Local Coverage Determination (LCD): Cardiac Radionuclide Imaging (L33457)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

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LCD Information

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<td>For services performed on or after 10/01/2015</td>
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CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A) allows coverage and payment for only those services that are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, §1862(a)(7) excludes routine physical examinations.

CMS Internet-Only Manual, Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 4, §220.6.1


Coverage Guidance

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Coverage Indications, Limitations, and/or Medical Necessity

The two types of radionuclide studies commonly used for cardiac evaluation are myocardial perfusion imaging (MPI) and cardiac blood pool imaging (multiple gated acquisition scanning (MUGA), ventriculography). MPI is used primarily for the evaluation of coronary artery disease (CAD). Ventriculography is sometimes referred to as MUGA or cardiac blood pool imaging and is primarily used to evaluate valvular disease and cardiomyopathies. Either type of study may be obtained at rest or with stress. Stress may be provided by exercise or with pharmacologic agents.

MPI is a diagnostic procedure that evaluates blood flow to cardiac muscle using radionuclides. A gamma camera is used to record images in planar or tomographic (single photon emission computed tomography (SPECT)) projections. Use of dual radiopharmaceuticals permits concurrent studies at rest and after stress, which are then compared and interpreted by a nuclear physician. Since the radiopharmaceutical accumulates in the myocardium in relation to blood flow, ischemic and infarcted myocardium can be detected.

With the use of technetium based radiopharmaceuticals, the perfusion imaging may be linked to acquisition of “first pass” data to visualize blood flow through the right heart, lungs and left heart giving diagnostically useful information about cardiac chamber shunts, wall motion, cardiac output, ejection fraction (EF), left ventricular volume, shunt fraction and valvular regurgitation.

Positron emission tomography (PET) scans performed for the diagnosis and management of patients with known or suspected coronary artery disease, using the Food and Drug Administration (FDA) approved Rubidium 82 (Rb 82), are covered when the following conditions are met:

- The PET scan (at rest or rest with stress) is performed in place of SPECT; or
- is performed following and inconclusive SPECT (results that are equivocal, technically uninterpretable, or discordant with the patient’s other clinical data).

In such cases the PET scan must have been determined to be medically necessary to guide further treatment of the patient.

When a PET scan is performed as an additional diagnostic test in the instance of an equivocal SPECT, the reason for performing the PET scan must be clearly documented in the patient’s record.

The following studies are considered investigational and will not be covered:

- Ambulatory radionuclide cardiac monitoring
- Monoclonal anti-myosin imaging
- Radionuclide imaging of thrombi
- Radionuclide imaging of cardiac adrenergic nerves

**Myocardial Perfusion Imaging**

Patients with a high pretest probability of disease are usually not candidates for this study unless determination of the size and reversibility of a defect are required for clinical decision making. Patients whose diagnosis is in question benefit most from this study. Patients with a low pretest probability of disease are usually not studied except when a prior exercise stress test by treadmill electrocardiogram (ECG) or echocardiogram (echo) is a presumed false positive. Stress MPI, preceded by satisfactory stress echo, is not medically necessary.

**Indications for Myocardial Perfusion Imaging**

1. Acute myocardial infarction (AMI) - MPI is not typically performed during the acute period of myocardial infarction
(MI), if the diagnosis is established by other means. In selected patients, imaging 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.

2. Unstable angina - 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. In selected patients, imaging 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).

3. Chronic ischemic heart disease - The use of 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

3. Congenital heart disease (CHD) - Echo is the method of choice for evaluating patients with known or suspected CHD. Selected patients may benefit from MPI when assessing for:

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

5. Post-transplant cardiac disease

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

**Cardiac Blood Pool Imaging (MUGA, Ventriculography)**

These services are allowed for the evaluation of ventricular size, wall motion, stroke volume, and EF when this
information is medically necessary to direct further evaluation and management of the cardiac condition.

Indications for Cardiac Blood Pool Imaging (MUGA, Ventriculography):
1. Cardiomyopathy - Cardiac blood pool imaging (MUGA, ventriculography) is covered for:
   - Diagnosis of hypertrophic cardiomyopathy and/or myocardial ischemia
   - Differentiation of ischemic from non-ischemic cardiomyopathy

2. Post-transplant cardiac disease
   - Assessment of coronary arteriopathy
   - Evaluation for ventricular dysfunction with post-transplant rejection

3. Assessment of cardiac function for cardiotoxic chemotherapy
   - A. One baseline study is considered medically necessary prior to the initiation of cardiotoxic chemotherapy when one of the following conditions is met:
     1. No echo is planned or performed
     2. Prior echocardiogram is uninterpretable due to poor visualization window
   - B. Cardiac function monitoring during or at the completion of cardiotoxic chemotherapy. Cardiotoxic chemotherapy includes any of the following medications:
     - 5-FU (5 fluorouracil)
     - Adriamycin® (doxorubicin)
     - Avastin® (bevacizumab)
     - Cerubidine® (daunorubicin)
     - Clolar® (clofarabine)
     - Cytoxan® (cyclophosphamide)
     - Epirubicin (Pharmorubicin®)
     - Gleevec® (imatinib)
     - Herceptin® (trastuzumab)
     - Ifex® (ifosfamide)
     - Mutamycin® (mitomycin)
     - Nexavar® (sorafenib)
     - Novantrone® (mitoxantrone)
     - Sutent® (sunitinib)
     - Taxol® (paclitaxel)
     - Taxotere® (docetaxel)
     - Tykerb® (lapatinib)
     - Valstar® (valrubicin)
     - Xeloda® (capecitabine)
     - Zavedos® (idarubicin)

Pharmacologic Stress Agents
For those patients who are unable to reach 75-100% of their age predicted maximum heart rate by physiologic exercise, vasodilation can be achieved with the use of either dipyridamole or adenosine. Use of pharmacologic agents in MPI is not a standard of care and is not medically necessary unless exercise is not possible. In some cases dobutamine may be used to effect stress through its inotropic effect.
1. Dipyridamole is typically administered intravenously (IV) at 0.57 mg/kg over a 4-minute period. The maximum dose should not exceed 60 mg. Since the dilation effect persists, after injection of the radiopharmaceutical, its effect is typically reversed with IV aminophylline, which must be available to reverse ischemia when it occurs. Dipyridamole is relatively contraindicated in patients with:

- Known bronchospastic lung disease (asthma)
- Systemic hypotension (systolic blood pressure (BP) below 100 mm Hg.)
- AMI less than 48 hours old
- Unstable angina

2. Adenosine is administered IV at 0.14 mg/kg/min over 6 minutes (0.84mg/kg). The vasodilation effect is short lived. Adenosine is contraindicated in patients with:

- Second or third degree atrioventricular (AV) block
- Sinus node disease, except for those with a functioning pacemaker
- Known or suspected bronchoconstrictive or bronchospastic lung disease
- Known hypersensitivity to adenosine

3. Dobutamine is administered IV, starting at 0.5-1.0 mcg/kg/min and titrated to reach the maximum heart rate for 2-5 minutes. The maximum dose is 40 mcg/kg/min. Atropine may be added in appropriate doses IV. Dobutamine is contraindicated in patients with:

- Idiopathic subaortic stenosis
- AMI

**Physician Supervision Requirements**

MPI and blood pool imaging require general supervision by a qualified physician licensed to administer radioactive materials. Cardiology stress procedures performed in conjunction with nuclear MPI studies are covered by Medicare only when performed under the direct supervision of a qualified physician, who provides:

- Medical expertise required for performance of the test
- Medical treatment for complications and side effects of the test
- Medical services required as part of the test such as injections of medications
- Medical expertise in the interpretation of the cardiovascular stress test component, some of which has to be provided during the test and before the patient is discharged from the testing suite

**Summary of Evidence**

N/A

**Analysis of Evidence**

(Rationale for Determination)
General Information

Associated Information

Documentation Requirements

The patient's medical record must document the medical necessity of services performed for each date of service submitted on a claim, and documentation must be available to the A/B MAC on request.

The medical record must document when significant resting ECG abnormalities are present, or a medication is being used and cannot be withdrawn, that would interfere with interpretation of a stress ECG, resulting in the selection of myocardial perfusion study.

The rationale for selecting pharmacologic stress rather than exercise stress must be indicated in the medical record.

Claims submitted for stress tests performed as preoperative evaluation of patients without symptoms of CAD who are deemed to be at moderate risk must document one of the following at-risk conditions in the medical record: Diabetes mellitus (DM) with complications, peripheral vascular disease (PVD), aortic aneurysm or cerebrovascular disease.

Utilization Guidelines

Services performed for excessive frequency are not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers and the reason for additional services is not justified by documentation.

Sources of Information

N/A

Bibliography


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<td>10/10/2019</td>
<td>R18</td>
<td>This LCD is being revised in order to adhere to CMS requirements per chapter 13, section 13.5.1 of the Program Integrity Manual, to remove all coding from LCDs. There has been no change in coverage with this LCD revision. Title XVIII of the Social Security Act, §1833(e) was removed from the CMS National Coverage Policy section of this LCD and placed in the related Billing and Coding: Cardiac Radionuclide Imaging A56476 article. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</td>
<td>• Provider Education/Guidance</td>
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<td>05/09/2019</td>
<td>R17</td>
<td>Under Coverage Indications, Limitations and/or Medical Necessity – Myocardial Perfusion Imaging, Cardiac Blood Pool Imaging (MUGA, Ventriculography), Pharmacologic Stress Agents and Physician Supervision Requirements removed all HCPCS and CPT® codes listed in each subsection. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</td>
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<td>04/11/2019</td>
<td>R16</td>
<td>All coding located in the Coding Information section has been moved into the related Billing and Coding: Cardiac Radionuclide Imaging A56476 article and removed from the LCD. Under Coverage Indications, Limitations and/or Medical Necessity removed quoted Internet Only Manual (IOM) text and changed verbiage to read &quot;Positron emission tomography (PET) scans performed for the diagnosis and management of patients with known or suspected coronary artery disease, using Food and Drug Administration (FDA) approved Rubidium 82 (Rb 82), are covered when the following conditions are met: The PET scan (at rest or rest with stress) is performed in place of SPECT; or is performed following and inconclusive</td>
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<td>11/08/2018</td>
<td>R15</td>
<td>Under <strong>Bibliography</strong> changes were made to citations to reflect AMA citation guidelines. Formatting, punctuation and typographical errors were corrected throughout the policy.</td>
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<td>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</td>
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<td>10/01/2018</td>
<td>R14</td>
<td>Under <strong>ICD-10 Codes that Support Medical Necessity: Group 1</strong> added ICD-10 codes I63.81, I63.89, I67.850 and I67.858. Under <strong>ICD-10 Codes that Support Medical Necessity: Group 1</strong> deleted ICD-10 code I63.8. This revision is due to the 2018 Annual ICD-10 Code Update and is effective on October 1, 2018.</td>
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<td>02/26/2018</td>
<td>R13</td>
<td>The Jurisdiction &quot;J&quot; Part B Contracts for Alabama (10112), Georgia (10212) and Tennessee (10312) are now being serviced by Palmetto GBA. The notice period for this LCD begins on 12/14/17 and ends on 02/25/18. Effective 02/26/18, these three contract numbers are being added to this LCD. No coverage, coding or other substantive changes (beyond the addition of the 3 Part B contract numbers) have been completed in this revision.</td>
<td>• Change in Affiliated Contract Numbers</td>
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<td>01/29/2018</td>
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<td>The Jurisdiction &quot;J&quot; Part A Contracts for Alabama (10111), Georgia (10211) and Tennessee (10311) are now being serviced by Palmetto GBA. The notice period for this LCD begins on 12/14/17 and ends on 01/28/18. Effective 01/29/18, these three contract numbers are being added to this LCD. No coverage, coding or other substantive changes (beyond the addition of the 3 Part A contract numbers) have been completed in this revision.</td>
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<td>12/02/2017</td>
<td>R11</td>
<td>Revisions were made to the Cardiac Radionuclide Imaging Local Coverage Determination (LCD) L33457. Under Coverage Indications, Limitations and/or Medical Necessity “multiple gated acquisition” and “Percutaneous Transluminal Coronary Angioplasty” verbiage was deleted, the first set of bulleted verbiage was italicized, corrected sentence grammar, corrected the maximum dose of Dobutamine to read “40mcg/kg/min, and the bullets throughout the policy were rearranged. Under CPT/HCPCS Codes, added the Group 3 paragraph verbiage: “Pharmacologic Stress Agents” and the following HCPCS codes were added: J0153, J0280, J0461, J1245, and J1250. Under ICD-10 Codes that Support Medical Necessity, Group 1 Paragraph, Myocardial Perfusion Imaging, added Group 3 codes J0153, J0280, J0461, J1245, and J1250. Under Associated Information corrected the spelling error in the title Documentation Requirements and added “the” to the first paragraph. Under Bibliography corrected the author initials to now read “JI” for the Circulation journal citation.</td>
<td>• Provider Education/Guidance • Other (Annual Validation)</td>
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At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.

Under **ICD-10 Codes That Support Medical Necessity**

Myocardial Perfusion Imaging Group 1: Codes added

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<td>12/30/2016</td>
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<td>Under <strong>Coverage Indications, Limitations and/or Medical Necessity</strong> the following acronyms were defined: Electrocardiogram (ECG); Percutaneous Transluminal Coronary Angioplasty (PTCA); and Coronary Artery Bypass Graft (CABG).</td>
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<td>10/01/2016</td>
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<td>Under <strong>ICD-10 Codes That Support Medical Necessity: Group 2</strong> added C58, C81.10, C81.11, C81.12, C81.13, C81.14, C81.15, C81.16, C81.17, C81.18, C81.19, C81.20, C81.21, C81.22, C81.23, C81.24, C81.25, C81.26, C81.27, C81.28, C81.29, C81.30, C81.31, C81.32, C81.33, C81.34, C81.35, C81.36, C81.37, C81.38, C81.39, C81.40, C81.41, C81.42, C81.43, C81.44, C81.45, C81.46, C81.47, C81.48, C81.49, C81.70, C81.71, C81.72, C81.73, C81.74, C81.75, C81.76, C81.77, C81.78 and C81.79. This revision is due to the Annual ICD-10 Code Update and becomes effective October 1, 2016.</td>
<td>• Provider Education/Guidance • Revisions Due To ICD-10-CM Code Changes</td>
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<td>05/19/2016</td>
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<td>Under <strong>ICD-10 Codes That Support Medical Necessity Group 2</strong> added an asterisk to ICD-10 code Z08.</td>
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<td>01/04/2016</td>
<td>R6</td>
<td>For clarification purposes, multiple gated acquisition scanning (MUGA) and ventriculography were added throughout the LCD to be synonymous with cardiac blood pool imaging. Under <strong>CMS National Coverage Policy</strong> deleted Title XVIII of the Social Security Act, §1862 (a)(1)(D) Investigational or Experimental and added CMS Internet-Only Manual, Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 4, §§220.6.1 and 220.12. Under <strong>Coverage Indications</strong>,</td>
<td>• Provider Education/Guidance • Creation of Uniform LCDs Within a MAC Jurisdiction • Typographical Error • Reconsideration Request</td>
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| 11/16/2015            | R5                      | **Limitations and/or Medical Necessity** added **Indications for Myocardial Perfusion Imaging** and **Indications for Cardiac Blood Pool Imaging** - (MUGA, Ventriculography) and renumbered the indications. A new indication #3 was added under **Indications for Cardiac Blood Pool Imaging** - (MUGA, Ventriculography). Under **Coverage Indications, Limitations and/or Medical Necessity - Pharmacologic Stress Agents** deleted J0151 and added J0153 to the listed HCPCS codes and added CPT codes 78491 and 78492 to the first paragraph. Under #1 corrected the dosage listed to now read 0.57mg/kg. Under #2 corrected the dosage listed to now read 0.14mg/kg/min. Under #3 corrected the dosage listed to now read 0.5-1.0 mcg/kg/min and corrected the maximum dose to read 40mcg/kg. Under **ICD-10 Codes That Support Medical Necessity for Myocardial Perfusion Imaging** added an asterisk beside Z01.810 and a *Note. Under **ICD-10 Codes That Support Medical Necessity for Cardiac Blood Pool Imaging** (MUGA, Ventriculography) added ICD-10 codes T45.1X5A, T45.1X5D, T45.1X5S and Z01.89 with asterisks and added a *Note. Under **Sources of Information and Basis for Decision** corrected the page numbers cited for the Federal Register 1997;62(211):59058-59260. Author initials were corrected for JL Ritchie and the title of the following journal was corrected to now read: Ritchie JL, Bateman TM, Bonow RO, et al. Guidelines for Clinical Use of Cardiac Radionuclide Imaging. Report of the American Heart Association/ American College of Cardiology Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Committee on Radionuclide Imaging), Developed in Collaboration with the American Society of Nuclear Cardiology. *Circulation*. 1995;91(4):1278-303. Under **Related Local Coverage Documents** added the Billing Requirements for Cardiac Blood Pool Imaging (Multiple Gated Acquisition Scanning -MUGA, Ventriculography) When Performed in Conjunction with Cardiotoxic Chemotherapy.                                                                 | • Provider Education/Guidance  
• Reconsideration Request                                                                                     |
| 10/01/2015            | R4                      | Under **ICD-10 Codes That Support Medical Necessity - Group 2 - Blood Pool Imaging** CPT codes 78472, 78473, 78481, 78483, 78494, and 78496 added Z08 (Encounter for follow-up examination after completed treatment for malignant neoplasm).                                                                 | • Revisions Due To ICD-10-CM Code                                                     |

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<td>Per CMS Internet-Only Manual, Pub 100-08, Medicare Program Integrity Manual, Chapter 13, §13.1.3 LCDs consist of only “reasonable and necessary” information. All bill type and revenue codes have been removed.</td>
<td>Changes</td>
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<td>10/01/2015</td>
<td>R2</td>
<td>Under CMS National Coverage Policy removed citation CMS Internet-Only Manuals, Pub 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 4, §220.8 per CR 9095, dated March 27, 2015, effective for dates of service on or after December 18, 2014.</td>
<td>• Other (Bill type and/or revenue code removal)</td>
</tr>
</tbody>
</table>
| 10/01/2015            | R1                      | This LCD was made identical to the new A/B MAC ICD-9 LCD that was published for notice. | • Provider Education/Guidance  
• Other (CR 9095 removed 220.8 from the National Coverage Determination Manual.)  
• Creation of Uniform LCDs Within a MAC Jurisdiction  
• Other (Maintenance Annual Review) |

## Associated Documents

### Attachments
N/A

### Related Local Coverage Documents

**Article(s)**
- A54768 - Billing and Coding: Cardiac Blood Pool Imaging (Multiple Gated Acquisition Scanning- MUGA, Ventriculography) When Performed in Conjunction with Cardiotoxic Chemotherapy
- A56476 - Billing and Coding: Cardiac Radionuclide Imaging

### Related National Coverage Documents
N/A

### Public Version(s)
Updated on 10/04/2019 with effective dates 10/10/2019 - N/A
Updated on 05/03/2019 with effective dates 05/09/2019 - 10/09/2019
Updated on 04/05/2019 with effective dates 04/11/2019 - 05/08/2019
Updated on 11/02/2018 with effective dates 11/08/2018 - 04/10/2019
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.
Keywords

- Radionuclide Imaging
- Myocardial Perfusion Imaging
- Cardiac Blood Pool Imaging
- Multiple gated acquisition scanning (MUGA)
- Ventriculography