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Subject: Positron Emission Tomography (PET) Cardiac Applications

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Position Statement Billing/Co		g <u>Reimbursement</u> <u>Progr</u> <u>Except</u>		Definitions	Related Guidelines
<u>Other</u>	References	<u>Updates</u>			

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 \leq 40% and revascularization is under consideration)

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

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
- 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:
 - o 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
 - 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 when TTE and TEE have been inconclusive with respect to diagnosis of infective endocarditis or characterization of paravalvular invasive complications
- Aortitis
 - o 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)

- 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):

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.

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	LOINC	LOINC Time Frame Modifier Codes
	Codes	Time Frame	Narrative
		Modifier Code	
Physician history and	28626-0	18805-2	Include all data of the selected type that
physical			represents observations made six months or
			fewer before starting date of service for the
			claim
Attending physician	18741-9	18805-2	Include all data of the selected type that
progress note			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	18752-6	18805-2	Include all data of the selected type that
study			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:

Federal Employee Plan (FEP): 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 positronemitting 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:

<u>Cardiac Radionuclide Imaging (Myocardial Perfusion Imaging, Cardiac Blood Pool Imaging) 04-78000-19</u>

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 Florida Blue Medical Policy and Coverage Committee on 02/23/23.

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.
07/01/22	Revision to Program Exceptions section.
09/30/23	Review: position statements and references updated.
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