MEDICAL POLICY

SUBJECT: POSITRON EMISSION TOMOGRAPHY (PET) NON-ONCOLOGIC APPLICATIONS

POLICY NUMBER: 6.01.07
CATEGORY: Technology Assessment

EFFECTIVE DATE: 10/18/01
REVISED DATE: 01/17/02, 10/16/02, 01/16/03, 10/15/03, 10/20/04, 10/20/05, 11/16/06, 08/16/07, 08/21/08, 09/17/09, 12/16/10, 01/20/11, 12/15/11, 01/17/13, 05/22/14, 02/19/15

• If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.
• Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.
• Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.

POLICY STATEMENT:

I. Based upon our criteria and assessment of peer reviewed literature, FDG positron emission tomography (PET) using a full ring dedicated PET scanner is considered medically appropriate for the following indications:

A. Epileptic Seizures:
   1. Seizure disorders with failed response to medical therapy when being considered for resection of suspected epileptogenic focus in a region of the brain accessible by surgery.
   2. When conventional techniques for seizure localization provide data that suggests a seizure focus but are not sufficiently conclusive to permit surgery.

B. Movement disorders:
   1. Suspected Huntington’s chorea when MRI is non diagnostic and genetic testing is inconclusive; or
   2. Progressive ataxia of undetermined etiology.

C. Chronic cerebrovascular disorders:
   1. Chronic internal carotid artery occlusion, prior to surgical intervention; or

D. Chronic osteomyelitis when bone scan and/or MRI is non-diagnostic.

E. To differentiate Alzheimer’s disease (AD) from frontotemporal lobe dementia (FTLD) in patients with a recent diagnosis of dementia and all of the following:
   1. Meets diagnostic criteria for AD and FTLD; and
   2. Has a documented cognitive decline of at least 6 months; and
   3. Evaluation has ruled out specific alternative neurodegenerative diseases or causative factors; and
   4. Cause of clinical symptoms is uncertain; and
   5. The results are expected to help clarify the diagnosis between FTLD and AD and help guide future treatment.

II. Based upon our criteria and assessment of the peer-reviewed literature, the use of beta amyloid PET imaging using amyloid specific tracers (e.g., Amyvid, Vizamyl) for dementia has not been medically proven to be effective and is considered investigational.

III. Based upon our criteria and assessment of the peer-reviewed literature, the use of PET scanning has not been medically proven to be effective and is considered investigational for all other indications, including, but not limited to:

A. Anorexia Nervosa;
B. Auto-immune disorders with CNS manifestations, including Behcets’ syndrome, lupus erythematosus;
C. Cerebral blood flow in newborns;
D. Cerebrovascular diseases, including arterial occlusive disease (arteriosclerosis, atherosclerosis), carotid artery disease, cerebral aneurysm, cerebrovascular malformations (AVM) hemorrhage, infarct, ischemia;
E. Chronic fatigue syndrome;
F. Degenerative motor neuron diseases, including amyotrophic lateral sclerosis (ALS), Friedreich’s ataxia, olivopontocerebellar atrophy, Parkinson’s disease, progressive suprnuclear palsy, Shy-Drager syndrome, spinocerebellar degeneration, Steele-Richardson-Olszewski disease, Tourette’s syndrome;
G. Dementias, including, dementia with Lewy-bodies, multi-infarct dementia, Pick’s disease, presenile dementia, Alzheimer’s disease, and frontotemporal dementia except as listed in Policy Statement IE;

H. Demyelinating diseases, such as multiple sclerosis;

I. Developmental, congenital, or inherited disorders, including adrenoleukodystrophy, Down’s syndrome, Kinky-hair disease (Menkes’ syndrome), Sturge-Weber syndrome (encephalofacial angiomatosis), and the phakomatoses;

J. Diagnosis and non-surgical treatment of epilepsy and convulsive disorders;

K. Fever of unknown origin, infectious process;

L. Giant cell arteritis;

M. Inflammatory bowel disease;

N. Joint replacement follow-up;

O. Migraines;

P. Mycobacterium infection;

Q. Nutritional or metabolic diseases and disorders, including acanthocytes, hepatic encephalopathy, hepatolenticular degeneration, metachromatic leukodystrophy, mitochondrial disease, and subacute necrotizing encephalomyelopathy;

R. Post-traumatic stress disorder;

S. Psychiatric disease and disorders, including affective disorders, depression, obsessive-compulsive disorder, psychomotor disorders, schizophrenia;

T. Pulmonary diseases, including adult respiratory distress syndrome, diffuse panbronchiolitis, emphysema, obstructive lung disease, and pneumonia;

U. Pyogenic infections, including aspergillosis and encephalitis;

V. Sarcoidosis; (cardiac sarcoid - please refer to Corporate Medical Policy #6.01.41 regarding Positron Emission Tomography (PET) Cardiac Applications)

W. Sick building syndrome;

X. Spondylodiscitis;

Y. Substance abuse, including CNS effects of alcohol, cocaine, and heroin;

Z. Trauma, including brain injury and carbon monoxide poisoning;

AA. Vasculitis;

BB. Vegetative versus “locked-in” state, differentiation;

CC. Viral infections, including acquired immune deficiency syndrome (AIDS), AIDS dementia complex, Creutzfeldt-Jakob syndrome, progressive multifocal leukoencephalopathy, progressive rubella encephalopathy, and subacute sclerosing panencephalitis.

III. MOLECULAR COINCIDENCE DETECTION is considered investigational as an alternative to PET. Refer to Corporate Medical Policy #6.01.29 regarding Positron Emission Tomography-Oncologic Applications. Refer to Corporate Medical Policy #6.01.41 regarding Positron Emission Tomography (PET) Cardiac Application Refer to Corporate Medical Policy #11.01.03 regarding Experimental or Investigational Services.

POLICY GUIDELINES:
The Federal Employees Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.
DESCRIPTION:

Positron emission tomography (PET) is an imaging technology that can reveal metabolic information in various tissue sites. The metabolic information is what distinguishes it from other imaging modalities such as magnetic resonance imaging (MRI) and computed tomography (CT) that provide primarily anatomic information. PET scans measure concentrations of radioactive chemicals that are partially metabolized in the body and are based on the use of positron emitting radionuclide tracers coupled to organic molecules, such as glucose, ammonia, or water. Dedicated PET scanners consist of multiple detectors arranged in a full or partial ring around the patient.

A variety of radiotracers are used for PET scanning including fluorine-18, rubidium-82, ammonia N-13, carbon-11, oxygen-15 and nitrogen-13. Fluorine-18 is often coupled with fluoredeoxyglucose (FDG) as a means of detecting glucose metabolism, which in turn reflects the metabolic activity, and thus viability, of the target tissue. Because of their short half-life, tracers must be made locally. With exception of fluorine and rubidium all the tracers must be manufactured with an on-site cyclotron.

Florbetapir (Amyvid™, Avid Radiopharmaceuticals), a radioactive dye for visualization of amyloid plaque in the brain, was approved by the FDA in 2012. The FDA document prepared for the advisory committee meeting indicated that while florbetapir may detect pathology, there could be no claim of disease detection, since beta amyloid aggregates can be found in cognitively normal elderly individuals, as well as patients with AD. Amyvid™ is indicated for PET (positron emission tomography) imaging of the brain to estimate beta-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer’s disease and other causes of cognitive decline. A second radioactive dye Fluemetamol F18 injection (Vizamyl™, GE Healthcare), was approved by the FDA in October, 2013. Fluemetamol F18 is not indicated to predict the development of AD or to check how patients respond to treatment for AD. Fluemetamol F18 PET images should be interpreted only by health care professionals who successfully complete training in an image interpretation program.

Molecular Coincidence Detection (MCD). PET using a gamma camera is a general term describing imaging techniques in which a SPECT gamma camera is used to detect photons emitted from decaying positrons associated with the metabolism of radiolabeled FDG. It produces images similar to those produced by a PET scanner. This technique is also referred to as FDG-SPECT, metabolic SPECT, FDG-collimated SPECT or dual-head-coincidence SPECT (FDG-DHC-SPECT). Researchers have investigated whether the more readily available SPECT cameras, routinely used to detect low-energy photons, could be adapted for use to detect higher energy photons.

FDG-collimated-SPECT screens out lower energy photons, thus only detecting the high-energy photons; however this approach decreases sensitivity and resolution compared to that associated with PET scanners. FDG-dual head coincidence-SPECT, operated in the “coincidence mode,” more closely resembles a PET scanner. However, the lower number of detectors in the SPECT approach compared to the full or partial ring of detectors used in PET imaging will result in a relative loss of sensitivity and resolution.

RATIONALE:

The U.S. Food and Drug Administration (FDA) has approved the scanner and imaging hardware for PET as being substantially equivalent to x-ray computed tomography (CT). The FDA requires PET radiotracers to be approved through a new drug approval (NDA) process. Because PET radiotracers have an extremely short half-life, they must be produced in the clinical setting. The FDA also intends to regulate drug manufacturing processes in PET facilities. In 1991 the FDA approved the use of Rubidium 82 (Rb 82) as a myocardial perfusion tracer and in 1999 approved the use of ammonia N-13 as a myocardial perfusion tracer.

Clinical evidence supports that the use of Rubidium 82 (Rb-82) PET and ammonia N-13 PET scans in clinical practice has the potential to improve net health outcomes through changes in patient management. Studies demonstrate that both tracers have high reliability and validity in the evaluation of myocardial perfusion.

Clinical evidence is inadequate to support the use of FDG PET for routine use in the diagnostic evaluation of dementia. Although FDG PET scanning appears to have promise for use as an adjunct to clinical diagnosis of Alzheimer’s disease,
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HCPCS:
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
A9555 Rubidium Rb-82, diagnostic, per study dose, up to 60 millicuries
A9599 (E/I) Radiopharmaceutical, diagnostic, for beta-amyloid positron emission tomography (pet) imaging, per study dose
S8085 (E/I) Fluorine-18 fluorodeoxyglucose (F-18 FDG) imaging using dual-head coincidence detection system (non-dedicated PET scan)

ICD9:
225.0 Benign neoplasm of brain
237.5 Neoplasm of uncertain behavior of brain and spinal cord
239.6 Neoplasm of unspecified nature, brain
345.10-.11 Generalized convulsive epilepsy (code range)
345.3 Grand Mal status
345.40-.41 Partial epilepsy, with impairment of consciousness
345.50-.51 Partial epilepsy, without impairment of consciousness
345.70-.71 Epilepsia partialis continual
345.90-.91 Epilepsy, unspecified

ICD10:
D33.0-D33.2 Benign neoplasm of brain and other parts of central nervous system (code range)
D43.0-D43.4 Neoplasm of uncertain behavior of brain and spinal cord (code range)
D49.6 Neoplasm of unspecified behavior of brain
G40.001-G40.219 Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset (code range)
G40.301-G40.3119 Generalized idiopathic epilepsy and epileptic syndromes (code range)
G40.901-G40.919 Epilepsy, unspecified (code range)

REFERENCES:


Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Beta amyloid imaging with positron emission tomography (PET) for evaluation of suspected Alzheimer's Disease or other causes of cognitive decline. TEC Assessments 2013; 27:5.


* key article

**KEY WORDS:**
FDG PET, FDG SPECT, Gamma Camera, Ammonia N-13, Rubidium 82.

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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There is currently a National Coverage Determination (NCD) for PET scans. Please refer to the following NCD website for Medicare Members:

There is currently a National Coverage Determination (NCD) for FDG PET for Dementia and Neurodegenerative Diseases. Please refer to the following NCD website for Medicare Members:

There is currently a National Coverage Determination (NCD) for Beta Amyloid Positron Tomography in Dementia and Neurodegenerative Disease. Please refer to the following NCD website for Medicare Members: