MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Positron Emission Tomography (PET) for Cardiac Applications**
Policy Number	**6.01.41**
Category	**Technology Assessment**
Original Effective Date	**04/19/12**
Committee Approval Date	**04/18/13, 02/20/14, 03/19/15, 02/18/16, 02/16/17, 02/15/18, 03/21/19, 03/19/20, 05/20/21, 03/24/22, 03/23/23, 06/22/23**
Current Effective Date	**07/01/23**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, a positron emission tomography (PET) scan using one of the following radiotracers fluoreodeoxyglucose (FDG), rubidium 82 (Rb-82) or nitrogen-ammonia 13 (ammonia N-13) is considered **medically appropriate** for the following cardiac indications (CPT code: 78429, 78430, 78431, 78432, 78433, 78459, 78491, 78492):

   A. To assess myocardial perfusion and, thus, diagnose coronary artery disease (CAD) in patients with indeterminate single-photon emission computerized tomography (SPECT) imaging.
   B. In place of SPECT imaging for patients with conditions that may cause significant attenuation problems with SPECT such as severe obesity (Body Mass Index greater than 40 kg/m^2), chest wall deformity, large breasts, breast implants, or incapable of exercise due to physical (musculoskeletal or neurological) inability to achieve target heart rate (refer to Policy Guideline II).
   C. To conduct routine, post-heart transplant assessment of transplant CAD.
   D. To assess myocardial viability in patients with severe left ventricular dysfunction as a technique to determine candidacy for a revascularization procedure.
   E. To confirm 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) and monitor therapy.

II. Based upon our criteria and assessment of the peer-reviewed literature, FDG PET/CT (CPT code: 78429) is considered **medically appropriate** for use in the assessment of suspected prosthetic heart valve endocarditis when echocardiography and/or transesophageal echocardiography are equivocal or nondiagnostic and suspicion remains high and **ALL** of the following criteria are met:

   A. C-reactive protein level of at least 40 mg/L; and
   B. No evidence of prolonged antibiotic therapy; and

C. The implantation was at least three months ago and there is no evidence of surgical adhesives used during the valve implantation.

III. Based upon our criteria and assessment of the peer-reviewed literature, FDG PET/CT (CPT code: 78429) is considered **medically appropriate** for use in the assessment of suspected left ventricular assist device (LVAD) infection if other studies and examination remain inconclusive.

IV. Based upon our criteria and assessment of the peer-reviewed literature, absolute quantification of myocardial blood flow (AQMBF) with PET (CPT code: 78434) is considered **medically appropriate** when criteria has been met per Policy Statement I for primary study Myocardial PET rest/stress perfusion (CPT code: 78492 or 78431).

Refer to Corporate Medical Policy #6.01.07 Positron Emission Tomography (PET) Non-Oncologic Applications.

Refer to Corporate Medical Policy #6.01.29 Positron Emission Tomography (PET) Oncologic Applications.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services.

POLICY GUIDELINES

I. 3D rendering, (CPT code 76376 or 76377), should not be billed in conjunction with PET imaging.

II. Target heart rate is calculated as 85% of maximum age predicted heart rate (MPHR). MPHR is estimated as 220 minus the individual's age.

III. Absolute quantification of myocardial blood flow (AQMBF) at rest with stress in ml/g/min and the calculation of myocardial perforation reserve (the ration of stress to rest flow) can be used for diagnosis and prognosis of coronary artery disease and cardiac endothelial dysfunction that can be seen in diabetes, left ventricular hypertrophy and heart transplantation vasculopathy.

IV. The American Society of Nuclear Medicine, the American College of Cardiology and the Society of Nuclear Medicine and Molecular Imaging agree that to minimize variables AQMBF should only be considered when performed by (all):

A. Laboratories that are Intersocietal Accreditation Commission (IAC), American College of Radiology (ACR), or Joint Commission cardiac PET accredited.
B. Interpreting physician(s) must be board certified in Nuclear Cardiology (CBNC), Nuclear Medicine (ABNM), or Radiology (ABR) and have additional training in measuring AQMBF.
C. Individual laboratories should have a standard protocol (same tracer, camera, software, stressor, model etc.) for use for all patients.
D. Reports should contain rest myocardial blood flow (MBF) and stress MBF in ml/g/min, and myocardial blood flow reserve (MBFR) reported as the ratio of the stress to rest MBF (with normal limits).
E. Laboratories should have the ability to perform rate-pressure-product (RPP) correction and include mention of the true measured resting MBF and MBFR as well as the RPP-corrected resting MBF and RPP-corrected MBFR in the conclusions of the report.

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), which 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 potentially 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. Tracers must be made locally because of their short half-life. With the exception of fluorine and rubidium, all of 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 are for plaque and molecular imaging and for use in inflammatory conditions.

Infective endocarditis (IE) is associated with significant morbidity and mortality and its clinical presentation is highly variable. IE is usually diagnosed using the modified Duke criteria, which rely on the presence of positive blood cultures and typical echocardiographic findings. The role of FDG PET/CT in assessing and managing infective endocarditis (IE), particularly device-related IE, is being investigated as FDG is taken up by inflammatory cells at the site of infection and/or inflammation. Given the high spatial and target-to-background contrast resolution of FDG PET/CT, recent publications including the TEPvENDO clinical trial (NCT02287792) advocate the use of FDG PET/CT for the detection of cardiac implantable device infections, as well as prosthetic valve endocarditis. A potential advantage of FDG PET/CT is in its detection of inflammatory cells early in the infectious process, before morphological damages occur.

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. As PET radiotracers have an extremely short half-life, they must be produced in the clinical setting. The FDA regulates 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-risk 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.

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

The 2015 European Society of Cardiology (ESC) guidelines included FDG PET/CT as a major criterion for the diagnosis of prosthetic valve endocarditis (PVE). The ESC also stated that FDG PET/CT may help reduce the number of misdiagnosed infective endocarditis classified in the ‘‘possible’’ category of the modified Duke criteria and may help visualize peripheral emboli and metastatic infective events. Two recent systematic reviews and meta-analyses (Tam et al. 2020 and Ten Hove et al. 2020) assessed the performance of 18F-FDG PET/CT in diagnosing VAD-related infections, and both reported high accuracy of this dual-modality imaging system, supported by pooled sensitivities of 92 percent and 95 percent, and specificities of 83 percent and 91 percent, respectively.

In 2021, the American College of Cardiology (ACC) in collaboration with several other medical societies published a guideline on the evaluation and diagnosis of chest pain. Per the guideline, after an acute coronary syndrome has been ruled out, PET or SPECT myocardial perfusion imaging (MPI) allows for detection of perfusion abnormalities, measures of left ventricular function, and high-risk findings, such as transient ischemic dilation. The guideline goes on to state that: "For PET, calculation of myocardial blood flow reserve (MBFR, the ratio of peak hyperemia to resting myocardial blood flow) adds diagnostic and prognostic information over MPI data."

In 2021, the American Society of Nucular Cardiology and the Society of Nuclear Medicine and Molecular Imaging published practical guides for interpreting and reporting cardiac positron emission tomography (PET) measurements of myocardial blood flow. The guide states quantification of the MBF can and should be performed in appropriate patients as an adjunct to spacially relative myocardial perfusion imaging (MPI). The guide addresses a step-by step approach to PET MBF quality control for interpreting physicians and the need to understand software (retention and compartment models). The compartment model approach for calculating MBF requires a series of dynamic images, compartment models are suited to newer generation list-mode systems. The retention model approach for MBF assumes that tracer retention can be determined by the blood pool concentration of the tracer and the irreversible extraction of the tracer from the blood pool onto the myocardium. The net retention software programs work on a wide range of instrumentation from dedicated PET frame mode to modern list-mode acquisition systems.

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 Codes

Code	Description
78429	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study; with concurrently acquired computed tomography transmission scan
78430	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability)
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan

Code	Description
78434	Absolute quantitation of myocardial blood flow (AQMBF), positron emission tomography (PET), rest and pharmacologic stress (List separately in addition to code for primary procedure)
78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s]; when performed), single study
78491	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic)
78492	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic)

HCPCS Codes

Code	Description
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)

ICD10 Codes

Code	Description
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 or nonautologous 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 for Perfusion of the Heart. Please refer to the following NCD website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=292&ncdver=2&bc=AAAAgAAAAAAA&]

There is currently a National Coverage Determination (NCD) for FDG PET for Myocardial Viability. Please refer to the following NCD website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=298&ncdver=1&DocID=220.6.8&ncd_id=220.6.8&ncd_version=1&basket=ncd%25253A220%25252E6%25252E8%25253A1%25253AFDG+PET+for+Myocardial+Viability&bc=gAAAAAgAAAAAAA%3d%3d&]