Cohere Medicare Advantage Policy - Positron Emission Tomography (PET), Cardiac

Clinical Guidelines for Medical Necessity Review

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Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Other Notices:

Guideline Information:

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Medical Necessity Criteria

Service: Positron Emission Tomography (PET), Cardiac

Benefit Category

Diagnostic Tests (Other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[1-13]

- National Coverage Determination (NCD). FDG PET for Myocardial Viability (220.6.8)
- National Coverage Determination (NCD). PET for Perfusion of the Heart. (220.6.1)
- National Coverage Determination (NCD). Positron Emission Tomography (FDG) for Oncologic Conditions. (220.6.17)
- Local Coverage Determination (LCD). Multiple Imaging in Oncology (L35391)
- Local Coverage Determination (LCD). Positron Emission Tomography (PET) Scan for Inflammation and Infection (L39521).
- Local Coverage Determination (LCD) Cardiac Radionuclide Imaging. (L33457)
- Local Coverage Determination (LCD) Cardiology Non-Emergency Outpatient Stress Testing. (L35083)
- Local Coverage Determination (LCD) Cardiology Non-Emergent Outpatient Stress Testing. (L38396)
- Billing and Coding: Multiple Imaging in Oncology. (A56848)
- Billing and Coding: Positron Emission Tomography (PET) Scan for Inflammation and Infection (A59318)
- Billing and Coding: Cardiac Radionuclide Imaging (A56476)
- Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing. (A56423)

- Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing. (A56952)

Recommended Clinical Approach

Cardiac PET is considered advanced imaging, and it is best utilized per institutional internal medicine and cardiology protocols. Radiologic and cardiology guidelines from the American Society of Nuclear Cardiology (ASNC), American College of Radiology (ACR), American College of Cardiology (ACC), Society of Nuclear Medicine and Molecular Imaging (SNMMI), and European Association of Nuclear Medicine (EANM) may be consulted prior to ordering.

Cardiac PET is specifically optimized for the evaluation of myocardial perfusion and viability. It may also be utilized to evaluate infection and inflammation. Myocardial perfusion in the setting of suspected or known coronary artery disease (CAD) can be evaluated with cyclotron-produced (^{13}N-ammonia) or generator-produced (^{82}Rb) PET agents.[14-29]

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of cardiac PET. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of PET imaging, including cumulative radiation exposure, allergy, and harm to breast milk.[30]
- Potential danger to pregnancy: PET imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy.[31] Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.[31]
- Increased healthcare costs and complications from the inappropriate

use of additional interventions.[32]

The clinical benefits of using these criteria include:

- Noninvasive: As an imaging modality, cardiac PET is noninvasive; it is widely accepted that noninvasive procedures are less costly, associated with fewer complications, and preferred by both patients and providers. It also utilizes no injected contrast agent, conferring an inherent safety benefit.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

➔ **Positron emission tomography (PET) cardiac or PET cardiac with stress testing** is considered appropriate if **ANY** of the following is **TRUE**:

◆ **Rubidium (^{82}Rb) cardiac PET or PET/CT** for **ANY** of the following[15]:

- The patient is asymptomatic with known CAD or a high pretest probability (PTP) of CAD (See the Pre-Test Probability of CAD published by the CAD Consortium) with **ANY** of the following:
  - Equivocal prior coronary CT angiography (CCTA, with 40-90% stenosis); **OR**
  - Equivocal exercise stress test; **OR**
  - History of coronary artery bypass grafting more than 5 years prior and no stress test performed in the last 2 years; **OR**

    - History of percutaneous coronary intervention and no stress test performed in the last 2 years prior; **OR**
    - Coronary artery calcium score equal to or above 400; **OR**
    - New or worsening left ventricular dysfunction (ejection fraction [EF] less than or equal to 45%); **OR**
- New or previously unrecognized or uninterpretable ECG, as qualified by **ANY** of the following:
    - Complete left bundle branch block; **OR**
    - Ventricular paced rhythm; **OR**
    - Pre-excitation pattern such as Wolff-Parkinson-White; **OR**
    - A less than 1 millimeter ST segment depression; **OR**
    - Left ventricular hypertrophy (LVH) with repolarization abnormalities; **OR**
    - Patients on beta blocker, calcium channel blocker, and/or antiarrhythmic medication; **OR**
    - Physical inability to perform a maximum exercise workload; **OR**
- The patient is symptomatic with suspected or known coronary artery disease (CAD) and imaging is recommended for **ANY** of the following reasons:
    - Detection of obstructive CAD with myocardial ischemia in patients with chest pain (acute but stabilized or chronic); **OR**
    - Intermediate or high pretest probability; **OR**
    - For clarification of equivocal or discordant prior tests and **ANY** of the following is **TRUE**:
        - Presence of anomalous coronary arteries with suspected ischemia; **OR**
        - Presence of borderline obstructive lesions on coronary angiography (50-70% non-left main stenosis or CCTA (40-90% stenosis); **OR**
    - New heart failure diagnosis without previous assessment for CAD with **ANY** of the following:
        - Heart failure with preserved ejection fraction (intermediate or high-risk of CAD); **OR**

        - ◆ Ejection fraction less than 45% (any clinical risk of CAD)[16]; **OR**
    - Pre-operative risk assessment before high-risk surgical procedures (e.g., vascular surgery, solid organ transplantation); **OR**
    - Post-operative assessment of reimplanted coronary arteries (e.g., surgically corrected transposition of the great arteries); **OR**
- Evaluation or surveillance for **ANY** of the following:
    - For assessment of myocardial blood flow in suspected microvascular disease; **OR**
    - Myocardial viability for detection of hibernating or stunned myocardium; **OR**
    - Transplant coronary artery disease (TCAD) or cardiac allograft vasculopathy (CAV) in patients with a history of organ transplantation; **OR**
- Hypertrophic cardiomyopathy; **OR**
- New-onset atrial fibrillation with no prior cardiac evaluation; **OR**
- Patients without clear cardiac symptoms in the presence of an elevated cardiac troponin; **OR**
- Patients who will be treated with interleukin-2 products for various malignant disorders; **OR**
- Evidence or high suspicion of ventricular arrhythmias; **OR**
- Syncope for patients with an intermediate or high CHD risk (ATP III risk criteria) and where cardiac etiology is suspected based on an initial evaluation, including history, physical examination, or ECG, and patient is unable to exercise; **OR**
- Worsening or continuing symptoms after normal or submaximal exercise stress test with suspicion of a false negative result; **OR**
- History of false positive exercise stress test; **OR**

◆ **FDG PET/CT** and **ANY** of the following is **TRUE**[25]:

- Evaluation of cardiac sources of infection or inflammation, as indicated by **ALL** of the following[5]:
    - Documented suspicion on clinical exam and laboratory evaluation; **AND**

    - Non-specific or inconclusive imaging from echocardiography and/or CT; **AND**
    - The patient is being evaluated for **ANY** of the following conditions:
        - Infective endocarditis with a prosthetic valve; **OR**
        - Suspected cardiac device infection (pacemaker, defibrillators, LVAD, metallic implants); **OR**
        - CTA or MRA are inconclusive or nondiagnostic for **ANY** of the following:
            - Aortitis; **OR**
            - Systemic vasculitis; **OR**
            - Vascular graft infection; **OR**
        - Cardiac sarcoidosis with **ANY** of the following:
            - Risk factors (such as systemic sarcoidosis); **OR**
            - Patient less than 60 years old with unexplained, new onset conduction system disease; **OR**
            - Heart failure without explanation; **OR**
            - Idiopathic sustained ventricular tachycardia unexplained by other causes; **OR**
- Neoplastic conditions for **ANY** of the following:
    - Initial staging; **OR**
    - Treatment planning; **OR**
    - Response assessment; **OR**
    - Restaging or treatment monitoring, and **ANY** of the following is **TRUE**[4,33]:
        - The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); **OR**
        - Suspected recurrence/progression; **OR**
        - Evaluation of response to treatment when a change in therapy is contemplated (no more often than after 2 cycles of chemotherapy

and/or 6-8 weeks since the prior imaging evaluation); **OR**

- An abnormality considered indeterminate by another imaging modality to determine whether glucose metabolism in that abnormality favors a benign or malignant process; **OR**
- Cardiomyopathy (inflammatory or restrictive) and ischemic cardiomyopathy have been excluded[26]; **OR**
- Ventricular arrhythmia (frequent PVCs, non-sustained ventricular tachycardia, sustained ventricular tachycardia, or cardiac arrest)[27-28]; **OR**
- Myocardial viability assessment prior to revascularization[1]; **OR**
- Nontraumatic chest wall pain with a normal chest radiography and **ANY** of the following[34]:
  - History of prior chest intervention; **OR**
  - Known or suspected malignancy; **OR**
  - Suspected infectious or inflammatory condition; **OR**

◆ Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if **ANY** of the following is **TRUE**:

- New or worsening symptoms, such that repeat imaging would influence treatment; **OR**
- One-time clarifying follow-up of a prior indeterminate finding; **OR**
- In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

➔ **Positron emission tomography (PET), cardiac** is not considered appropriate if **ANY** of the following is **TRUE**:

◆ The imaging request is for **myocardial perfusion PET** and **ANY** of the following is **TRUE**:

- Acute nonspecific chest pain with a low probability of CAD[20]; **OR**

- Asymptomatic patients with less than an intermediate risk for CAD who may benefit from CT coronary calcium or coronary CT angiography; **OR**
- Chest trauma[18,35]; **OR**
- Nonischemic myocardial disease (excluding sarcoidosis)[17-18]; **OR**
- Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**

◆ The imaging request is for FDG PET/CT with **ANY** of the following:

- If used as first-line diagnostic test; **OR**
- If **ANY** of the following tests have already been done or are planned as part of diagnostic evaluation without documented medical necessity:
  - Labeled WBC scan; **OR**
  - 67Ga SPECT/CT; **OR**
  - Cardiac MRI; **OR**
- Endocarditis in a native valve; **OR**
- If used for monitoring response to treatment with the exception of cardiac sarcoidosis; **OR**
- Acute chest pain with suspected aortic dissection; **OR**
- Incompatible implantable devices (e.g., pacemakers, defibrillators, cardiac valves); **OR**
- The use of PET scan for inflammation and infection of other conditions not specifically addressed in the indications will be considered investigational.

*NOTE: PET in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.
**NOTE: PET scans should be scheduled at least 4–6 weeks after radiation therapy or surgery to avoid false positives due to inflammation from recent treatments.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and

the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.[36-37]

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.[36-37]

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.[36-37]

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.[36-37]

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
78429	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study; with concurrently acquired computed tomography transmission scan
78430	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall

	motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography
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 (CT) 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 (CT) 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
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)
78811	Positron emission tomography (PET) imaging; limited area (e.g., of chest, head/neck)

Medical Evidence

Patel et al. (2020) assess the use of positron emission tomography (PET) myocardial perfusion imaging (MPI) as a way to non-invasively measure myocardial blood flow reserve (MBFR). One aim was to determine if patients with MBFR with a survival benefit after revascularization, which helps guide post-test management. A total of 12594 patients who underwent Rb82 rest/stress PET MPI were included. The MBFR observed on PET MPI correlates with overall mortality risk and can pinpoint individuals who would potentially derive survival advantages from early revascularization as opposed to medical management alone. The authors conclude that utilization of the metric can inform decision-making regarding revascularization strategies, however, further validation through prospective studies is warranted.[38]

Gulati et al. (2021) recommended for 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.[39]

Swart et al. (2018) performed a multicenter study to enhance the accuracy of ^{18}F-Fluorodeoxyglucose (FDG) positron-emission tomography/computed tomography (PET/CT) in patients suspected of having prosthetic heart valve endocarditis (PVE). Notably, FDG-PET is not appropriate to image suspected endocarditis of the native valve, as sensitivity for detecting native valve endocarditis has been reported at 0%.[29] The study identified and eliminated potential confounding factors using visual and standardized quantitative evaluations. A total of 160 patients with a prosthetic heart valve were included (median age 62; 68% male; 82 mechanical valves; 62 biological; 9 transcatheter aortic valve replacements; 7 other). All patients underwent FDG PET/CT for suspicion of PVE. Early integration of FDG PET/CT into the diagnostic protocol is shown to mitigate the potential impact of low inflammatory activity (for example, that induced by prolonged antibiotic treatment).[40]

Chen et al. (2017) conducted the CORE320 Multicenter Study (NCT00934037) to compare the prognostic significance of combined CT angiography and CT myocardial stress perfusion imaging vs a combination of invasive coronary

angiography (ICA) and stress single photon emission CT myocardial perfusion imaging. The study also addressed the time to major adverse cardiovascular events (MACE). Results indicate that the combined use of CT angiography and CT myocardial perfusion demonstrates comparable predictive ability for 2-year MACE-free survival. This encompasses the necessity for myocardial revascularization procedures compared to the standard approach involving ICA and single photon emission CT perfusion imaging.[21]

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