CT scan or PET scan, or both. If the patient stays reasonably immobile between the scans, the PET and CT data are aligned and can be accurately fused (ACR, 2007).

U.S. Food and Drug Administration (FDA)

PET scanning devices are typically approved by the FDA via the 510(k)-approval process. Regulation of PET centers and PET radiopharmaceuticals is also addressed by the FDA. FDA approval for PET radiopharmaceuticals may be limited not only to a particular indication but also to the particular area where the compound is produced.

Literature Review - Oncology

The use of PET or PET/CT in oncology is supported by multiple sources in the medical literature including technology assessments, meta-analyses, medical specialty organization position statements and opinions, systematic reviews, governmental agency reports, as well as clinical studies and practice in the medical community. PET or PET/CT is not a first-line test but may be indicated when the findings on other imaging modalities are inconclusive and the results of PET or PET/CT are needed to determine clinical management.

Unknown or Occult Primary Cancer: PET or PET/CT may be performed if other imaging studies fail to identify the site of primary cancer (National Comprehensive Cancer Network[®] [NCCN[®]], 2011; Kwee, et al., 2009; Dong, et al., 2008; Pelosi, et al., 2006; Delgado-Bolton, et al., 2003).

Bone Cancer: PET or PET/CT is useful in Ewing's Sarcoma Family of Tumors (ESFT), osteosarcoma and for suspected metastases to the bone (NCCN[®], 2011; American College of Radiology [ACR] Appropriateness Criteria[®], 2010 and 2009; Tateishi, et al., 2010; Hawkins, et al., 2009; Kumar, et al., 2008; Hawkins, et al., 2005; Hawkins, et al., 2002).

Brain Cancer: PET or PET/CT is indicated to distinguish recurrent tumor from radiation necrosis in patients with known anaplastic tumors of glial origin (e.g., glioblastoma, anaplastic astrocytoma, and anaplastic oligodendroglioma) (NCCN[®], 2011; ACR Appropriateness Criteria[®], 2009; Terakawa, et al., 2008).

Breast Cancer: PET or PET/CT is useful in staging evaluation of unresectable clinical Stage III and Stage IV disease including if needed to clarify positive findings on other studies; in Stage IV disease to document response to therapy; and for the detection and evaluation of metastatic disease (NCCN[®], 2011; ACR Appropriateness Criteria[®], 2011 and 2009; Cooper, et al., 2011; Pennant, et al., 2010; Fletcher, et al., 2008; Facey, et al., 2007).

Cervical Cancer: PET or PET/CT may be performed in Stage IB1 or less to explain abnormal findings on other imaging studies; for staging of Stage IB2 or higher; when incidental cervical cancer is found in a hysterectomy specimen (regardless of size); and for restaging following radiation therapy (RT) if RT was the primary treatment therapy and if surgical salvage is an option (NCCN[®], 2011; ACR Appropriateness Criteria[®], 2010 and 2008; AHRQ, 2008; Choi, et al., 2010; Chung, et al., 2007; Schwarz, et al., 2007; Sironi, et al., 2006)

Colorectal Cancer: PET or PET/CT is indicated for staging when an abnormality on standard imaging suggests a possible solitary metastatic lesion that might be amenable to resection. Also, PET/CT is useful for restaging if postoperative carcinoembryonic antigen (CEA) or liver function tests (LFTs) remain elevated and other attempts at imaging are negative; to evaluate a potentially resectable metastatic lesion in order to confirm that it is resectable and to confirm absence of other sites of disease; or in differentiating local tumor recurrence from postoperative and/or post-radiation scarring (NCCN[®], 2011; Fletcher, et al., 2008; ACR Appropriateness Criteria[®], 2008; Scott, et al., 2008; Facey, et al., 2007).

Esophageal Cancer: PET or PET/CT is useful in staging and restaging if other imaging studies inconclusive and the individual is a candidate for aggressive therapy. Additionally, PET/CT can be performed if proceeding to an open biopsy is potentially very morbid (NCCN[®], 2011; Williams, et al., 2009; Lordick, et al., 2007; Cunningham, et al., 2006; American Gastroenterological Association/Wang, et al., 2005).

Gastric Cancer: PET or PET/CT may be performed in staging or restaging if other imaging inconclusive. PET is not indicated in T1 gastric cancers due to the risk of false positives. (NCCN[®], 2011; Oh, et al., 2011; Hur, et al., 2010; Mukai, et al., 2006; Chen, et al., 2005)

Head and Neck Cancer: PET or PET/CT is indicated in staging including ruling out distant metastases however, PET should not be used for imaging of a T1 lesion in sites with low risk of nodal spread, such as the larynx, when there is no clinical evidence of adenopathy. PET/CT may provide information for directing biopsy for patients who present with a neck mass when initial attempts to find a primary source are difficult. PET/CT may be useful in restaging, except if surgery only was the primary treatment modality (NCCN[®], 2011; Xu, et al., 2011; Fletcher, et al., 2008; Isles, et al., 2008; Facey, et al., 2007).

Hepatobiliary Cancer: PET or PET/CT may be useful for gallbladder cancer to detect the presence of lymph node involvement and distant metastatic disease in individuals with otherwise potentially resectable disease (NCCN[®], 2011; Moon, et al., 2008; Kim, et al., 2008)

Lung Cancer: PET or PET/CT may be performed for staging and restaging non-small cell lung cancer (NSCLC); for initial staging small cell lung cancer (SCLC) only, and only if no obvious extensive disease; and for evaluating pulmonary nodule(s) greater than or equal to 7 millimeters in size confirmed on CT and/or MRI (exception: lesions on previous CT demonstrate a ground-glass or pneumonia-like appearance) (NCCN[®], 2011; Fischer, et al., 2011; Maziak, et al., 2009; Fischer, et al., 2009; AHRQ, 2008; ACR Appropriateness Criteria[®], 2010 and 2008; Fletcher, et al., 2008; Facey, et al., 2007; American College of Chest Physicians/Alberts, et al., 2007; Cheng, et al., 2007; MacMahon, et al., 2005).

Lymphoma: PET or PET/CT is indicated for staging and restaging lymphoma (exception: indolent non-Hodgkin lymphomas, including chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), gastric mucosa-associated lymphoid tissue (MALT) lymphomas, and low-grade follicular). PET/CT is also useful for diagnosis if biopsy of an inaccessible body region is contemplated (NCCN, 2011; ACR Appropriateness Criteria[®], 2011 and 2010; Fletcher, et al., 2008; Facey, et al., 2007).

Malignant Pleural Mesothelioma: PET or PET/CT is useful in staging malignant pleural mesothelioma (NCCN, 2011; Wilcox, et al., 2009; Erasmus, et al., 2005).

Melanoma: PET or PET/CT may be performed in Stage III or Stage IV only, to address specific signs and symptoms not explained by other imaging studies (NCCN[®], 2011; Xing, et al., 2011; Fletcher, et al., 2008; Maubec, et al., 2007; Facey, et al., 2007; Brady, et al., 2006; Clark, et al., 2006).

Multiple Myeloma: PET or PET/CT may be indicated for staging or restaging if standard imaging and lab tests cannot define extent of disease and also for plasmacytoma (NCCN, 2011; Bartel, et al., 2009; Nanni, et al., 2008).

Neuroendocrine Tumors: PET or PET/CT may be performed for pheochromocytomas or any symptomatic neuroendocrine tumor when an apparently complete resection fails to resolve secretion of pathologic levels of hormones or neurotransmitter compounds (NCCN, 2011; Ozcan Kara, et al., 2011; Binderup, et al., 2010).

Ovarian Cancer: PET or PET/CT is useful in restaging recurrence if the individual is symptomatic and other imaging is inconclusive or negative (NCCN[®], 2011; ACR Appropriateness Criteria[®], 2009; Fulham, et al., 2009; Risum, et al., 2009; AHRQ, 2008).

Pancreatic Cancer: PET or PET/CT may be indicated if there is clinical suspicion that a pancreatic malignancy is a possible metastasis from an unknown primary, pre-operative staging or post-radiation therapy (NCCN[®], 2011; AHRQ, 2008; Fletcher, et al., 2008; Wakabayashi, et al., 2008; Heinrich, et al., 2005).

Prostate Cancer: PET or PET/CT may aid in restaging individuals presenting a progressive increase of prostate-specific antigen (PSA) (ACR Appropriateness Criteria[®], 2011, Picchio, et al., 2011; Minamimoto, et al., 2011; Castellucci, et al., 2011).

Renal/Kidney Cancer: PET or PET/CT is useful if recurrence or metastatic disease is suspected or if a positive PET will avoid an invasive biopsy (Revheim, et al., 2011; ACR Appropriateness Criteria[®], 2009 and 2008; Bouchelouche, et al., 2008).

Soft Tissue Sarcoma: PET or PET/CT is indicated: if the grade of an unresectable tumor remains in doubt after biopsy; when a solitary metastasis amenable to resection needs to be assessed; if needed to differentiate tumor from radiation or surgical fibrosis; to determine response to therapy. PET/CT may be useful in gastrointestinal stromal tumors (GIST) for initial staging and re-staging if there is documented recurrence (NCCN[®], 2011; ACR Appropriateness Criteria[®], 2011 and 2009; Tateishi, et al., 2007; Bastiaannet, et al., 2004; Ioannidis, et al., 2003).

Testicular cancer: PET or PET/CT may be performed in seminoma if post-chemotherapy residual mass (NCCN[®], 2011).

Thyroid Cancer: PET or PET/CT is useful in anaplastic cancer for diagnosis and staging, and in medullary cancer if calcitonin levels are elevated post-operatively. Also, PET or PET/CT may be useful in papillary, follicular and Hürthle cell cancer for restaging and monitoring if the patient was previously treated by thyroidectomy and radioiodine ablation, has a serum thyroglobulin (Tg) >10 nanograms per milliliter (ng/ml), and also has a negative iodine I-131 whole body (scintigraphy) scan (NCCN[®], 2011; Dong, et al., 2009; ACR Appropriateness Criteria[®] 2009; Salvatore, et al., 2008).

Urinary Bladder Cancer: There is a paucity of evidence in the peer-reviewed scientific literature supporting the use of PET or PET/CT in urinary bladder cancer.

Uterine/Endometrial Cancer: There is insufficient evidence in the peer-reviewed scientific literature to support the use of PET or PET/CT in uterine/endometrial cancer.

American College of Radiology (ACR): The ACR states that the information obtained by PET/CT has been shown to be more accurate in evaluating patients with known or suspected malignancy than either PET or CT alone or PET and CT obtained separately but interpreted together. FDG-PET and CT are proven diagnostic procedures. The advantages of having both PET and CT in a single device have resulted in rapid dissemination

of this technology in the United States. Techniques for registration and fusion of images obtained from separate PET and CT scanners have been available for several years and have been shown to improve diagnostic accuracy. According to the ACR, the goal of PET/CT imaging in oncology is to enable the interpreting physician to: 1) distinguish benign from malignant disease, 2) determine the extent of disease, 3) detect residual and recurrent tumors, 4) monitor the effect of therapy, and 5) guide therapy. The ACR notes the oncologic indications for combined PET/CT devices include, but are not limited to, the following:

- evaluating an abnormality detected by another imaging method to determine the level of metabolism and the likelihood of malignancy.
- searching for an unknown primary tumor when metastatic disease is discovered as the first manifestation of cancer.
- staging patients with known malignancy.
- monitoring the effect of therapy on known malignancies.
- determining if residual abnormalities on imaging studies following treatment represent tumor or post-treatment inflammation, fibrosis, or necrosis.
- detecting recurrence, especially in the presence of elevated tumor markers.
- assisting in treatment planning.

The ACR states that PET/CT does not work equally well for all tumors. A continuing review of the literature is recommended to determine the most effective applications (ACR, 2007).

Literature Review - Seizures

In addition to oncology, the use of PET is also indicated in individuals with refractory seizures. FDG-PET is the most established functional imaging modality in the evaluation of individuals with epilepsy. Presurgical epilepsy FDG-PET scans are typically performed in the interictal state with the goal of detecting focal areas of decreased metabolism, relative hypometabolism, that are presumed to reflect focal functional disturbances of cerebral activity associated with epileptogenic tissue. It is in the evaluation of medically refractory epilepsy surgery candidates with clinically suspected temporal lobe epilepsy that FDG-PET has been best proven to be valuable (ACR Appropriateness Criteria[®], 2011; Willmann, et al., 2007; Uijl, et al., 2007; Knowlton, 2006).

Literature Review - Cardiac

Nitrogen 13 ammonia and rubidium 82 are accepted myocardial perfusion agents for rest and stress PET myocardial imaging. FDG uptake in the myocardium has been validated as an indicator of myocardial viability. PET provides improved resolution compared with SPECT and allows gated analysis of wall motion and ejection fraction (Husmann, et al., 2008; Bateman, et al., 2006). PET provides prognostic value for predicting cardiac events (Yoshinaga, et al., 2006). Stress PET for ischemia may be conducted if an individual is unable to adequately exercise on a treadmill or similar device or has an uninterpretable resting EKG for assessment of ischemia in a standard exercise stress test and may have characteristics that can cause an inconclusive SPECT such as obesity or large or implanted breasts. Myocardial viability PET is useful if a previous study has shown severe left ventricular dysfunction in an individual who is under consideration for a revascularization procedure and there is a need to determine myocardial viability. Also, PET is indicated identifying and monitoring response to therapy for cardiac sarcoidosis (American College of Cardiology (ACC)/Hendel, et al. 2009; Society of Nuclear Medicine, 2008; Mehta, et al., 2008; Beanlands, et al., 2007; Sampson, et al., 2007; Yoshinaga, et al., 2006; Ishimaru, et al., 2005; ACC/ Klocke, et al., 2003)

Literature Review - Alzheimer's Disease (AD) and Dementia

Dementia is the loss of intellectual ability. Alzheimer's disease is the most common cause of dementia. The National Institute of Neurologic, Communicative Disorders and Stroke–Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) or the Diagnostic and Statistical Manual (DSM) diagnostic criterion are routinely used to diagnose dementia. The primary role of neuroimaging in the workup of patients with probable or possible AD is to exclude other significant intracranial abnormalities. PET is proposed for the differential diagnosis of fronto-temporal dementia (FTD, Pick's Disease). PET imaging has been shown to provide greater diagnostic accuracy when compared with clinical evaluations without functional neuroimaging (Small et al. 2006). PET accurately discriminates AD patients from normal subjects with a sensitivity of 96% and specificity of 100% (Mosconi et al. 2008). In patients presenting with cognitive symptoms of dementia, regional brain metabolism is a sensitive indicator of AD and of neurodegenerative disease in general (Silverman, et al., 2001). PET studies assessing regional glucose metabolism with FDG show the metabolic disturbance most prominent in the frontal and temporal lobes (Heiss, et al., 1991). Although PET and SPECT could help to make the differential diagnosis between AD and FTD, they are not recommended for routine use at the present time

(American Academy of Neurology/Knopman et al. 2001, 2004). Although some small observational studies state that PET can demonstrate changes in cerebral glucose metabolism, there remains a lack of direct evidence demonstrating any positive impact of PET imaging on longer-term health outcomes in the management of patients with suspected or known dementia.

Literature Review - Huntington's disease

Huntington's disease (Huntington's chorea) is an inherited, progressive, degenerative disease. It is diagnosed by a blood test that analyzes deoxyribonucleic acid (DNA) for the Huntington's chorea mutation in an individual who is exhibiting Huntington's chorea-like symptoms. Functional neuroimaging modalities such as PET imaging are currently utilized only in a research setting.

Literature Review - Psychiatric Disorders

Although differences in radiotracer uptake between patients with mood and other psychiatric disorders and healthy controls have been found, PET imaging does not play a role in the diagnosis and treatment of psychiatric disorders and remains a research tool. The American Psychiatric Association (APA) Practice Guideline for the Psychiatric Evaluation of Adults (Vergare, 2006) states that "in patients with schizophrenia and mood and anxiety disorders, structural and functional neuroimaging studies have reported differences between patients and healthy control persons as well as differences in some patient subgroups and in responders and nonresponders to some treatments. Nevertheless, the clinical utility of neuroimaging techniques for planning of individualized treatment has not yet been shown. Further research is needed to demonstrate a clinical role for structural and functional neuroimaging in establishing psychiatric diagnoses, monitoring illness progression, and predicting prognoses."

Literature Review - Parkinson disease

Parkinson's disease occurs when neurons in the substantia nigra die or become impaired. When approximately 80% of the dopamine-producing cells are damaged, the symptoms of Parkinson disease appear. Parkinson disease is diagnosed after thorough medical examination; there is no confirmatory blood test or imaging procedure. The key signs of Parkinson disease are tremor, slowness of movement, rigidity, and difficulty with balance. There is insufficient evidence in the current peer-reviewed scientific literature to support the use of PET in the diagnosis or treatment of patients with suspected or known Parkinson disease. PET is frequently used in the research setting. The American Academy of Neurology (AAN) Practice Parameter: Diagnosis and prognosis of new onset Parkinson disease states "there is insufficient evidence to support or refute the following as a means of distinguishing Parkinson disease from other parkinsonian syndromes: urodynamics, autonomic testing, urethral or anal electromyogram (EMG), MRI, brain parenchyma sonography, and FDG-PET" (Suchowersky, et al., 2006, reaffirmed October 2009).

Literature Review - Stroke

Stroke can be caused either by a clot obstructing the flow of blood to the brain (ischemic stroke) or by a blood vessel rupturing (hemorrhagic stroke) and preventing blood flow to the brain. Ischemic stroke accounts for about 83% of all cases. There is insufficient evidence in the peer-reviewed scientific literature to support the use of PET in the diagnosis or treatment of patients with suspected transient ischemic attack or stroke. The American Heart Association Recommendations for Imaging of Acute Ischemic Stroke (Latchaw, et al., 2009) does not address PET. The American Heart Association/American Stroke Association (AHA/ASA) Scientific Statement Definition and Evaluation of Transient Ischemic Attack states under vessel imaging, under extracranial disease, that recent reports with PET and MRI correlate plaque inflammation with plaque stability. At present, there is no defined clinical role for these findings (Easton, et al., 2009).

Other Indications

In a Decision Memo for Positron Emission Tomography (FDG) for Infection and Inflammation (2008), Centers for Medicare & Medicaid Services (CMS) proposes 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. The decision memo stated the scientific literature has significant limitations. CMS has therefore determined that FDG-PET for chronic osteomyelitis, infection of hip arthroplasty and fever of unknown origin is not reasonable and necessary.

Summary

The use of positron emission tomography (PET) or PET/computed tomography (CT) is supported in the peer-reviewed scientific literature for numerous oncologic scenarios. Also supported by the current peer-reviewed scientific literature is the use of PET in individuals with refractory seizures and with certain cardiac situations.

PET or PET/CT is not indicated for cancer screening; routine monitoring of therapy unless otherwise specified; surveillance of an asymptomatic individual previously treated for a malignant disease; adrenal carcinomas; carcinoid tumors; gastric cancer, T1 gastric cancers; head and neck, imaging of a T1 lesion in sites with low risk of nodal spread, such as the larynx, when there is no clinical evidence of adenopathy OR PET for restaging if surgery only was the primary treatment modality; hepatocellular carcinoma; lymphoma, indolent non-hodgkin's lymphomas, including chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), gastric mucosa-associated lymphoid tissue (MALT) lymphomas, and low-grade follicular; non-seminomatous germ cell tumors, including mixed histology; pulmonary nodules less than 7 mm or nodules that present on CT as a ground-glass or pneumonia-like appearance; non-melanoma skin cancers; small cell carcinoma, except for initial staging of apparently limited disease; urinary bladder cancer; and uterine/endometrial cancer.

There is insufficient evidence in the peer-reviewed scientific literature to support the clinical utility of PET in patients with suspected or known Alzheimer's disease, dementia (including fronto-temporal dementia), Huntington's disease, psychiatric disorders, Parkinson disease, stroke, chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin. Additional well-designed multicenter clinical trials are needed to establish optimal radiotracers as well as to clearly define the diagnostic utility of PET, compared to other established imaging modalities, for these indications.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

ONCOLOGIC

Covered when medically necessary:

CPT®* Codes	Description
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
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh.
78813	Positron emission tomography (PET) imaging; whole body.
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; limited area.
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; Skull base to mid-thigh.
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; Whole body.

ICD-9-CM Diagnosis Codes	Description
150.0-150.9	Malignant neoplasm of esophagus
151.0-151.9	Malignant neoplasm of stomach
153.0-153.9	Malignant neoplasm of colon
157.0-157.9	Malignant neoplasm of pancreas
154.0	Malignant neoplasm of rectosigmoid junction
154.1	Malignant neoplasm of rectum
155.2	Malignant neoplasm of liver, not specified as primary or secondary

162.3	Malignant neoplasm of upper lobe, bronchus or lung
162.4	Malignant neoplasm of middle lobe, bronchus, or lung
162.5	Malignant neoplasm of lower lobe, bronchus or lung
162.8	Malignant neoplasm of other parts of bronchus or lung
162.9	Malignant neoplasm of bronchus and lung, unspecified
163.0-163.9	Malignant neoplasm of pleura
170.0-170.9	Malignant neoplasm of bone and articular cartilage
172.0-172.9	Malignant neoplasm of skin
174.0-174.9	Malignant neoplasm of female breast
175.0-175.9	Malignant neoplasm of male breast
176.1	Malignant neoplasm of soft tissue
180.0-180.9	Malignant neoplasm of cervix
183.0	Malignant neoplasm of ovary
185	Malignant neoplasm of prostate
186.0-186.9	Malignant neoplasm of testis
189.0	Malignant neoplasm of kidney, except pelvis
189.1	Malignant neoplasm of renal pelvis
191.0-191.9	Malignant neoplasm of brain
193	Malignant neoplasm of thyroid
195.0	Malignant neoplasm of head, face and neck
197.2	Secondary malignant neoplasm of pleura
197.5	Secondary malignant neoplasm of large intestine and rectum
197.7	Secondary malignant neoplasm of liver, specified as secondary
197.8	Secondary malignant neoplasm of othr digestive organs and spleen
198.0	Secondary malignant neoplasm of kidney
198.3	Secondary malignant neoplasm of brain and spinal cord
198.5	Secondary malignant neoplasm of bone and bone marrow
198.6	Secondary malignant neoplasm of ovary
198.81	Secondary malignant neoplasm of breast
198.82	Secondary malignant neoplasm of other genital organs
198.89	Secondary malignant neoplasm of other specified sites
200.00-200.88	Lymphosarcoma and reticulosarcoma and other specified malignant tumors of lymphatic tissue
201.00-201.98	Hodgkin's disease
202.00-202.98	Other malignant neoplasms of lymphoid and histiocytic tissue
203.00-203.02	Multiple myeloma
209.30-209.36	Malignant poorly differentiated neuroendocrine carcinoma, any site
209.70-209.79	Secondary neuroendocrine tumors
238.6	Neoplasm of uncertain behavior of plasma cells
518.89	Other diseases of lung, not elsewhere classified
785.6	Enlargement of lymph nodes
V58.11	Encounter for antineoplastic chemotherapy

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
155.0	Malignant neoplasm of liver, primary
156.0	Malignant neoplasm of gallbladder
173.0-173.9	Other malignant neoplasm of skin

179	Malignant neoplasm of uterus, part unspecified
182.0-182.8	Malignant neoplasm of body of uterus
188.0-188.9	Malignant neoplasm of bladder
194.0	Malignant neoplasm of adrenal gland
198.1	Secondary malignant neoplasm of other urinary organs
198.7	Secondary malignant neoplasm of adrenal gland
209.00-209.03	Malignant carcinoid tumors of the small intestine
209.10-209.17	Malignant carcinoid tumor of the large intestine, unspecified portion
209.20-209.29	Malignant carcinoid tumor of other and unspecified sites
209.40-209.43	Benign carcinoid tumors of the small intestine
209.50-209.57	Benign carcinoid tumors of the appendix, large intestine and rectum
209.60-209.69	Benign carcinoid tumor of other and unspecified sites
V10.00-V10.91	Personal history of malignant neoplasm
V76.0-V76.9	Special screening for malignant neoplasms

HCPCS Codes	Description
G0219	PET imaging whole body; full and partial ring PET scanners only, for non-covered indications
G0235	PET imaging, any site, not otherwise specified
G0252	PET imaging, full and partial-ring PET scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes)
S8085	Fluorine-18 fluorodeoxyglucose (F-18 FDG) imaging using dual-head coincidence detection system (nondedicated PET scan)

SEIZURES

Covered when medically necessary:

CPT^{®*} Codes	Description
78608	Brain imaging, positron emission tomography (PET); metabolic evaluation
78811	Positron emission tomography (PET) imaging; limited area
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; limited area.

ICD-9-CM Diagnosis Codes	Description
345.00-345.91	Epilepsy and recurrent seizures
780.33	Post traumatic seizures

Experimental/Investigational/Unproven/Not Covered:

HCPCS Codes	Description
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G0235	PET imaging, any site, not otherwise specified
S8085	Fluorine-18 fluorodeoxyglucose (F-18 FDG) imaging using dual-head coincidence detection system (nondedicated PET scan)

CARDIAC

Covered when medically necessary:

CPT®* Codes	Description
78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation
78491	Myocardial imaging, positron emission tomography (PET), perfusion; single study at rest or stress
78492	Myocardial imaging, positron emission tomography (PET), perfusion; multiple studies at rest and/or stress

ICD-9-CM Diagnosis Codes	Description
413.1	Prinzmetal angina
413.9	Other and unspecified angina pectoris
414.00- 414.07	Coronary atherosclerosis
425.0-425.9	Cardiomyopathy
428.0-428.9	Heart failure
786.05	Shortness of breath
786.50	Chest pain, unspecified
786.59	Other chest pain
794.30	Abnormal cardiovascular function study, unspecified
794.31	Abnormal electrocardiogram [ECG] [EKG]

Experimental/Investigational/Unproven/Not Covered:

HCPCS Codes	Description
G0235	PET imaging, any site, not otherwise specified
S8085	Fluorine-18 fluorodeoxyglucose (F-18 FDG) imaging using dual-head coincidence detection system (nondedicated PET scan)

OTHER

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
290.0 – 319	Psychiatric disorders
331.0	Alzheimer's disease
331.11- 331.19	Frontotemporal dementia
332.0-332.1	Parkinson's disease
333.4	Huntington's disease
434.91	Unspecified cerebral artery occlusion with cerebral infarction
730.10- 730.19	Chronic osteomyelitis
780.60	Fever of unknown origin

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	6/15/2008	0091	Positron Emission Tomography (PET)

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