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Subject: Positron Emission Tomography (PET) Cardiac Applications

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DESCRIPTION:

Positron emission tomography (PET) scans are based on the use of positron emitting radionuclide tracers, which simultaneously emit 2 high energy photons in opposite directions. These photons can be simultaneously detected (referred to as coincidence detection) by a PET scanner, consisting of multiple stationary detectors that encircle the thorax. Compared to single photon emission photon emission computed tomography (SPECT) scans, coincidence detection offers greater spatial resolution.

A variety of radiopharmaceuticals (tracers, radiotracers) are used for PET scanning, (e.g., e.g., ammonia N-13, Fluorodeoxyglucose F-18 FDG, Rubidium Rb-82). Because of their short half-life, radiopharmaceuticals must be made locally. With the exception of fluorine and rubidium, radiopharmaceuticals must be manufactured with an on-site cyclotron.

POSITION STATEMENT:

Myocardial imaging positron emission tomography (PET) with FDA approved radioisotope **meets the definition of medical necessity** for the following:

Suspected coronary artery disease (CAD)

- When neither stress echocardiography (SE) nor myocardial perfusion imaging (MPI) have provided or are expected to provide optimal imaging.

Symptomatic members without known CAD (refer to Diamond Forrester Table)

- Low or intermediate pretest probability and unable to exercise
- High pretest probability

- Repeat testing in a member with new or worsening symptoms and negative result at least one year ago **AND** meets one of the criteria above

Asymptomatic members without known CAD

- Previously unevaluated electrocardiogram (ECG) evidence of possible myocardial ischemia including substantial ischemic ST segment or T wave abnormalities
- Previously unevaluated pathologic Q waves
- Unevaluated complete left bundle branch block
- History of diabetes mellitus, > 40 years old, with calcium score >400

Inconclusive CAD evaluation within the past 2 years and obstructive CAD remains a concern (When neither SE nor MPI have provided or are expected to provide optimal imaging)

- Exercise stress ECG with low risk Duke treadmill score (≥5), but member's current symptoms indicate an intermediate or high pretest probability.
- Exercise stress ECG with an intermediate Duke treadmill score.
- Inconclusive/borderline coronary computed tomography angiography (CCTA) (e.g. 40 - 70% lesions).
- Non-diagnostic exercise stress test with physical inability to achieve target heart rate (THR).
- An intermediate evaluation by prior stress imaging (within the past 2 years).

Follow-up of member's post coronary revascularization (PCI or CABG) (when LVEF is ≤ 40% and revascularization is under consideration)

- Asymptomatic, follow-up stress imaging at a minimum of 2 years post coronary artery bypass grafting (CABG), or percutaneous coronary intervention (PCI), (whichever is later), is appropriate only for members with a history of silent ischemia, or a history of a prior left main stent; **OR**
- For members with high occupational risk (e.g., associated with public safety, airline and boat pilots, bus and train drivers, bridge and tunnel workers/toll collectors, police officers, firefighters)
- New, recurrent, or worsening symptoms post coronary revascularization is an indication for stress imaging, if it will alter management.

Follow-up of known CAD (When neither SE nor MPI have provided or are expected to provide optimal imaging)

- For assessment of suspected significant hibernating myocardium in the presence of known severe major vessel CAD, when EF is below 40%, in order to determine a member's potential benefit from coronary revascularization
- Routine follow-up of asymptomatic or stable symptoms when last invasive or non-invasive assessment of coronary disease showed hemodynamically significant CAD (ischemia on stress test, FFR ≤ 0.80, or stenosis greater than or equal to 70% of a major vessel), over two years ago, without intervening coronary revascularization is an appropriate indication for stress imaging in members if it will alter management.

Special diagnostic conditions requiring coronary evaluation (When neither SE nor MPI have provided or are expected to provide optimal imaging)

- Prior acute coronary syndrome (as documented in physician notes), without subsequent invasive or non-invasive coronary evaluation.
- Newly diagnosed systolic heart failure (EF < 50%), especially with symptoms or signs of ischemia unless invasive coronary angiography is immediately planned.
- Reduced LVEF ≤ 50% requiring myocardial viability assessment to assist with decisions regarding coronary revascularization (Diversion from PET not required when LVEF less than or equal to 40%).
- Ventricular arrhythmias
    - Sustained ventricular tachycardia (VT) > 100 bpm, ventricular fibrillation (VF), or exercise induced VT, when invasive coronary arteriography is not the immediately planned test
    - Nonsustained VT, multiple episodes, each ≥ 3 beats at ≥ 100 bpm, frequent PVC's (defined as greater than or equal to 30/hour on remote monitoring) without known cause or associated cardiac pathology, when an exercise ECG cannot be performed
- Prior to Class IC antiarrhythmic drug initiation (Propafenone or Flecanide), as well as annually in intermediate and high global risk members (SE diversion not required)
- Assessment of hemodynamic significance of one of the following documented conditions:
    - Anomalous coronary arteries
    - Muscle bridging of coronary artery (perform with exercise stress).
- Coronary aneurysms in Kawasaki's disease or due to atherosclerosis.
- Following radiation therapy to the anterior or left chest, at 5 years post initiation and every 5 years thereafter.
- Cardiac sarcoidosis
    - Evaluation and therapy monitoring in members with sarcoidosis, after documentation of suspected cardiac involvement by echo or ECG, when CMR has not been performed.
    - Evaluation of suspected cardiac sarcoid, after CMR has shown equivocal or negative findings in the setting of a high clinical suspicion
    - Evaluation of CMR findings showing highly probable cardiac sarcoidosis, when PET could serve to identify inflammation and the consequent potential role for immunosuppressive therapy
    - Initial and follow up PET in monitoring therapy for cardiac sarcoid with immunosuppressive therapy, typically about 4 times over 2 years
- Infective endocarditis
    - In suspected infective endocarditis with moderate to high probability (i.e. staph bacteremia, fungemia, prosthetic heart valve, or intracardiac device), when TTE and TEE have been inconclusive with respect to diagnosis of infective endocarditis or characterization of paravalvular invasive complications
- Aortitis
    - For diagnosis and surveillance of aortitis, PET/CT or PET/MRI hybrid imaging.

Prior to elective non-cardiac surgery (when neither SE nor MPI have provided or are expected to provide optimal imaging)

- Members who have no other indication for a non-invasive coronary evaluation, but are referred for preoperative cardiac evaluation, are eligible for myocardial perfusion imaging (MPI) when **ALL** of the following criteria are met:
    - Surgery is supra-inguinal vascular, intrathoracic, or intra-abdominal; **AND**
    - The member has at least one of the additional cardiac complication risk factors:
        - Ischemic heart disease
        - History of stroke or TIA
        - History of congestive heart failure or ejection fraction ≤ 35%
        - Insulin-requiring diabetes mellitus
        - Creatinine ≥ 2.0 mg/dl

    AND
- The member has limited functional capacity (< 4 METS), such as one of the following:
    - Unable to take care of their activities of daily living (ADLs) or ambulate
    - Unable to walk 2 blocks on level ground
    - Unable to climb 1 flight of stairs.

    AND
- There has not been a conclusive stress evaluation, CTA, or heart catheterization within the past year, and the results of such a test would be likely to substantially alter therapy and/or preclude proceeding with the intended surgery.
- Planning for solid organ transplantation is an indication for preoperative MPI, if there has not been a conclusive stress evaluation, CTA, or heart catheterization within the past year, and with ≥ 3 of the following risk factors: (SE diversion not required)
    - Age > 60
    - Smoking
    - Hypertension
    - Dyslipidemia
    - Left ventricular hypertrophy
    - 1 year on dialysis (for renal transplant members)
    - Diabetes mellitus
    - Prior ischemic heart disease.

Post cardiac transplant (SE diversion not required)

- Annually, for the first five years post cardiac transplantation, in a member not undergoing invasive coronary arteriography.

- After the first five years post cardiac transplantation, in members with documented transplant coronary vasculopathy can be screened annually if invasive coronary arteriography is not planned.

Additional Information:

PET Scan

- PET is indicated when all of the criteria for MPI are met, and there is likely to be equivocal imaging results because of BMI, large breasts, implants, prior thoracic surgery, or results of a prior MPI
- Can identify regions of myocardial viability with hibernating myocardium (viable, with poor flow and contractility) by imaging with fluorine18 (F-18) fluorodeoxyglucose (FDG or 18-FDG) for this purpose
- Useful in the evaluation of inflammation: e.g., evaluation and therapy monitoring in members with sarcoidosis, after documentation of cardiac involvement by echo or electrocardiography (ECG), in place of, or subsequent to CMR if needed to help with an uncertain diagnosis

Coronary application of PET includes evaluation of stable members without known CAD, who fall into two categories:

- Asymptomatic, for whom global risk of CAD events can be determined from coronary risk factors, using calculators available online.
- Symptomatic, for whom we estimate the pretest probability that their chest-related symptoms are due to clinically significant (≥ 50%) CAD (below):

Three types of chest pain or discomfort

- **Typical angina (definite)** is defined as including all of the following characteristics*:
    - Substernal chest pain or discomfort with characteristic quality and duration
    - Provoked by exertion or emotional stress
    - Relieved by rest and/or nitroglycerin.
- **Atypical angina (probable)** has only 2 of the above characteristics*.
- **Non-anginal chest pain** has only 0-1 of the above characteristics*.

Once the type of chest pain has been established from the medical record, the pretest probability of CAD (meaning obstructive CAD defined as coronary arterial narrowing ≥ 50%) is estimated from the Diamond Forrester Table (see below Table 1), recognizing that in some cases multiple additional coronary risk factors could increase pretest probability.

Determination of Pretest Probability for Coronary Artery Disease (CAD)

Table 1: Determination of Pretest Probability for Coronary Artery Disease Based on Age, Sex, and Symptoms (Source: American College of Cardiology Criteria for Pretest Probability of Coronary Artery Disease (CAD).

The following risk assessment may be used to determine pre-test probability of coronary artery disease.

Age (years)	Sex	Typical/Definite Angina Pectoris	Atypical/Probable Angina Pectoris	Non-anginal Chest Pain	Asymptomatic

≤ 39	Men	Intermediate	Intermediate	Low	Very low
	Women	Intermediate	Very low	Very low	Very low
40 – 49	Men	High	Intermediate	Intermediate	Low
	Women	Intermediate	Low	Very low	Very low
50 – 59	Men	High	Intermediate	Intermediate	Low
	Women	Intermediate	Intermediate	Low	Very low
≥ 60	Men	High	Intermediate	Intermediate	Low
	Women	High	Intermediate	Intermediate	Low

Very low: Less than 5% pretest probability of CAD

Low: Between 5% and 10% pretest probability of CAD

Intermediate: Between 10% and 90% pretest probability of CAD

High: Greater than 90% pretest probability of CAD

Adapted from: Wolk MJ, Bailey SR, Doherty JU et al. ACCF/AHA/ASE/ASNC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2013 Multimodality appropriate use criteria for the detection and risk assessment of stable ischemic heart disease. Journal of the American College of Cardiology 2014; 63(4): 380-406.

Taylor AJ, Cerqueira M, Hodgson JM, et al. ACCF/SCCT/ACR/AHA/ASE/ASNC/NASCI/SCAI/SCMR 2010 appropriate use criteria for cardiac computed tomography. Journal of the American College of Cardiology 2010;56(22):1864-1894.

Myocardial metabolic PET imaging **does not meet the definition of medical necessity** for screening for coronary artery disease.

Definitions of Coronary Artery Disease

Percentage stenosis refers to the reduction in diameter stenosis when angiography is the method and can be estimated or measured using angiography, or more accurately measured with intravascular ultrasound (IVUS).

- Coronary artery calcification is a marker of risk, as measured by Agatston score on coronary artery calcium imaging. It is not a diagnostic tool so much as it is a risk stratification tool. Its incorporation into global risk can be achieved by using the MESA risk calculator.
- Ischemia-producing disease (also called hemodynamically or functionally significant disease, for which revascularization might be appropriate) generally implies at least one of the following:
    - Suggested by percentage diameter stenosis ≥ 70% by angiography; borderline lesions are 40 - 70%
    - For a left main artery, suggested by a percentage stenosis ≥ 50% or minimum lumen cross sectional area on IVUS ≤ 6 square mm
    - Fractional flow reserve (FFR) ≤ 0.80 for a major vessel
    - Instantaneous wave-free ratio (iFR) ≤ 0.89 for a major vessel

- Demonstrable ischemic findings on stress testing (ECG or stress imaging), that are at least mild in degree

- A major vessel would be a coronary vessel that would be amendable to revascularization, if it were indicated. This assessment is made based on the diameter of the vessel and/or the extent of myocardial territory served by the vessel.
- FFR (fractional flow reserve) is the distal to proximal pressure ratio across a coronary lesion during maximal hyperemia induced by either intravenous or intracoronary adenosine. Less than or equal to 0.80 is considered a reduction in coronary flow.
- Instantaneous wave-free ratio (iFR) measures the ratio of distal coronary to aortic pressure during the wave free period of diastole, with a value ≤ 0.89 considered hemodynamically significant.

Anginal Equivalent

Development of an anginal equivalent (e.g., shortness of breath, fatigue, or weakness) either with or without prior coronary revascularization should be based upon the documentation of reasons to suspect that symptoms other than chest discomfort are not due to other organ systems (e.g., dyspnea due to lung disease, fatigue due to anemia), by presentation of clinical data such as respiratory rate, oximetry, lung exam. (as well as d-dimer, chest CT(A) and/or pulmonary function tests (PFTs) when appropriate) and then incorporated into the evaluation of coronary artery disease as would chest discomfort. Syncope per se is not an anginal equivalent.

Global Risk of Cardiovascular Disease (coronary disease (CAD))

Global risk of CAD is defined as the probability of manifesting cardiovascular disease over the next 10 years and refers to asymptomatic members without known cardiovascular disease. It should be determined using one of the cardiac risk calculators below. A high risk is considered greater than 20% risk of a cardiovascular event over the ensuing 10 years. High global risk by itself generally lacks scientific support as an indication for stress imaging. There are rare exemptions, such as members requiring IC antiarrhythmic drugs, who might require coronary risk stratification prior to initiation of the drug, or members with a CAC score > 400 Agatston units, when global risk is moderate or high.

CAD Risk—Low: 10-year absolute coronary or cardiovascular risk less than 10%.

CAD Risk—Moderate: 10-year absolute coronary or cardiovascular risk between 10% and 20%.

CAD Risk—High: 10-year absolute coronary or cardiovascular risk of greater than 20%.

Duke Treadmill Score

- The equation for calculating the Duke treadmill score (DTS) is: DTS = exercise time in minutes - (5 x ST deviation in mm or 0.1 mV increments) - (4 x exercise angina score), with angina score being 0 = none, 1 = non-limiting, and 2 = exercise-limiting.
- The score typically ranges from -25 to +15. These values correspond to low-risk (with a score of ≥ +5), intermediate risk (with scores ranging from - 10 to + 4), and high-risk (with a score of ≤ -11) categories.

Online cardiac risk calculator and assessment tools

The links for the online cardiac risk calculator and assessment tools are to an outside source and is provided for your convenience. Use of the links and related calculator and assessment tools are subject to the terms and conditions of the website and is not warranted, maintained or affiliated with Florida Blue.

Framingham Risk Score Calculator

http://www.medcalc.com/heartrisk.html

Reynolds Risk Score

http://www.reynoldsriskscore.org/

Pooled Cohort Risk Assessment Equations

http://clincalc.com/Cardiology/ASCVD/PooledCohort.aspx

ACC/AHA Risk Calculator

http://tools.acc.org/ASCVD-Risk-Estimator-Plus/#!/calculate/estimate/

MESA Risk Calculator (With addition of coronary artery calcium score, for CAD-only risk.)

https://www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx

Documentation Requirements

Documentation containing the medical necessity of the myocardial imaging positron emission tomography (PET) results (e.g., images, clinical reports) should be maintained in the member's medical record. Documentation may be requested as part of the review process.

LOINC Codes

The following information may be required documentation to support medical necessity: physician history and physical, physician progress notes, plan of treatment and reason for myocardial imaging positron emission tomography (PET).

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Plan of treatment	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim

Exercise stress test study	18752-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim

BILLING/CODING INFORMATION:

CPT Coding

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
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
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

REIMBURSEMENT INFORMATION:

PET scans are performed using a camera that has either been approved or cleared for marketing by the Food and Drug Administration (FDA) to image positron annihilation gamma photons in the body.

PET scans are performed using FDA approved or radiopharmaceutical (tracer, radiotracer) (e.g., ammonia N-13, Fluorodeoxyglucose F-18 FDG, Rubidium Rb-82). The radiopharmaceutical may be manufactured on site, or manufactured at a regional delivery center with delivery to the institution performing the PET scan. When the radiopharmaceutical is provided by an outside distribution center, there may be a separate charge for both the radiopharmaceutical and transportation of the radiopharmaceutical.

PROGRAM EXCEPTIONS:

Coverage for the radiology services referenced in this guideline performed and billed in an outpatient or office location will be handled through the Radiology Management program for select products. The National Imaging Associates (NIA) will determine coverage for these services for select products. Refer to member's contract benefits.

Federal Employee Plan (FEP): FEP is excluded from the National Imaging Associates (NIA) review; follow FEP guidelines.

Medicare Advantage products: The following National Coverage Determinations (NCDs) were reviewed on the last guideline reviewed date: PET (FDG) for Myocardial Viability (220.6.8), and PET for Perfusion of the Heart (220.6.1), located at cms.gov.

DEFINITIONS:

Equivocal: of uncertain nature or classification.

Myocardial metabolic PET imaging: the cardiac muscle is imaged using data received from positron-emitting radionuclides administered to the patient. The collision of the positrons emitted by the radionuclide with the negatively charged electrons normally present in tissue is then computer synthesized to produce an image, usually in color. This image will show the presence or absence of ischemic cardiac tissue.

Myocardial perfusion PET imaging: imaging of the cardiac muscle is performed using data received from positron-emitting radionuclides administered to the patient. Collision of the positrons emitted by the radionuclide with the negatively charged electrons normally present in tissue is then computer synthesized to produce an image, usually in color. The procedure may be performed at rest or stress.

RELATED GUIDELINES:

Cardiac Radionuclide Imaging (Myocardial Perfusion Imaging, Cardiac Blood Pool Imaging) 04-78000-19

FDG-SPECT, 04-78000-15

Positron Emission Tomography (PET Scan) Oncologic Applications, 04-78000-17

Positron Emission Tomography (PET Scans) Miscellaneous Applications, 04-78000-18

OTHER:

Other names used to report positron emission tomography (PET):

Positron emission transverse tomography (PETT)
Positron emission coincident imaging (PECI)

Abbreviations

CAD = coronary artery disease

FDA = Food and Drug Administration

MPI= myocardial perfusion imaging

MRI= magnetic resonance imaging

SPECT= single photon emission computed tomography

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the BCBSF Medical Policy & Coverage Committee on 04/28/22.

GUIDELINE UPDATE INFORMATION:

10/15/03	Annual review. Developed separate policy for PET Scans Cardiac Applications.
01/01/04	2004 HCPCS update: deleted Q4078 and replaced with A9526.
03/15/05	Added program exception for Health Options, Blue Care, and Medicare Advantage products.
12/15/05	Revised the when services are covered section; ICD-9-CM diagnoses codes (expand the code range for coronary atherosclerosis, revise the descriptor for: V45.09 and V45.89). Revised reimbursement information section; revise IDC-9 diagnoses code description, deleted FDA statement regarding the camera and radiotracer. Revised program exception section; add 78459 to NIA's general statement, and updated references. No longer scheduled for review.
03/15/06	HCPCS update, deleted G0030, G0031, G0032, G0033, G0034, G0035, G0036, G0037, G0038, G0039, G0040, G0041, G0042, G0043, G0044, G0045, G0046, G0047, and G0230.
06/15/06	Added A9552. Revised program exception; NIA statement, and updated references.
07/01/07	Reformatted guideline. Revised coverage statement for PET myocardial imaging. Revised reimbursement statement. Deleted generation of automated data (78890, 78891) reimbursement statement. Added HCPCS code A9555. Deleted HCPCS code Q3000. Added information regarding myocardial perfusion imaging and myocardial viability to section entitled "Other", and updated references.
01/21/08	Updated Program Exceptions.
07/15/08	Scheduled reviewed. No change in position statement. Changed PET myocardial imaging to PET cardiac imaging. Added code S8085, and updated references.
05/21/09	Removed Federal Employee Plan (FEP) from BCBSF Radiology Management program exception statement. Added FEP program exception statement: FEP is excluded from the National Imaging Associates (NIA) review; follow FEP guidelines.
07/01/09	Updated BCBSF Radiology Management program exception; added BlueSelect.
07/15/09	Annual review. Revised description. Revised position statements to include medically necessary indications for myocardial perfusion PET imaging and myocardial metabolic PET imaging. Deleted S8085. Added guideline specific definitions. Added program exception for Medicare Advantage products. Added related guideline link for FDG-SPECT. Updated references.
01/01/10	Revised BCBSF Radiology Management program exception section.
06/15/10	Annual review. Revised Medicare Advantage products program exception; ICD-9 code descriptor (428.20 – 428.23, 428.30 – 428.33, and 428.40 – 428.43). Updated references.
10/01/11	Revision; Formatting changes.
06/15/12	Scheduled review; deleted Medicare ICD-9 codes and updated references.
01/01/14	Review. Updated program exception and references.

04/15/17	Code update; deleted A9526, A9552 and A9555.
01/01/18	Annual HCPCS code update. Added 0482T.
09/15/18	Revision; revised position statement. Removed scan from guideline subject. Updated references.
03/15/20	Review/Revision. Revised and expanded indications and criteria. Revised description and definitions and format position statement. Updated references.
05/15/22	Review. Revised position statement. Deleted code 0482T, added code 78434. Updated references.
06/09/22	Code update; added 78429, 78430, 78431, 78432 and 78433.