Positron Emission Tomography (PET) Scan for Myocardial Imaging

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Instructions for Use

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Related Medicare Advantage Medical Policy

- Radiation and Oncologic Procedures

Coverage Rationale

Overview

Positron emission tomography (PET) is a minimally invasive diagnostic imaging procedure used to evaluate metabolism and myocardial perfusion in normal tissue as well as in diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders. A radiopharmaceutical is injected into the patient that gives off sub-atomic particles, known as positrons, as it decays. PET uses a positron camera (tomography) to measure the location of, and the decay of the radiopharmaceutical. The rate of decay provides biochemical information on the metabolism of the tissue being studied.

Positron Emission Tomography Perfusion of the Heart

Medicare has a National Coverage Determination (NCD) for positron emission tomography perfusion of the heart, refer to the tables for Perfusion of the Heart and Perfusion of the Heart / Myocardial Viability.

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the tables for Perfusion of the Heart and Perfusion of the Heart/Myocardial Viability.

For coverage guidelines for states/territories with no LCDs/LCAs for indications not specifically addressed in the NCD 220.6.1, refer to the indications for use of myocardial imaging below.

Acute Myocardial Infarction (AMI)

PET myocardial perfusion imaging (MPI) is not typically performed during the acute period of myocardial infarction (MI), if the diagnosis is established by other means. PET MPI is appropriate in the assessment of:

- Disease severity
- Risk assessment and/or prognosis
- Efficacy of acute reperfusion therapy
- Evidence of myocardial salvage
- Suspected infarction when the combination of history and other tests is not diagnostic

Unstable Angina

PET MPI may be useful as an adjunct to other tests in the diagnosis or treatment of unstable angina only when the combination of history and other tests is not diagnostic. PET MPI is appropriate for:

- Identification of ischemia in the distribution of a known lesion or in remote areas
- Identification of the severity/extent of disease in patients with medically unstable angina or ongoing ischemia
- Measurement of left ventricular function (LVF)

Chronic Ischemic Heart Disease

The use of PET MPI is well established in the diagnosis and management of CAD and is covered in these situations:

- Diagnosis of CAD, especially in patients with atypical chest pain
- Evaluation of abnormal or suspected false positive stress ECG
- Evaluation of other symptoms suspicious for the diagnosis of CAD such as syncope and ventricular arrhythmia
- Assessment of myocardial viability after revascularization or medical management
- Planning percutaneous transluminal coronary angioplasty (PTCA) to identify lesions causing ischemia, if unknown
- Evaluation of suspected or known CAD prior to high-risk surgical procedure
- Identification of the presence, location, extent, and severity of myocardial ischemia
- Assessment of drug therapy
- Assessment of symptoms suggesting restenosis following PTCA
- Assessment of symptoms suggesting ischemia following coronary artery bypass graft (CABG)
- Follow up of symptomatic ischemic heart disease

Congenital Heart Disease (CHD)

Echo is the method of choice for evaluating patients with known or suspected CHD.

Positron Emission Tomography (PET) MPI may be used when assessing for:

- Diagnosis of anomalies of the coronary circulation
- Kawasaki's disease

Post-Transplant Cardiac Disease

PET MPI may be used when assessing for:

- Assessment of coronary arteriopathy
- Evaluation for ventricular dysfunction with post-transplant rejection

Positron Emission Tomography Myocardial Viability

Medicare has a NCD for positron emission tomography myocardial viability, refer to the tables for refer to the tables for Perfusion of the Heart and Perfusion of the Heart/Myocardial Viability.

LCDs/LCAs exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the tables for Myocardial Viability and Perfusion of the Heart/Myocardial Viability.

For coverage guidelines for states/territories with no LCDs/LCAs for sarcoidosis and other infiltrative disorders (indications not specifically addressed in the NCD 220.6.8):

- PET myocardial viability testing with cardiac imaging will be considered medically reasonable and necessary in the determination of cardiac involvement in sarcoidosis using fluorodeoxyglucose (F-18 FDG), in patients who are unable to undergo MRI, have inconclusive MRI findings, or when high probability of disease exists even after a negative MRI. Examples of patients who are unable to undergo MRI include, but are not limited to, patients with metal implants.
- PET myocardial viability studies using fluorodeoxyglucose (F-18 FDG) are reasonable to determine response to immunosuppressive therapy in patients diagnosed with cardiac sarcoidosis.

Combination Positron Emission Tomography Myocardial Perfusion/Viability

Imaging of myocardial perfusion can also be combined with myocardial metabolism imaging with fluorodeoxyglucose (F-18 FDG) for the assessment of myocardial viability in areas of resting hypoperfusion and dysfunctional myocardium. The stress protocols are, for the most part, similar for all cardiac PET perfusion agents. The specific differences in acquisition protocols for rubidium (Rb-82) and ammonia N-13 are related to the duration of uptake and clearance of these radiopharmaceuticals and their physical half-lives.

UnitedHealthcare uses the criteria above to supplement NCD criteria in NCD 220.6.1 and NCD 220.6.8 related to myocardial PET imaging to ensure consistency in determining that the service is reasonable and necessary. The use of the criteria may decrease inappropriate denials by creating a consistent set of review criteria when medically appropriate for a particular patient. Further, use of the criteria should limit the circumstances where myocardial PET imaging scans

are incorrectly approved, which itself provides benefits because performing the test when it is not indicated can lead to false positive findings requiring otherwise unnecessary testing and or procedures and downstream complications. The benefits of myocardial PET imaging include its ability to accurately measure blood flow between the coronary arteries and heart muscle and to detect dead or injured tissue through images of high resolution and clarity. Some studies have found myocardial PET imaging to reduce adverse outcomes and recurrences. The potential clinical harms of using these criteria may include inappropriately denying a myocardial PET imaging scan when it is otherwise indicated, which could lead to diagnostic and treatment errors; and/or may result in obtaining alternate studies. Use of this criteria to supplement the general provisions noted above provides clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services, because these additional criteria will provide greater consistency in determining when a patient's medical factors would support the use of these imaging studies, thus decreasing inappropriate denials.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service; however, language may be included in the listing below to indicate if a code is non-covered. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
Positron Emission Tomography Perfusion of the Heart	
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
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)
Positron Emission Tomography Myocardial Viability	
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
78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study;
Positron Emission Tomography Perfusion of the Heart / Myocardial Viability	
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 (e.g., 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 (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan
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)

Diagnosis Code
Positron Emission Tomography (PET) Scan: Myocardial Imaging Diagnosis Code List

Centers for Medicare and Medicaid Services (CMS) Related Documents

After checking the table below and searching the Medicare Coverage Database, if no NCD, LCD, or LCA is found, refer to the criteria as noted in the Coverage Rationale section above.

NCD	LCD	LCA	Contractor Type	Contractor Name
Perfusion of the Heart (CPT Codes 78430, 78431, and 78434)				
NCD 220.6.1 PET for Perfusion of the Heart	L38396 Cardiology Non-emergent Outpatient Stress Testing	A56952 Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing	Part A and B	First Coast
NCD 220.6.1 PET for Perfusion of the Heart	L35083 Cardiology Non-emergent Outpatient Stress Testing	A56423 Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing	Part A and B	Novitas**
NCD 220.6.1 PET for Perfusion of the Heart	L39521 Positron Emission Tomography (PET) Scan for Inflammation and Infection	A59318 Billing and Coding: Positron Emission Tomography (PET) Scan for Inflammation and Infection	Part A and B	CGS
Myocardial Viability (CPT Codes 78429 and 78459)				
NCD 220.6.8 FDG PET for Myocardial Viability	L38396 Cardiology Non-emergent Outpatient Stress Testing	A56952 Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing	Part A and B	First Coast
NCD 220.6.8 FDG PET for Myocardial Viability	L35083 Cardiology Non-emergent Outpatient Stress Testing	A56423 Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing	Part A and B	Novitas**
NCD 220.6.8 FDG PET for Myocardial Viability	L39521 Positron Emission Tomography (PET) Scan for Inflammation and Infection	A59318 Billing and Coding: Positron Emission Tomography (PET) Scan for Inflammation and Infection	Part A and B	CGS
Perfusion of the Heart/Myocardial Viability (CPT Codes 78432, 78433, 78491, and 78492)				
NCD 220.6.1 PET for Perfusion of the Heart and NCD 220.6.8 FDG PET for Myocardial Viability	L33457 Cardiac Radionuclide Imaging	A56476 Billing and Coding: Cardiac Radionuclide Imaging	Part A and B	Palmetto**
NCD 220.6.1 PET for Perfusion of the Heart and NCD 220.6.8 FDG PET for Myocardial Viability	L38396 Cardiology Non-emergent Outpatient Stress Testing	A56952 Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing	Part A and B	First Coast

NCD	LCD	LCA	Contractor Type	Contractor Name
Perfusion of the Heart/Myocardial Viability CPT Codes 78432, 78433, 78491, and 78492				
NCD 220.6.1 PET for Perfusion of the Heart and NCD 220.6.8 FDG PET for Myocardial Viability	L35083 Cardiology Non-emergent Outpatient Stress Testing	A56423 Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing	Part A and B	Novitas**
NCD 220.6.1 PET for Perfusion of the Heart and NCD 220.6.8 FDG PET for Myocardial Viability	L39521 Positron Emission Tomography (PET) Scan for Inflammation and Infection	A59318 Billing and Coding: Positron Emission Tomography (PET) Scan for Inflammation and Infection	Part A and B	CGS

Medicare Administrative Contractor (MAC) With Corresponding States/Territories	
MAC Name (Abbreviation)	**States/Territories**
CGS Administrators, LLC (CGS)	KY, OH
First Coast Service Options, Inc. (First Coast)	FL, PR, VI
National Government Services, Inc. (NGS)	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
Noridian Healthcare Solutions, LLC (Noridian)	AS, AK, AZ, CA, GU, HI, ID, MT, NV, ND, Northern Mariana Islands, OR, SD, UT, WA, WY
Novitas Solutions, Inc. (Novitas)	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX, VA**
Palmetto GBA (Palmetto)	AL, GA, NC, SC, TN, VA**, WV
Wisconsin Physicians Service Insurance Corporation (WPS)*	IA, IN, KS, MI, MO, NE
Notes	
*Wisconsin Physicians Service Insurance Corporation: Contract Number 05901 applies only to WPS Legacy Mutual of Omaha MAC A Providers. **For the state of Virginia: Part B services for the city of Alexandria and the counties of Arlington and Fairfax are excluded for the Palmetto GBA jurisdiction and included within the Novitas Solutions, Inc. jurisdiction.	

CMS Claims Processing Manual

Chapter 13; § 60 Positron Emission Tomography (PET) Scans – General Information

Clinical Evidence

O'Gorman et al. (2023) performed a systematic review and meta-analysis to determine the sensitivity and specificity of ^{18}F-fluorodeoxyglucose (^{18} F-FDG) positron emission tomography/computed tomography (PET/CT) in diagnosing prosthetic valve endocarditis (PVE) and utilized individual patient data (IPD) to assess the effects of various patient covariates. Seventeen studies (537 patients, 538 scans) met inclusion criteria which consisted of a PET/CT performed for suspicion of PVE and IPD of both the PET/CT result and final diagnosis defined by a gold-standard assessment was available. "Definite PVE," "possible PVE," and "rejected PVE" were the three final diagnoses possible. The summary sensitivity and specificity were 85% and 86.5% respectively when patients with final diagnosis of "possible PVE" were classified as positive for PVE. When this group was classified as negative for PVE, sensitivity was 87.4% and specificity was 84.9%. Patients with a known pathogen (especially coagulase negative staphylococcal species), elevated C Reactive Protein (CRP), a biological or aortic valve infection appeared more likely to have an accurate PET/CT diagnosis. Those with a mechanical valve, prior antibiotic treatment or a transcatheter aortic valve replacement valve were less likely to have an accurate test. Time since valve implantation and the presence of surgical adhesive did not appear to affect test accuracy. Of the patients with a preliminary Duke classification of "possible PVE," 84% received a more conclusive final diagnosis of "definite" or "rejected" PVE after the PET/CT study. The authors concluded ^{18} F-FDG PET/CT has a high

sensitivity and specificity in diagnosing PVE and the diagnostic utility is greatest in patients with a preliminary Duke classification of “possible PVE” as most of these patients received a more definitive classification of “definite” or “rejected” PVE following the PET study. Additionally, the authors note prior antibiotic treatment, transcatheter aortic valve replacement (TAVR), and mechanical valves, may reduce accuracy and larger patient cohort studies to explore this association is recommended.

Xu et al. (2021) conducted a systematic review and meta-analysis designed to compare cardiac magnetic resonance (CMR), single-photon emission computerized tomography (SPECT), and PET in the detection of coronary artery disease (CAD). A systematic search of the available literature through July 31, 2020 was performed and a total of 203 articles (23,942 patients) were included in the meta-analysis. The pooled sensitivity values of CMR, SPECT, and PET were 0.86, 0.83, and 0.85, respectively. Their respective overall specificity values were 0.83, 0.77, and 0.86. Results in subgroup analysis of the performance of SPECT with 201Tl showed the highest pooled sensitivity [0.85 (0.82, 0.88)] and specificity [0.80 (0.75, 0.83)]. 99mTc-tetrofosmin had the lowest sensitivity [0.76 (0.67, 0.82)]. In the subgroup analysis of PET tracers, results indicated that 13N had the lowest pooled sensitivity [0.83 (0.74, 0.89)], and the specificity was the highest [0.91 (0.81, 0.96)]. The authors concluded the PET and CMR performed better for diagnostic detection of CAD when compared with SPECT. Significant heterogeneities among studies were noted as a limitation of this review.

Ten Hove et al. (2020) performed a systematic review and meta-analysis aimed to provide a detailed overview of the current evidence to establish the role of FDG-PET/CT in diagnosing infections related to left ventricular assistance devices (LVADs). For the analysis, a distinction was made between driveline infections and infections of the pump/pocket. Ten studies were included in the systematic review, and eight were eligible for the meta-analysis, including 256 FDG-PET/CT scans in 230 patients. Pooled sensitivity of FDG-PET/CT was 0.95 (95% confidence interval (CI) 0.89–0.97) and pooled specificity was 0.91 (95% CI 0.54–0.99) for the diagnosis of device-related infection. For pump/pocket infection, sensitivity and specificity of FDG-PET/CT were 0.97 (95%CI 0.69–1.00) and 0.93 (95%CI 0.64–0.99), respectively. For driveline infection, sensitivity and specificity were 0.96 (95%CI 0.88–0.99) and 0.99 (95%CI 0.13–1.00) respectively. Significant heterogeneity existed across studies for specificity, mostly caused by differences in scan procedures. Predefined criteria for suspicion of LVAD and/or driveline infection were lacking in all included studies. The authors concluded FDG-PET/CT for establishing or excluding the diagnosis of device specific infection in patients with a LVAD has a high sensitivity and a high, variable, specificity. The authors note future studies regarding standardization of FDG-PET/CT procedures and criteria for suspected device-related LVAD infections are needed for consistent reporting. Limitations include small sample sizes of the studies and differing types and generations of LVADs used in the studies.

In a 2020 case series, systematic review and meta-analysis, Tam et al. aimed to determine the diagnostic accuracy of fluorine-18 fluorodeoxyglucose (FDG) PET/CT scanning for suspected device infections in patients with LVADs. The single-center case series was a retrospective study of consecutive FDG PET/CT scans between September 2015 and February 2018 performed on patients with LVAD devices at the time of the scan. Nineteen FDG PET/CT scans were identified for the retrospective case series. The systematic review identified three additional publications, for a total of four studies involving 119 scans assessing diagnostic performance. Axial (n = 36) and centrifugal (n = 83) flow LVADs were represented. Pooled sensitivity was 92% (95% confidence interval [CI]: 82% to 97%) and specificity was 83% (95% CI: 24% to 99%) for FDG PET/CT in diagnosing LVAD infections. Summary receiver-operating characteristic curve analysis demonstrated an area under the curve (AUC) of 0.94 (95% CI: 0.91 to 0.95). The authors concluded good diagnostic accuracy, with overall high sensitivity but variable specificity was demonstrated by FDG PET/CT scans for suspected LVAD infections. Limitations include the retrospective nature of the study and small sample size.

Wang et al. (2020) conducted a meta-analysis to determine the performance of ^{18}F-FDG PET/CT for diagnosing infective endocarditis (IE) overall and the different subtypes. Studies reporting both sensitivity and specificity of ^{18}F-FDG PET/CT for IE from January 1980 to September 2019 were included in the search; 26 studies for a total of 1358 patients (n = 509 IE cases) were included. Pooled sensitivity and specificity (95% CI, inconsistency I-square statistic) were 0.74 (0.70–0.77, 71.5%) and 0.88 (0.86–0.91, 78.5%) for all cases of endocarditis. Corresponding parameters for native valve IE were sensitivity 0.31 (0.21–0.41, 29.4%) and specificity 0.98 (0.95–0.99, 34.4%); for prosthetic valve IE: sensitivity 0.86 (0.81–0.89, 60.0%) and specificity 0.84 (0.79–0.88, 75.2%); and for cardiac implantable electronic devices IE: sensitivity 0.72 (0.61–0.81, 76.2%) and specificity 0.83 (0.75–0.89, 83.6%). Pooled sensitivities and specificities were higher for the 17 studies since 2015 than the 9 studies published before 2015. The authors concluded 18F-FDG PET/CT in all IE subtypes had a high specificity although native valve sensitivity was significantly lower for native valve IE than prosthetic valve IE and implantable cardiac electronic devices. The authors state 18F-FDG PET/CT may be especially useful as an adjunct diagnostic imaging modality for assessing endocarditis in the challenging situations of cardiac implantable electronic devices IE and prosthetic valve IE. Limitations noted include all studies were observational or retrospective, overall sample size was moderate, and eligible studies rarely compared 18F-FDG PET/CT with other modalities. The authors recommend future larger, prospective studies.

Patel et al. (2019) conducted a single-center RCT to determine post-test clinical effectiveness of pharmacologic stress myocardial perfusion imaging (MPI) and PET, compared to SPECT in patients with known CAD and symptoms suggestive of ischemia. Patients (n = 322) were randomized to either undergo PET or attenuation-corrected SPECT MPI. Diagnostic failure was the primary end-point and secondary endpoints were post-test escalation of antianginal therapy, referral for angiography, coronary revascularization, and health status at three, six, and twelve months. At baseline, 88.8% of patients were receiving aspirin therapy, 76.7% were taking beta-blockers, and 77.3% were taking statin therapy. Diagnostic failure within 60 days occurred in only seven patients (2.2%) (3 [1.9%] in the PET group and 4 [2.5%] in the SPECT group; p = 0.70). There were no significant differences between the two groups in subsequent rates of coronary angiography, coronary revascularization, or health status at three, six, and twelve months of follow-up (all p values ≥ 0.20); however, when subjects were stratified by findings on MPI in a post hoc analysis, those with high-risk MPI on PET testing had higher rates of angiography and revascularization on follow-up than those who had SPECT MPI, whereas those undergoing low-risk PET studies had lower rates of both procedures than those undergoing SPECT (interaction between randomized modality ∗high-risk MPI for 12-month catheterization [p = 0.001] and 12-month revascularization [p = 0.09]). The authors concluded that in patients evaluated by pharmacologic PET compared with those evaluated by SPECT MPI, there were no distinct differences in diagnostic failure at 60 days, revascularization, subsequent coronary angiography, or patient health status at one year. The authors recommend future larger, multiple-centered RCTs are needed. Limitations include the single-center nature of the study and small study size.

Youssef et al. (2012) conducted a systematic review and meta-analysis to assess the accuracy of ^{18}F-FDG PET for the diagnosis of cardiac sarcoidosis compared with the Ministry of Health, Labour, and Welfare of Japan (MHLW) guidelines. The meta-analysis also includes data from a prospective Ontario provincial registry (the Cardiac FDG-PET Registry [CADRE]). Seven studies, including the Ontario registry were included in the review for a total of 164 patients, most of whom had a diagnosis of systemic sarcoidosis. The prevalence of cardiac sarcoidosis was 50% in the whole population. Pooled estimates for 18F-FDG PET yielded 89% sensitivity (95% confidence interval [CI], 79%–96%), 78% specificity (95% CI, 68%–86%), a 4.1 positive likelihood ratio (95% CI, 1.7–10), and a 0.19 negative likelihood ratio (95% CI, 0.1–0.4). The overall diagnostic odds ratio was 25.6 (95% CI, 7.3–89.5), and the area under the summary receiver operator characteristic curve was 93% ± 3.5. The Ontario study yielded sensitivity and specificity of 79% and 70%, respectively. The authors concluded there was a high diagnostic accuracy for ^{18}F-FDG PET that could provide a potentially valuable technique for diagnosis of cardiac sarcoidosis. The authors recommend future large-scale studies.

Clinical Practice Guidelines

The ACR/ACNM/SNMMI/SPR/STR Practice Parameter (2023) for performing and interpreting PET/CT exams for cardiac diseases in children and adults notes the primary goals of cardiac PET/CT include evaluation of perfusion, function, viability, inflammation, anatomy, and risk stratification for cardiac-related events such as myocardial infarction and death. The Practice Parameter states cardiac PET/CT is a preferred test for those with suspected or known CAD who are appropriate for stress imaging but are unable to tolerate an exercise stress test and is the preferred test for all who are appropriate for pharmacological stress imaging. Clinical indications for cardiac PET/CT are noted to include (but not limited to): myocardial perfusion imaging, measurement of myocardial blood flow and coronary flow reserve and detection of balanced ischemia or microvascular disease, myocardial viability, cardiac sarcoidosis, heart transplants for detection of coronary artery vasculopathy, and cardiac infection (including infected cardiac implanted devices).

Gulati et al. (2021) developed a guideline for the evaluation and diagnosis of chest pain designed to provide recommendations for providers to assess and diagnose chest pain in adult patients. Randomized and nonrandomized trials, observational studies, registries, reviews, and other literature conducted on human subjects published from November 11, 2017 to April 2021 were considered for inclusion. The guideline states that (not all-inclusive):

- Intermediate risk patients with acute chest pain and no known CAD who are eligible for cardiac testing, either exercise ECG, stress echocardiography, stress PET/SPECT MPI, or stress cardiovascular magnetic resonance (CMR) is useful for the diagnosis of myocardial ischemia. (Class of recommendation 1-strong, level of evidence- B-NR-non-randomized).
- Intermediate-risk patients with acute chest pain and no known CAD, with an inconclusive coronary computed tomographic angiography (CCTA), stress imaging (with echocardiography, PET/SPECT MPI, or CMR) can be useful for the diagnosis of myocardial ischemia. (Class of recommendation 2a-moderate, level of evidence- C-EO- expert opinion).
- Intermediate-risk patients with known CAD and acute chest pain who have new onset or worsening symptoms, stress imaging (PET/SPECT MPI, CMR, or stress echocardiography) is reasonable. (Class of recommendation 2a-moderate, level of evidence- B-NR-non-randomized).
- Intermediate-high risk patients with stable chest pain and no known CAD, stress imaging (stress echocardiography, PET/SPECT MPI or CMR) is effective for diagnosis of myocardial ischemia and for estimating risk of major adverse cardiovascular events. (Class of recommendation 1-strong, level of evidence- B-R-randomized).

- Intermediate-high risk patients with stable chest pain and no known CAD for whom rest/stress nuclear MPI is selected, PET is reasonable in preference to SPECT, if available to improve diagnostic accuracy and decrease the rate of nondiagnostic test results. (Class of recommendation 2a-moderate, level of evidence- B-R-randomized).
- For patients with obstructive CAD who have stable chest pain despite optimal guideline-directed medical therapy, stress PET/SPECT MPI, CMR, or echocardiography is recommended for diagnosis of myocardial ischemia, estimating risk of major adverse cardiovascular events, and guiding therapeutic decision-making. (Class of recommendation 1-strong, level of evidence- B-NR-non-randomized).
- For patients with obstructive CAD who have stable chest pain despite optimal guideline-directed medical therapy, when selected for rest/stress nuclear MPI, PET is reasonable in preference to SPECT, if available, to improve diagnostic accuracy and decrease the rate of nondiagnostic test results. (Class of recommendation 2a-moderate, level of evidence- B-NR-non-randomized).
- For patients with obstructive CAD who have stable chest pain symptoms undergoing stress PET MPI or stress CMR, the addition of myocardial blood flow reserve is useful to improve diagnosis accuracy and enhance risk stratification. (Class of recommendation 2a-moderate, level of evidence- B-NR-non-randomized).
- For patients with known extensive nonobstructive CAD with stable chest pain symptoms, stress imaging (PET/SPECT, CMR, or echocardiography) is reasonable for the diagnosis of myocardial ischemia. (Class of recommendation 2a-moderate, level of evidence- C-LD- limited data).
- For patients with persistent stable chest pain and nonobstructive CAD, stress PET MPI with myocardial blood flow reserve is reasonable to diagnose microvascular dysfunction and enhance risk stratification. (Class of recommendation 2a-moderate, level of evidence- B-NR-non-randomized).

Schindler et al. (2020) assembled members of the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the American College of Cardiology (ACC), the American Society of Nuclear Cardiology (ASNC), the Canadian Cardiovascular Society (CCS), the Canadian Society of Cardiovascular Nuclear and CT Imaging (CSCNCTI), the Society of Cardiovascular CT (SCCT), the American Heart Association (AHA), the American College of Physicians (ACP), and the European Association of Nuclear Medicine (EANM) to develop an appropriate use criteria (AUC) regarding PET myocardial perfusion imaging (MPI). A systematic review of the evidence was used to develop a list of common indications for PET use in MPI in patients with suspected or known CAD or coronary microvascular disease (CMD). The summary of recommendations are as follows (not all-inclusive):

- Rest-stress PET MPI is considered appropriate in those with or without known CAD who have symptoms with an intermediate-to-high pretest likelihood of disease regardless of whether the patient has normal electrocardiogram (ECG) results or can exercise.
- For patients in the emergency department or for inpatients with chest pain or symptoms related potentially to ischemia with no clear markers such as elevated Tn levels or ECG changes, PET MPI is generally considered appropriate.
- In asymptomatic patients, stress–rest PET MPI is generally limited to indications such as an intermediate-to-high probability of CAD, an indeterminate resting ECG, coronary artery calcifications of ≥ 400 HU, or familial hyperlipidemia in the appropriate clinical setting, and in asymptomatic patients with abnormal or equivocal prior test results.
- In patients with intermediate and higher clinical risk, PET MPI evaluation for ischemic contributions to individuals with ischemia may be appropriate.
- For many patients with heart failure, rest–stress PET MPI is an appropriate test for the evaluation of CAD.
- Rest PET MPI was noted as appropriate in those undergoing assessment of myocardial inflammation with ^{18}F-FDG PET at baseline and for recurrent inflammation or during reevaluation for response to therapy.
- The AUC notes Pet MPI appropriateness for use in evaluation of CAD in patients with arrhythmias requires optimal patient selection and depends on the type of arrhythmia, patient stability and risk of CAD.
- The evaluation of CMD with PET should be targeted to a particular clinical scenario that will convey important diagnostic and prognostic information; most clinical scenarios were noted as appropriate. However, PET perfusion and flow quantification should not be applied to asymptomatic individuals or in an uncritical manner to assess for CMD.
- The use of PET MPI may be appropriate in specific populations such as: symptomatic young men and women, children/adolescents with congenital heart disease, symptomatic patients with CAD with known left main or multivessel disease, for use of rest or stress-rest perfusion in patients with ^{18}F-FDG PET to assess cardiac sarcoidosis or myocardial viability, symptomatic patients with suspected cardiac graft rejection, and those with vasculitis and arteritis (Kawasaki and Takayasu disease), those with a BMI > 35m^2/kg, women with large or dense breast tissue that causes attenuation artifacts, patients with familial hypercholesterolemia, asymptomatic patients with CAD and left main or multivessel disease, patients who have had a coronary artery bypass graft (CABG), and those who have undergone percutaneous coronary intervention in multivessel disease.
- Patients with prior testing or revascularization that are most likely to benefit from PET MPI are those with new signs or symptoms of ischemic disease, high residual risk, unexplained ECG changes, incomplete revascularization; who have

been assessed by calcium scoring, coronary angiography, or global coronary risk factor outcome; or who have had prior revascularization.
- PET MPI is considered appropriate for those being considered for kidney, liver, or lung transplantation and those undergoing vascular surgery.

Bateman et al. (2016) published a joint recommendation of the American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging that provides general guidance for rest/stress myocardial perfusion PET and its usefulness in the diagnosis and management of patients with CAD. The clinical indication recommendations are as follows:

- Rest-stress myocardial perfusion PET is a first line preferred test for patients with known or suspected CAD who meet appropriate criteria for a stress imaging test and are unable to complete a diagnostic level exercise stress imaging study.
- Rest-stress myocardial perfusion PET is recommended for patients with suspected active CAD, who meet appropriate criteria for a stress imaging test, and who also meet one or more of the following criteria:
  - Prior stress imaging study was equivocal or inconclusive.
  - Body characteristics that affect image quality (i.e., BMI > 30, large breasts or breast implants, chest wall deformities).
  - Young patients with established CAD who need repeated exposures to radiation-associated cardiac imaging.
  - High-risk patients in whom diagnostic errors carry even greater clinical implications (i.e., diabetes, chronic kidney disease, suspected potentially high-risk CAD, suspected transplant vasculopathy).
  - Patients in whom myocardial blood flow quantification is identified by clinicians to be a needed adjunct to the image findings, to better identify or exclude multivessel CAD, for improved risk stratification, and when assessment of microcirculatory function is needed for clinical decision making.

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Policy History/Revision Information

Date	Summary of Changes
12/01/2024	**Related Policy** • Updated reference link to the UnitedHealthcare Medicare Advantage Medical Policy titled *Radiation and Oncologic Procedures*
11/01/2024	**Template Update** • Previously titled *Positron Emission Tomography (PET) Scan* • Reformatted and reorganized policy; transferred content to new template • Changed policy type classification from "Policy Guideline" to "Medical Policy" • Added *Clinical Evidence* and *References* sections • Updated *Instructions for Use* **Related Policies** • Added reference link to the UnitedHealthcare Medicare Advantage Medical Policy titled *Radiation and Oncologic Procedures* **Coverage Rationale** ***Overview*** • Replaced language indicating: ○ "Positron emission tomography (PET) is a minimally invasive diagnostic imaging procedure used to evaluate metabolism in normal tissue as well as in diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders" with "PET is a minimally invasive diagnostic imaging procedure used to evaluate metabolism *and myocardial perfusion* in normal tissue as well as in diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders" ○ "PET uses a positron camera (tomography) to measure the decay of the radiopharmaceutical" with "PET uses a positron camera (tomography) to measure *the location of and* the decay of the radiopharmaceutical" ***Coverage Guidelines*** • Revised language to indicate: Positron Emission Tomography Perfusion of the Heart ○ Medicare has a National Coverage Determination (NCD) for positron emission tomography perfusion of the heart [NCD 220.6.1], refer to the table [in the *Centers for Medicare & Medicaid (CMS) Related Documents* section of the policy] ○ Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable; refer to the table [in the *Centers for Medicare & Medicaid (CMS) Related Documents* section of the policy] ○ For coverage guidelines for states/territories with no LCDs/LCAs for indications not specifically addressed in NCD 220.6.1, refer to the following indications for use of myocardial imaging: *Acute Myocardial Infarction (AMI)* ▪ PET myocardial perfusion imaging (MPI) is not typically performed during the acute period of myocardial infarction (MI), if the diagnosis is established by other means – PET MPI is appropriate in the assessment of: – Disease severity – Risk assessment and/or prognosis – Efficacy of acute reperfusion therapy – Evidence of myocardial salvage – Suspected infarction when the combination of history and other tests is not diagnostic *Unstable Angina* ▪ PET MPI may be useful as an adjunct to other tests in the diagnosis or treatment of unstable angina only when the combination of history and other tests is not diagnostic ▪ PET MPI is appropriate for: – Identification of ischemia in the distribution of a known lesion or in remote areas – Identification of the severity/extent of disease in patients with medically unstable angina or ongoing ischemia – Measurement of left ventricular function (LVF)

Date	Summary of Changes
	Chronic Ischemic Heart Disease ▪ The use of PET MPI is well established in the diagnosis and management of CAD and is covered in these situations: – Diagnosis of CAD, especially in patients with atypical chest pain – Evaluation of abnormal or suspected false positive stress ECG – Evaluation of other symptoms suspicious for the diagnosis of CAD such as syncope and ventricular arrhythmia – Assessment of myocardial viability after revascularization or medical management – Planning percutaneous transluminal coronary angioplasty (PTCA) to identify lesions causing ischemia, if unknown – Evaluation of suspected or known CAD prior to high-risk surgical procedure – Identification of the presence, location, extent, and severity of myocardial ischemia – Assessment of drug therapy – Assessment of symptoms suggesting restenosis following PTCA – Assessment of symptoms suggesting ischemia following coronary artery bypass graft (CABG) – Follow up of symptomatic ischemic heart disease *Congenital Heart Disease (CHD)* ▪ Echo is the method of choice for evaluating patients with known or suspected CHD ▪ PET MPI may be used when assessing for: – Diagnosis of anomalies of the coronary circulation – Kawasaki's disease *Post-Transplant Cardiac Disease* ▪ PET MPI may be used when assessing for: – Assessment of coronary arteriopathy – Evaluation for ventricular dysfunction with post-transplant rejection Positron Emission Tomography Myocardial Viability ○ Medicare has a NCD [220.6.8] for positron emission tomography myocardial viability, refer to the table [in the *Centers for Medicare & Medicaid (CMS) Related Documents* section of the policy] ○ LCDs/LCAs exist and compliance with these policies is required where applicable; for specific LCDs/LCAs, refer to the table [in the *Centers for Medicare & Medicaid (CMS) Related Documents* section of the policy] ○ For coverage guidelines for states/territories with no LCDs/LCAs for sarcoidosis and other infiltrative disorders: ▪ PET myocardial viability testing with cardiac imaging will be considered medically reasonable and necessary in the determination of cardiac involvement in sarcoidosis using fluorodeoxyglucose (F-18 FDG), in patients who are unable to undergo MRI, have inconclusive MRI findings, or when high probability of disease exists even after a negative MRI ▪ Examples of patients who are unable to undergo MRI include but are not limited to patients with metal implants ▪ PET myocardial viability studies using fluorodeoxyglucose (F-18 FDG) are reasonable to determine response to immunosuppressive therapy in patients diagnosed with cardiac sarcoidosis Combination Positron Emission Tomography Myocardial Perfusion/Viability ○ Imaging of myocardial perfusion can also be combined with myocardial metabolism imaging with fluorodeoxyglucose (F-18 FDG) for the assessment of myocardial viability in areas of resting hypoperfusion and dysfunctional myocardium ○ The stress protocols are, for the most part, similar for all cardiac PET perfusion agents ○ The specific differences in acquisition protocols for rubidium (Rb-82) and ammonia N-13 are related to the duration of uptake and clearance of these radiopharmaceuticals and their physical half-lives ○ UnitedHealthcare uses the criteria above to supplement NCD criteria in NCD 220.6.1 and NCD 220.6.8 related to myocardial PET imaging to ensure consistency in determining that the service is reasonable and necessary ○ The use of the criteria may decrease inappropriate denials by creating a consistent set of review criteria when medically appropriate for a particular patient; further, use of the criteria

Date	Summary of Changes
	should limit the circumstances where myocardial PET imaging scans are incorrectly approved, which itself provides benefits because performing the test when it is not indicated can lead to false positive findings requiring otherwise unnecessary testing and or procedures and downstream complications ○ The benefits of myocardial PET imaging include its ability to accurately measure blood flow between the coronary arteries and heart muscle and to detect dead or injured tissue through images of high resolution and clarity ○ Some studies have found myocardial PET imaging to reduce adverse outcomes and recurrences ○ The potential clinical harms of using these criteria may include inappropriately denying a myocardial PET imaging scan when it is otherwise indicated, which could lead to diagnostic and treatment errors and/or may result in obtaining alternate studies ○ Use of this criteria to supplement the general provisions noted above provides clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services, because these additional criteria will provide greater consistency in determining when a patient's medical factors would support the use of these imaging studies, thus decreasing inappropriate denials **Applicable Codes** • Removed coding clarifications ***CPT Codes*** • Removed CPT codes 78608, 78609, 78811, 78812, 78813, 78814, 78815, and 78816 ***HCPCS Codes*** • Removed list of applicable HCPCS codes: A9515, A9526, A9552, A9555, A9580, A9586, A9587, A9588, A9591, A9592, A9593, A9594, A9595, A9596, A9597, A9598, A9601, A9602, A9609, A9800, G0219, G0235, G0252, Q9982, and Q9983 ***Modifier Codes*** • Removed list of applicable modifier codes: PI and PS ***Diagnosis Codes*** • Removed I20.8, I22.9, I24.8, I25.2, I25.3, I25.41, I25.42, I25.83, I34.8, I47.1, I47.2, I47.20, I71.01, I71.1, I71.2, I71.3, I71.4, I71.5, I71.6, Q21.1, and Q21.2 **Centers for Medicare & Medicaid (CMS) Related Documents** • Updated list of documents available in the *Medicare Coverage Database* to reflect the most current information • Added list of applicable *Medicare Administrative Contractors (MACs) With Corresponding States/Territories* • Added notation for the state of Virginia to indicate Part B services for the city of Alexandria and the counties of Arlington and Fairfax are excluded for the Palmetto GBA jurisdiction and included within the Novitas Solutions, Inc. jurisdiction • Removed reference link to Title XVIII of the Social Security Act § 1861(s)(3), § 1862 (a)(1)(A), § 1862 (a)(1)(D) Investigational or Experimental, § 1862 (a)(7)), and § 1833 (e) **Supporting Information** • Archived previous policy version MPG242.15

Instructions for Use

The Medicare Advantage Policy documents are generally used to support UnitedHealthcare coverage decisions. It is expected providers retain or have access to appropriate documentation when requested to support coverage. This document may be used as a guide to help determine applicable:

- Medical necessity coverage guidelines; including documentation requirements, and/or
- Medicare coding or billing requirements.

Medicare Advantage Policies are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates. This Policy is provided for informational purposes and does not constitute medical advice. It is intended to serve only as a general reference and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Treating physicians and healthcare providers are solely

responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes this policy. For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.

Medicare Advantage Policies are developed as needed, are regularly reviewed, and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policies at any time by publishing a new version on this website. Medicare source materials used to develop these policies may include, but are not limited to, CMS statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and manuals. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. The information presented in this Policy is believed to be accurate and current as of the date of publication. Where there is a conflict between this document and Medicare source materials, the Medicare source materials apply. Medicare Advantage Policies are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing certain items or services referenced in this Medical Policy have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, in these circumstances, UnitedHealthcare applies internal coverage criteria as referenced in this Medical Policy. The internal coverage criteria in this Medical Policy was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Providers are responsible for submission of accurate claims. Medicare Advantage Policies are intended to ensure that coverage decisions are made accurately. UnitedHealthcare Medicare Advantage Policies use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

For members in UnitedHealthcare Medicare Advantage plans where a delegate manages utilization management and prior authorization requirements, the delegate’s requirements need to be followed.