Coverage Indications, Limitations, and/or Medical Necessity

Cardiovascular nuclear imaging employs non-invasive techniques to assess alterations in coronary artery flow, as well as ventricular function. A variety of radionuclides may be used.

The specific imaging technique (perfusion versus ventricular function) and the reason for the imaging determine what radionuclide agent is employed. In its simplest terms, a perfusion study utilizes an imaging isotope agent that reflects myocardial blood flow and, dependent on the agent and timing of image acquisition, the presence of scar and/or ischemia. Ventricular function studies utilize specific imaging isotopes to outline the borders of the left ventricular endocardium or to identify the ventricular blood pool independent of the surrounding myocardium. The motion of the left ventricle is synchronized with the electrocardiogram to generate wall motion and ejection fraction information. Both modalities may use rest and exercise images.

In instances where an exercise test cannot be performed, provocative agents may be used to alter coronary flow, thereby unmasking a suspected lesion in the coronary bed. The acquisition of the images may be planar (single plane) or by multiple planes with computer integration, Single-Photon Emission Computer Tomography (SPECT).

INDICATIONS

Radionuclide imaging may be employed in the assessment of a variety of conditions associated with primary coronary artery disease. Some of these conditions include:

1. Assessment of the functional and prognostic importance of angina, chest pain, or angina equivalent symptoms.
2. Diagnostic evaluation of patients with chest pain and uninterpretable or equivocal ECG changes occurring naturally or caused by drugs, bundle branch block, or left ventricular hypertrophy.
3. Risk assessment of re-evaluation of disease in patients who are asymptomatic or have stable symptoms, with known atherosclerotic heart disease on catheterization or SPECT perfusion imaging, who have not had a revascularization procedure within the past two years or greater than 2 years since last imaging study.

4. Detection of coronary artery disease in patients, without chest pain syndrome, with new-onset of diagnosed heart failure or left ventricular systolic dysfunction.

5. Evaluation of ischemic versus non-ischemic cardiomyopathy when cardiac catheterization / coronary angiography is not planned.

6. Evaluation of myocardial perfusion viability and/or function before and more than or equal to 5 years after coronary artery bypass surgery or greater than or equal to 2 years after percutaneous perfusion procedures, unless new clinical signs or symptoms necessitate reevaluation.

7. Quantification and surveillance of myocardial infarction and prognostication in patient with infarction.

8. Preoperative assessment for non-cardiac surgery, when used to determine risk for surgery and/or perioperative management in:
   a. Patients with minor or intermediate clinical risk predictors and poor functional capacity.
   b. Patients with intermediate or high likelihood of coronary heart disease, or patients with poor functional capacity undergoing high risk non-cardiac surgery.

   The ACA/AHA 2014 Guidelines on Perioperative Cardiovascular Evaluation and Care for Non-Cardiac Surgery (JACC 2014) provides the following information regarding categorization of surgical risk. They include:
   - high risk/intermediate risk surgery: aortic and peripheral vascular surgery; intraperitoneal and intrathoracic surgery, carotid endarterectomy, head and neck surgery, orthopedic surgery and prostate surgery;
   - low risk surgery: endoscopic procedure, superficial surgery, cataract surgery, breast surgery, ambulatory surgery;
   - The Guidelines establish poor functional capacity as = less than 4 METS;
   - Utilization of these tests is based on the presence of multiple risk factors, the level of functional capacity, the risk of surgery proposed, and the likelihood that the results of the cardiac testing would change the management.


10. Evaluation of patients in whom an accurate measure of the ejection fraction is needed to make a determination of whether to implant a defibrillator or biventricular pacemaker.

11. Evaluation of patient receiving chemotherapeutic drugs which are potentially cardiotoxic (e.g., Adriamycin, Herceptin).

First pass studies will be considered medically necessary only when information sought is immediately relevant to the management of the patient’s clinical condition and has not been previously obtained or likely to be obtained from other planned tests such as echocardiography or equilibrium gated blood pool studies. First pass studies may be indicated for the assessment and identification of shunts and are more likely to be done in
suspected congenital events. It is noted that occasionally first pass studies and gated blood pool studies may be additive when RVEF is needed on the same day.

Infarct Avid Scintigraphy is indicated in patients in whom it is not possible to make a definitive diagnosis of myocardial infarction by EKG or enzyme testing.

Patient selection should be based on clinical grounds:
- Patients with a high pretest probability of disease are not usually candidates for a study for diagnostic purposes, though the size and reversibility of a defect and its functional consequences may be required for clinical decision-making.
- Patients with a moderate probability of disease benefit the most from the study when the diagnosis is in question.
- Selection of tests should be made within the context of other tests, scheduled and previously performed so that the anticipated information obtained is unique and not redundant.
- Redundant testing where multiple tests are done revealing the same information is not medically necessary and should be appropriately denied if reviewed.

LIMITATIONS

Given the limitations of uptake, low photon energy and redistribution, it would not be considered reasonable and necessary for the cardiac blood pool codes and perfusion imaging codes to be performed on the same date of service.

Cardiac blood pool imaging studies are described by the codes 78472, 78473, 78481, 78483, 78494 (with add on code 78496). It is not considered reasonable and necessary for more than one code from this series (with appropriate add-on) to be reported on a single date of service.

All cardiovascular nuclear tests and stress tests must be referred by a physician or a qualified non-physician. (i.e., a Nurse Practitioner (NP) or Physician Assistant (PA)).

All stress tests must be performed under the direct supervision of a physician (even in a facility). The nuclear test components must be performed under the general supervision of a physician.

Myocardial perfusion studies performed based on the presence of risk factors in the absence of cardiac symptoms, cardiac abnormalities on physical examination, or abnormalities on cardiac testing (e.g., electrocardiographic tests, echocardiography, treadmill stress testing, etc.) will be considered screening and denied as not covered by Medicare.

Tests that are anticipated to provide information duplicative of another test already performed will be denied as not medically necessary.

Tests performed when the results would not be anticipated to influence medical
management decisions will be denied as not medically necessary.

Myocardial perfusion studies performed subsequent to a diagnostic myocardial PET scan will be denied as not medically necessary.

Infarct avid scintigraphy will be denied if the diagnosis of myocardial infarction has already been confirmed by enzymes and/or EKG.

Tests performed unrelated to changes in a patient’s signs or symptoms, or for immediate preoperative screening without signs or symptoms will be denied as medically unnecessary. Please see preoperative testing indications above.

Tests performed for risk assessment prior to high risk non-cardiac surgery in asymptomatic patients within one year following normal catheterization or non-invasive test will be considered medically unnecessary and denied.

Tests performed for preoperative evaluation in patients undergoing low-risk surgery will be denied.

**CPT/HCPCS Codes**

**Group 1 Paragraph:** Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book.

**Group 1 Codes:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>78451</td>
<td>Ht muscle image spect sing</td>
</tr>
<tr>
<td>78452</td>
<td>Ht muscle image spect mult</td>
</tr>
<tr>
<td>78453</td>
<td>Ht muscle image planar sing</td>
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<td>78466</td>
<td>Heart infarct image</td>
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<td>78468</td>
<td>Heart infarct image (ef)</td>
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<td>78469</td>
<td>Heart infarct image (3D)</td>
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<tr>
<td>78472</td>
<td>Gated heart planar single</td>
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<tr>
<td>78473</td>
<td>Gated heart multiple</td>
</tr>
<tr>
<td>78481</td>
<td>Heart first pass single</td>
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</table>
78483 Heart first pass multiple
78494 Heart image spect
78496 Heart first pass add-on
A9500 Tc99m sestamibi
  Technetium TC-99m
teboroxime
A9502 Tc99m tetrofosmin
A9505 TL201 thallium
A9512 Tc99m pertechnetate
A9538 Tc99m pyrophosphate
A9560 Tc99m labeled rbc
J0153 Adenosine inj 1mg
J1245 Dipyridamole injection
  Inj dobutamine HCL/250 mg
J1250
J2785 Regadenoson injection
  Drugs unclassified
J3490
Q9969 Non-HEU TC-99M add-on/dose

Please refer to the CMS website for the ICD-10 Codes that Support Medical Necessity.

Documentation Requirements
1. All documentation must be maintained in the patient’s medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
4. Medical records must substantiate the medical necessity of the services, including a clinical diagnosis and the specific reason for the study.
5. All segments of the service must have a formal interpretation and report.
6. Requested records must be accompanied by a copy of the formal report and the reason for the referral for the test.
7. The referral order must be kept on file in the patient’s medical record.
8. When HCPCS procedure code A9505 is submitted with CPT procedure codes 78451, 78452, 78453 or 78454, the formal report must indicate that the laboratory is equipped with at least a double-headed camera as well as the appropriate software to complete the study satisfactorily.
9. When CPT code 78472 and add-on code 78496 are submitted with perfusion codes 78451, 78452, 78453, 78454, 78466, 78468 or 78469, the formal reports must document that simultaneous cardiac function studies using the first-pass technique were performed and the laboratories are equipped to perform such studies.
10. When billing for the purchase of radiopharmaceutical(s), a copy of the bill indicating the dosage administered, unit price per dose, name and total charge of the radioactive drug must be made available to Medicare upon request.
11. When requesting a written redetermination (formerly appeal), providers must include all relevant documentation with the request.

Reviewed/Approved by Michael Pentecost, MD, Chief Medical Officer