MEDICAL POLICY

SUBJECT: POSITRON EMISSION TOMOGRAPHY (PET) CARDIAC APPLICATIONS
POLICY NUMBER: 6.01.41
CATEGORY: Technology Assessment
EFFECTIVE DATE: 04/19/12
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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 cardiac indications using radiotracer FDG rubidium 82 (Rb-82) or nitrogen ammonia 13 (ammonia N-13):
   
   A. To assess myocardial perfusion and thus diagnose coronary artery disease in patients with indeterminate SPECT imaging.
   
   B. May be used in place of SPECT imaging for patients with conditions that may cause significant attenuation problems with SPECT; such as morbid obesity (Body Mass Index greater than 40), chest wall deformity, or silicone breast implants.
   
   C. To assess myocardial viability in patients with severe left ventricular dysfunction as a technique to determine candidacy for a revascularization procedure.
   
   D. Clinical suspicion of cardiac sarcoid in patients unable to undergo MRI scanning (e.g., patients with pacemakers, automatic implanted cardioverter-defibrillators (AICDs), or other metal implants).

II. **MOLECULAR COINCIDENCE DETECTION** is considered **investigational** as an alternative to PET. Refer to Corporate Medical Policy #6.01.07 regarding Positron Emission Tomography-NonOncologic Applications. Refer to Corporate Medical Policy #6.01.29 regarding Positron Emission Tomography-Oncologic Applications. Refer to Corporate Medical Policy #11.01.03 regarding Experimental or Investigational Services.

POLICY GUIDELINES:

I. PET scanning for cardiac indications is unlikely to be a cost-effective alternative to other invasive tests (e.g. angiography) or to another non-invasive test (e.g., stress echocardiography, SPECT scanning).

II. 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 fluoreodeoxyglucose (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.

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PET has emerged as an important alternative perfusion imaging modality due to recent shortages of molybdenum-99/technetium-99m (99mTc). It is a well-established modality for evaluation of myocardial blood flow (MBF) as well as, for assessment of myocardial metabolism and viability in patients with ischemic left ventricular (LV) dysfunction. Potential future applications of PET for plaque and molecular imaging and for use in inflammatory conditions.

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.

In 2003, the American college of Cardiology (ACC) and the American Heart Association (AHA) published updated guidelines for cardiac radionuclide imaging. Cardiac applications of PET scanning were included in these guidelines. Data and consensus opinion favors limiting a pet scan to those situations in which a prior SPECT scan is inconclusive. The guidelines note, “Overall, because of the higher resolution of PET and the routine application of attenuation correction, it is probable that sensitivity and specificity are slightly higher for pet compared with SPECT, but there is not a robust database of head-to-head comparisons.” The ACC/AHA guidelines categorize specific indications for PET scanning to: Class I (evidence and/or general agreement that a given procedure or treatment is useful and effective), Class IIa (conflicting evidence or a divergence of opinion but the weight of the evidence/opinion is in favor of usefulness/efficacy), Class IIb (similar to IIa except that the usefulness/efficacy is less well established by evidence/opinion) or Class III (not useful/effective and may be harmful. The medically appropriate indications for PET myocardial perfusion studies in this policy are consistent with Class I and class IIa indications in the ACC guidelines. For comparison of SPECT and PET, the guidelines indicate (1) To identify extent, severity and location of ischemia: SPECT is Class I, PET is Class IIa. (2) Repeat test 3-5 years after revascularization in selected high-risk asymptomatic patients: SPECT is Class IIa, none given for PET. (3) Initial test in patients who are considered to be at high risk: SPECT is Class IIa, none given for PET. (4) Myocardial perfusion PET when prior SPECT study has been found to be equivocal for diagnostic or risk stratification purposes: PET is Class I.

CODES:

| Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract. |
| CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY. |
| Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates. |
| Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN). |
| CPT: 78459 Myocardial imaging, (PET), metabolic evaluation |
| 78491 Myocardial imaging, positron emission tomography, (PET), perfusion; single study at rest or stress |
| 78492 multiple studies at rest and/or stress |
| HCPCS: A9526 Nitrogen N-13 ammonia, diagnostic, per study dose, up to 40 millicuries |

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Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose, up to 45 millicuries
Rubidium Rb-82, diagnostic, per study dose, up to 60 millicuries
Fluorine-18 fluorodeoxyglucose (F-18 FDG) imaging using dual-head coincidence detection system (non-dedicated PET scan)
Coronary atherosclerosis
Heart disease, unspecified (includes left ventricular dysfunction)

ICD-9:
414.00-.05 Coronary atherosclerosis
429.9 Heart disease, unspecified (includes left ventricular dysfunction)

REFERENCES:


* 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**


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