MEDICAL POLICY

Excellus

SUBJECT: POSITRON EMISSION TOMOGRAPHY (PET) CARDIAC APPLICATIONS	**EFFECTIVE DATE: 04/19/12** **REVISED DATE: 04/18/13, 02/20/14**
POLICY NUMBER: 6.01.41	
CATEGORY: Technology Assessment	**PAGE: 1 OF: 4**

- ***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-defbrillators (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:

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 scanning can be used to identify coronary artery disease by identifying perfusion defects, to assess myocardial viability in patients with left ventricular dysfunction as a technique to determine candidacy for a revascularization procedure and may potentially be used to measure myocardial blood flow and blood flow reserve. Cardiac PET is also being studied for evaluation of coronary artery inflammation. 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.

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 2009, the American College of Cardiology (ACC) and the American Heart Association (AHA) published updated guidelines for cardiac radionuclide imaging. Sixty-seven clinical scenarios were developed by a writing group and scored by a separate technical panel on a scale of 1 to 9 to designate appropriate use, inappropriate use, or uncertain use. In general, use of cardiac RNI for diagnosis and risk assessment in intermediate- and high-risk patients with coronary artery disease (CAD) was viewed favorably, while testing in low-risk patients, routine repeat testing, and general screening in certain clinical scenarios were viewed less favorably. Additionally, use for perioperative testing was found to be inappropriate except for high selected groups of patients. It is anticipated that these results will have a significant impact on physician decision making, test performance, and reimbursement policy, and will help guide future research.

2011 Appropriateness Criteria from the American College of Radiology (ACR) considers both SPECT and PET to be appropriate for the evaluation of patients with a high probability of coronary artery disease. (15) ACR states that PET perfusion imaging has advantages over SPECT, including higher spatial and temporal resolution. Routine performance of both PET and SPECT are not necessary.

CODES:	Number	Description

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
	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
	S8085 **(E/I)**	Fluorine-18 fluorodeoxyglucose (F-18 FDG) imaging using dual-head coincidence detection system (non-dedicated PET scan)
ICD-9:	414.00-414.05	Coronary atherosclerosis
	429.9	Heart disease, unspecified (includes left ventricular dysfunction)
ICD10:	I25.10-I25.119	Atherosclerotic heart disease of native coronary artery with or without angina pectoris (code range)
	I25.700-I25.739	Atherosclerosis of autologous vein or artery coronary artery bypass graft(s) with angina pectoris (code range)
	I25.790-I25.799	Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris (code range)
	I25.810	Atherosclerosis of coronary artery bypass graft(s) without angina pectoris
	I51.9	Heart disease, unspecified
	I52	Other heart disorders in diseases classified elsewhere

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* key article

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

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: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=211&ncdver=4&bc=AgAAgAAAAAAA&.