CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

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Coverage Policy Number 0169

Subject **Cardiac Nuclear Imaging**

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Heart Transplantation
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INSTRUCTIONS FOR USE

*Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of CIGNA. Copyright ©2011 CIGNA*

Coverage Policy

In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

CIGNA covers cardiac nuclear imaging including planar or single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI) as medically necessary for ANY of the following indications:

SYMPTOMATIC CORONARY ARTERY DISEASE (CAD)

- new or worsening cardiac symptoms and EITHER of the following:
  - suspected CAD in a known diabetic 50 years of age or older
  - known CAD

KNOWN CAD

- CAD and ANY of the following:
  - new or worsening cardiac symptoms
  - unclear functional significance of a stenosis in a major coronary branch found on recent angiography (invasive or computed tomography)
  - newly elevated cardiac Troponin
  - equivocal, borderline, or discordant stress testing where obstructive CAD remains a concern
  - syncope (true syncope, not near syncope)

EVALUATION FOR INDUCIBLE ISCHEMIA WITHIN 3 MONTHS OF AN ACUTE CORONARY SYNDROME

- acute coronary event (i.e., ST segment elevation myocardial infarction [STEMI]/ unstable angina [UA]/ non-ST segment elevation myocardial infarction [NSTEMI]) within the last 3 months and ALL of the following:
  - evaluation for inducible ischemia
  - hemodynamically stable
  - absence of recurrent chest pain symptoms and signs of heart failure
  - no prior coronary angiography or imaging stress test related to the most recent acute coronary event

FOLLOW-UP MPI

- documentation of previous silent ischemia on the imaging portion of a stress test but not on the electrocardiography (ECG) portion (may be performed every 2 years)
- it has been at least 5 years from coronary artery bypass graft (CABG)
- it has been at least 2 years from most recent percutaneous coronary intervention (PCI) (e.g., stent, percutaneous transluminal coronary angioplasty [PTCA]) AND at least 2 years since last re-evaluation of coronary arteries (e.g., stress test, angiography)

OTHER

- syncope (true syncope, not near syncope) in the absence of known CAD and EITHER of the following:
  - newly diagnosed or known left ventricular dysfunction
  - three or more recognized risk factors for CAD (e.g., male gender, hypertension, smoking, abnormal lipid levels, diabetes, known vascular disease, obesity, family history of premature CAD, metabolic syndrome, elevated high sensitivity C-Reactive Protein level)
- history of a false positive exercise treadmill test
- ventricular tachycardia
- ventricular paced rhythm (ventricular pacemakers create altered contraction pattern)
- pre-excitation pattern such as Wolff-Parkinson-White
- rate related complete left bundle branch block (LBBB) (not right bundle branch block)
- resting heart rate <50 due to beta-blocker or calcium channel-blocker medication
- severe aortic valve dysfunction
- limited echocardiography window or difficulty visualizing the endocardium on echocardiography
- poorly controlled hypertension despite medical therapy
- poorly controlled atrial fibrillation (resting heart rate >100 bpm) or concern for exercise- or dobutamine-induced tachyarrhythmias
- segmental wall motion abnormalities at rest (e.g. due to cardiomyopathy, prior MI, or pulmonary hypertension)
- current digoxin treatment
- ST segment depression (greater than or equal to 1 mm)

PRE-OPERATIVE

- For pre-operative evaluation and ANY of the following:
  - new, progressive or changing angina
  - worsening or poorly controlled heart failure
  - severe valvular heart disease
  - malignant arrhythmias recently documented
  - planned high risk* surgery and EITHER of the following:
    - two clinical risk factors** are present
    - exercise treadmill stress test cannot be performed because ECG is uninterpretable or the individual cannot adequately exercise on a treadmill or similar device
  - planned surgery is intermediate risk* and at least one clinical risk factor** is present and exercise treadmill stress test cannot be performed because ECG is uninterpretable or the individual cannot adequately exercise on a treadmill or similar device

*Cardiac Risk Stratification List:	**Clinical Risk Factors that predict risk of cardiac death and non-fatal myocardial infarction at time of non-cardiac surgery:

High risk (cardiac risk >5%): ❖ Open aortic and other major open vascular surgery ❖ Open peripheral vascular surgery Intermediate risk (cardiac risk 1%-5%): ❖ Open intraperitoneal and intrathoracic surgery ❖ Open carotid endarterectomy ❖ Head and neck surgery ❖ Open orthopedic surgery ❖ Open prostate surgery Low risk (cardiac risk <1%): ❖ Endoscopic procedures ❖ Superficial procedures ❖ Cataract surgery ❖ Breast surgery ❖ Ambulatory surgery ❖ Laparoscopic procedures and endovascular procedures unlikely to require further open surgical intervention	❖ History of ischemic heart disease (previous MI, previous positive stress test, use of nitroglycerin, typical angina, ECG Q waves, previous PCI or CABG) ❖ History of compensated congestive heart failure (history of heart failure, previous pulmonary edema, third heart sound, bilateral rales, chest x-ray showing heart failure) ❖ History of TIA or stroke ❖ Diabetes mellitus ❖ Serum creatinine >2 mg/dL

MUGA

CIGNA covers multigated acquisition (MUGA) (i.e., equilibrium gated radionuclide angiography [ERNA], radionuclide ventriculography [RVG] or gated blood pool imaging) as medically necessary for ANY of the following indications:

- impaired systolic right or left ventricular function noted on echocardiography
- echocardiography windows preclude accurate assessment of right or left ventricular function
- individual is being considered for, is receiving, or has received cardiotoxic chemotherapy drugs and ANY of the following:
  - previous attempts at echocardiography were technically limited
  - left ventricular ejection fraction determinations are less than 50% or echocardiographic studies demonstrates impaired systolic function and there is documented clinical need for a quantitative measurement of left ventricular ejection fraction (LVEF).
  - left ventricular wall motion abnormalities from ischemic or non-ischemic cardiomyopathies
- candidacy determination for ANY of the following:
  - implantable cardioverter defibrillator (ICD)
  - heart transplantation
  - biventricular pacing/cardiac resynchronization therapy
- measurement of response to cardiac medications for congestive heart failure when there is a clinical need for a quantitative measurement of left ventricular ejection fraction beyond what echocardiography can provide

CIGNA does not cover cardiac SPECT with concurrently-acquired computed tomography (SPECT/CT) for any indication because it is considered experimental, investigational or unproven.

CIGNA does not cover cardiac nuclear imaging for any other indication because it is considered experimental, investigational, or unproven.

General Background

Generally, a treadmill stress test or exercise electrocardiograms (ECG) is the initial test for the cardiac patient. Other tests that may be performed include stress testing with imaging, such as stress echocardiography,

perfusion magnetic resonance imaging (MRI), or nuclear imaging. Of these tests, only a nuclear scan requires exposure to radiation, so it is utilized only in certain population subsets.

Cardiac nuclear imaging studies are recommended to examine the anatomy and function of the heart. Types of cardiac nuclear imaging studies may include:

- positron emission tomography (PET)
- planar and single-photon emission computed tomography myocardial perfusion imaging (i.e. SPECT MPI)
- equilibrium radionuclide angiography or ventriculography (i.e., gated blood pool imaging, multiple gated acquisition [MUGA] scanning, ERNA, RVG)
- first-pass radionuclide angiography or ventriculography

In standard practice, stress and rest myocardial perfusion images are compared to determine the presence, extent, and severity of stress-induced perfusion defects and to determine whether such defects represent regions of myocardial ischemia or infarction. The most widely used agents for pharmacological stress testing can be divided into those that act as coronary arteriolar vasodilators: adenosine, dipyridamole, and regadenoson; and adrenergic agents such as dobutamine. Currently utilized myocardial perfusion tracers for myocardial perfusion imaging include thallium 201 and two technetium 99m agents (Tc-99m sestamibi and Tc-99m tetrofosmin). Gated imaging is recommended.

- Planar and SPECT MPI: SPECT MPI scanning provides two critical pieces of clinical information—perfusion, by comparing rest and stress images to look for fixed or reversible defects; and function—by evaluating wall motion, including ejection fraction. SPECT is preferable to planar for myocardial perfusion scintigraphy; however, planar imaging still has a role as the anatomy of the heart is sufficiently simple that the imaging specialist can comprehend the location and extent of defects from multiple projections without need of computer reconstruction. Imaging at the bedside of acutely ill patients, or instrumented patients, can only be performed using planar imaging technique and portable gamma cameras. Planar imaging may be the only way to acquire images in very obese patients who are too heavy for the imaging table of a SPECT camera; or in severely claustrophobic patients.

- ERNA/MUGA: In planar equilibrium RVG studies, data are recorded in a computer system synchronized with the R wave of the patient's ECG, similar to ECG-gated SPECT. It is used to determine global and regional measures of ventricular function (primarily LV function) at rest and/or during exercise stress or pharmacologic intervention. These measures of ventricular function may include evaluations of ventricular wall motion, ejection fraction, and other parameters of systolic and diastolic function. Most commonly, Tc-99m labeling is applied to red blood cells.

- First-pass Radionuclide Angiography or Ventriculography: First-pass can also assess LV and right ventricular (RV) function at rest or during stress (evaluation of wall motion, ejection fraction, and other systolic and diastolic parameters); also to assess and measure left-to-right shunts. First pass studies are very rarely performed any more. They have generally been replaced by RVG.

Radiation Exposure
The American College of Radiology White Paper on Radiation Dose in Medicine (Amis, et al., 2007) recognizes the rapid growth of CT and certain nuclear medicine studies over the past quarter century. The White Paper proposes practical suggestions, such as education for all stakeholders in the principles of radiation safety, the appropriate utilization of imaging to minimize any associated radiation risk, the standardization of radiation dose data to be archived during imaging for its ultimate use in benchmarking good practice, and, finally, the identification and perhaps alternative imaging of patients who may have already reached threshold levels of estimated exposure from diagnostic imaging.

The American Association of Physicists in Medicine (AAPM) reports the following radiation doses per test:
- Sestamibi myocardial perfusion study (MPI): 9-12 mSv
- Thallium myocardial perfusion study (MPI): 25 mSv
- Diagnostic conventional coronary angiogram (cath): 5-10 mSv
- Computed tomography coronary angiography (CTCA): 5-15 mSv

- CT of Abdomen and pelvis: 8-14 mSv
- Chest x-ray: <0.1 mSv

U.S. Food and Drug Administration (FDA)
Radiopharmaceuticals and imaging systems are regulated by the U.S. Food and Drug Administration (FDA). Premarket 510(k) notification is required by the FDA for an emission computed tomography diagnostic device or nuclear tomography system, which are Class II medical devices. Radio-pharmaceutical approvals may or may not specify the types of imaging systems they can be used with or the types of conditions or diagnoses they can be used to help detect.

Literature Review
There is evidence in the peer-reviewed scientific literature to support the use of SPECT MPI as an accurate and effective imaging tool. Because of radiation exposure, SPECT is not generally recommended as a first line test, especially if stress echocardiography can adequately provide the needed information. There are frequently the same "appropriate" indications listed in both the ACC Appropriate Use Criteria for Echocardiography (Douglas, et al., 2011) and the ACC Appropriate Use Criteria for Cardiac Radionuclide Imaging (Hendel, et al., 2009). Studies in the literature demonstrate SPECT provides clinical utility. SPECT has prognostic ability, as independent SPECT results are significantly associated with an increased risk of sudden cardiac death. Also, SPECT result may safely reduce unnecessary hospitalizations and invasive coronary angiographies (Nakajima, et al. 2009; Piccini, et al., 2008; Heijenbrok-Kal, et al., 2007; Metz, et al., 2007; Mowatt, et al., 2005; Udelson, et al., 2003). SPECT is particularly useful in individuals with diabetes. For example, SPECT accurately identifies silent ischemia and can predict cardiovascular events including death (Lièvre, et al., 2011; Jacqueminet, et al., 2010; Yamasaki, et al., 2010; Wiersma, et al., 2009; Young, et al., 2009; Rajagopalan, et al., 2005; Wackers, et al., 2004; Giri, et al. 2002).

Perioperative Cardiovascular Assessment of Patients Undergoing Non-cardiac Surgery: Freeman and Gibbons (2009) speaks to ACC/AHA guidelines on perioperative cardiovascular evaluation and care for noncardiac surgery (Fleisher, et al., 2007) noting preoperative laboratory testing is warranted, but only if the results could substantially affect patient management. Freeman et al. includes the following table:

Clinical Risk Factors That Predict Risk of Cardiac Death and Nonfatal Myocardial Infarction at Time of Noncardiac Surgery

- History of ischemic heart disease
- History compensated previous congestive heart failure
- History of cerebrovascular disease
- Diabetes mellitus, with or without preoperative insulin therapy
- Renal insufficiency (e.g., creatinine level >2 mg/dL)

Kertai et al. (2003) conducted a meta-analysis, comparing the predictive performance of six noninvasive tests used for perioperative cardiac risk stratification in patients undergoing major vascular surgery. The meta-analysis included 8119 patients. Results indicated that dobutamine stress echocardiography showed a positive trend for better diagnostic performance than the other tests, but this was only significant in comparison with myocardial perfusion scintigraphy. Ambulatory ECG, exercise ECG, and radionuclide ventriculography yielded a lower sensitivity and reasonable specificity, but no significant difference in predictive performance. Radionuclide ventriculography had the highest specificity but a relatively low sensitivity, with a limited predictive performance for perioperative events. The authors stated that myocardial perfusion scintigraphy is a valuable test for cardiac risk assessment, especially in patients with contraindications to stress echocardiography, with a reported complication rate of 3.9% in the studies included in the meta-analysis. The authors noted myocardial perfusion scintigraphy should be avoided in patients with significant bronchospasm, critical carotid disease, or on regular theophylline treatment.

MUGA: Multigated acquisition (MUGA) (i.e., equilibrium gated radionuclide angiography [ERNA], radionuclide ventriculography [RVG] or gated blood pool imaging) aids in obtaining ventricular function and left ventricular wall motion abnormalities, particularly in patients receiving cardiotoxic chemotherapy drugs, implantable cardioverter defibrillator (ICD), heart transplantation, and biventricular pacing/cardiac resynchronization therapy (Fatima, et al., 2011; Geiger, et al., 2010; Godkar, et al., 2007).

Professional Societies/Organizations
American College of Cardiology (ACC): The ACC has a Practice Guideline for Radionuclide Imaging (Klocke, et al., 2003) and also an Appropriateness Use Criteria for Cardiac Radionuclide Imaging (Hendel, et al., 2009). The American College of Cardiology (ACC)/American Society of Nuclear Cardiology (ASNC), American College of Radiology (ACR) 2009 Appropriate Use Criteria for Cardiac Radionuclide Imaging (Hendel, et al., 2009) replaces Brindis, et al., 2005. The Working Group devised 67 clinical scenarios and rated them as follows:

- "Appropriate" test for specific indication (test is generally acceptable and is a reasonable approach for the indication).
- "Uncertain" for specific indication (test may be generally acceptable and may be a reasonable approach for the indication). (Uncertainty also implies that more research and/or patient information is needed to classify the indication definitively.)
- "Inappropriate" test for that indication (test is not generally acceptable and is not a reasonable approach for the indication).

Among the 67 indications, 33 were classified as appropriate, while uncertain and inappropriate designations were assigned for 9 and 25 indications, respectively. Unless otherwise noted, all indications referred to SPECT and PET myocardial perfusion imaging. All radionuclide perfusion imaging indications also assume the use of electrocardiogram (ECG) gating, whenever possible, with determination of global ventricular function (i.e., left ventricular ejection fraction) and regional wall motion as part of the evaluation. For all stress imaging, the mode of stress testing was assumed to be exercise for patients able to exercise. For patients unable to exercise, pharmacologic stress testing was assumed to be used.

The Appropriateness Use Criteria is organized into the eight areas below, groupings of similar indications for SPECT myocardial perfusion imaging. They are as follows:

Indication 1: Detection of CAD, Symptomatic

A. For evaluation of ischemic equivalent* (non-acute), SPECT MPI is:
- Inappropriate, if low pretest probability of CAD; and ECG interpretable AND able to exercise.
- Appropriate, if low pretest probability of CAD; and ECG uninterpretable OR unable to exercise
- Appropriate, if intermediate pretest probability of CAD; and ECG interpretable AND able to exercise
- Appropriate, if intermediate pretest probability of CAD; and ECG uninterpretable OR unable to exercise
- Appropriate, if high pretest probability of CAD; and regardless of ECG interpretability and ability to exercise

B. If acute chest pain, SPECT MPI is:
- Appropriate, if possible Acute Coronary Syndrome** (ACS) and ECG-no ischemic changes or with LBBB or electronically ventricular paced rhythm; and low-risk TIMI score; and peak troponin: borderline, equivocal, minimally elevated
- Appropriate, if possible ACS; and ECG-no ischemic changes or with LBBB or electronically ventricular paced rhythm; and high-risk TIMI score; and peak troponin: borderline, equivocal, minimally elevated
- Appropriate, if possible ACS; and ECG-no ischemic changes or with LBBB or electronically ventricular paced rhythm; and low-risk TIMI score; and negative peak troponin levels
- Appropriate, if possible ACS; and ECG-no ischemic changes or with LBBB or electronically ventricular paced rhythm; and high-risk TIMI score; and negative peak troponin levels
- Inappropriate, if definite ACS*

C. If acute chest pain (rest imaging only), SPECT MPI is:
- Appropriate, if possible ACS; and ECG-no ischemic changes or with LBBB or electronically ventricular paced rhythm; and initial troponin negative; and recent or ongoing chest pain

* The definition of "ischemic equivalent" is as follows: "Chest Pain Syndrome, Anginal Equivalent, or Ischemic ECG Abnormalities; Any constellation of clinical findings that the physician feels is consistent with obstructive CAD. Examples of such findings include, but are not exclusive to, chest pain, chest

tightness, burning, shoulder pain, palpitations, jaw pain, and new ECG abnormalities suggestive of ischemic heart disease. Non-chest pain symptoms, such as dyspnea or worsening effort tolerance, that are felt to be consistent with CAD may also be considered to be an anginal equivalent."

** ACS definition based on ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction

Indication 2: Detection of CAD/Risk Assessment Without Ischemic Equivalent

A. If asymptomatic, SPECT MPI is:
- Inappropriate, if low CHD risk (ATP III risk criteria)
- Inappropriate, if intermediate CHD risk (ATP III risk criteria); and ECG interpretable
- Uncertain, if intermediate CHD risk (ATP III risk criteria); and ECG uninterpretable
- Appropriate, if high CHD risk (ATP III risk criteria)

B. If new-onset or newly diagnosed heart failure with left ventricular systolic dysfunction without ischemic equivalent, SPECT MPI is:
- Appropriate, if no prior CAD evaluation AND no planned coronary angiography

C. If new-onset atrial fibrillation, SPECT MPI is:
- Uncertain, if part of evaluation when etiology unclear

D. If ventricular tachycardia, SPECT MPI is:
- Appropriate, if low CHD risk (ATP III risk criteria)
- Appropriate, if intermediate or high CHD risk (ATP III risk criteria)

E. If syncope, SPECT MPI is:
- Inappropriate, if low CHD risk (ATP III risk criteria)
- Appropriate, if intermediate or high CHD risk (ATP III risk criteria)

F. If elevated troponin, SPECT MPI is:
- Appropriate, if troponin elevation without additional evidence of acute coronary syndrome

Indication 3: Risk Assessment With Prior Test Results and/or Known Chronic Stable CAD

A. If asymptomatic or stable symptoms, normal prior stress imaging study, SPECT MPI is:
- Inappropriate, if low CHD risk (ATP III risk criteria); and last stress imaging study done less than 2 years ago
- Inappropriate:, if intermediate to high CHD risk (ATP III risk criteria); and last stress imaging study done less than 2 years ago
- Inappropriate, if low CHD risk (ATP III risk criteria); and last stress imaging study done more than or equal to 2 years ago
- Uncertain, if intermediate to high CHD risk (ATP III risk criteria); and last stress imaging study done more than or equal to 2 years ago

B. If asymptomatic or stable symptoms, abnormal coronary angiography or abnormal prior stress imaging study, no prior revascularization, SPECT MPI is:
- Inappropriate, if known CAD on coronary angiography OR prior abnormal stress imaging study; and last stress imaging study done less than 2 years ago
- Uncertain, if known CAD on coronary angiography OR prior abnormal stress imaging study; and last stress imaging study done more than or equal to 2 years ago

C. If prior noninvasive evaluation, SPECT MPI is:
- Appropriate, if equivocal, borderline, or discordant stress testing where obstructive CAD remains a concern

D. If new or worsening symptoms, SPECT MPI is:

- Appropriate, if abnormal coronary angiography OR abnormal prior stress imaging study
- Uncertain, if normal coronary angiography OR normal prior stress imaging study

E. If coronary angiography (invasive or noninvasive), SPECT MPI is:
- Appropriate, if coronary stenosis or anatomic abnormality of uncertain significance

F. If asymptomatic, prior coronary calcium Agatston score, SPECT MPI is:
- Inappropriate, if Agatston score less than 100
- Uncertain, if low to intermediate CHD risk; and Agatston score between 100 and 400
- Appropriate, if high CHD risk; and Agatston score between 100 and 400
- Appropriate, if Agatston score greater than 400

G. If Duke treadmill score, SPECT MPI is:
- Inappropriate, if low-risk Duke treadmill score
- Appropriate, if intermediate-risk Duke treadmill score
- Appropriate, if high-risk Duke treadmill score

Indication 4: Risk Assessment: Preoperative Evaluation for Noncardiac Surgery Without Active Cardiac Conditions*

A. If low-risk surgery, SPECT MPI is:
- Inappropriate, if preoperative evaluation for noncardiac surgery risk assessment

B. If intermediate-risk surgery, SPECT MPI is:
- Inappropriate, if moderate to good functional capacity (greater than or equal to 4 METs)
- Inappropriate, if no clinical risk factors*
- Appropriate, if greater than or equal to 1 clinical risk factor; and poor or unknown functional capacity (less than 4 METs)
- Inappropriate, if asymptomatic up to 1 year postnormal catheterization, noninvasive test, or previous revascularization

C. If vascular surgery, SPECT MPI is:
- Inappropriate, if moderate to good functional capacity (greater than or equal to 4 METs)
- Inappropriate, if no clinical risk factors
- Appropriate, if greater than or equal to 1 clinical risk factor; and poor or unknown functional capacity (less than 4 METS)
- Inappropriate, if asymptomatic up to 1 year postnormal catheterization, noninvasive test, or previous revascularization

*refer to Table A1 and Table A2 in Hendel, et al., 2009.

Indication 5: Risk Assessment: Within 3 Months of an Acute Coronary Syndrome

A. If ST segment elevation myocardial infarction (STEMI), SPECT MPI is:
- Inappropriate, if primary PCI with complete revascularization; and No recurrent symptoms
- Appropriate, if hemodynamically stable, no recurrent chest pain symptoms or no signs of HF; and to evaluate for inducible ischemia; and no prior coronary angiography
- Inappropriate, if hemodynamically unstable, signs of cardiogenic shock, or mechanical complications

B. If unstable angina/non-ST segment myocardial infarction (NSTEMI), SPECT MPI is:
- Appropriate, if hemodynamically stable, no recurrent chest pain symptoms or no signs of HF; and to evaluate for inducible ischemia; and no prior coronary angiography

C. If ACS, asymptomatic postrevascularization (PCI or CABG), SPECT MPI is:
- Inappropriate, if evaluation prior to hospital discharge

D. If cardiac rehabilitation, SPECT MPI is:
- Inappropriate, if prior to initiation of cardiac rehabilitation (as a stand-alone indication)

Indication 6: Risk Assessment: Postrevascularization (Percutaneous Coronary Intervention or Coronary Artery Bypass Graft)*

A. If symptomatic, SPECT MPI is:
- Appropriate, if evaluation of ischemic equivalent

B. If asymptomatic, SPECT MPI is:
- Appropriate, if incomplete revascularization; and additional revascularization feasible
- Uncertain, if less than 5 years after CABG
- Appropriate, if greater than or equal to 5 years after CABG
- Inappropriate, if less than 2 years after PCI
- Uncertain, if greater than or equal to 2 years after PCI

C. If cardiac rehabilitation, SPECT MPI is:
- Inappropriate, if prior to initiation of cardiac rehabilitation (as a stand-alone indication)

*In patients who have had multiple coronary revascularization procedures, consider the most recent procedure.

Indication 7: Assessment of Viability/Ischemia

A. If ischemic cardiomyopathy/assessment of viability, SPECT MPI is:
- Appropriate, if known severe LV dysfunction; and eligible for revascularization

Indication 8: Evaluation of Ventricular Function

A. For evaluation of LV function, SPECT MPI or other is:
- Appropriate, if assessment of LV function with equilibrium gated radionuclide angiography (ERNA) or first-pass radionuclide angiography (FP RNA); and in absence of recent reliable diagnostic information regarding ventricular function obtained with another imaging modality
- Appropriate, if routine* use of rest/stress ECG-gating with SPECT or PET MPI
- Inappropriate, if routine* use of stress FP RNA in conjunction with rest/stress gated SPECT MPI
- Uncertain, if selective use of stress FP RNA in conjunction with rest/stress gated SPECT MPI; and borderline, mild, or moderate stenoses in 3 vessels OR moderate or equivocal left main stenosis in left dominant system

B. If use of potentially cardiotoxic therapy (e.g., doxorubicin), SPECT MPI or other is:
- Appropriate, if serial assessment of LV function with radionuclide angiography (ERNA or FP RNA); and baseline and serial measures after key therapeutic milestones or evidence of toxicity

*Performed under most clinical circumstances, except in cases with technical inability or clear-cut redundancy of information.

ACC: The ACC, American Society of Echocardiography (ASE), American Heart Association (AHA), American Society of Nuclear Cardiology (ASNC) and other societies published Appropriate Use Criteria for Echocardiography (Douglas, et al., 2011). Below, only appropriate indications are listed:

Stress Echocardiography for Detection of CAD/Risk Assessment: Symptomatic or Ischemic Equivalent Evaluation of Ischemic Equivalent (Nonacute)
Low pretest probability of CAD and ECG uninterpretable or unable to exercise
- Intermediate pretest probability of CAD and ECG interpretable and able to exercise
- Intermediate pretest probability of CAD and ECG uninterpretable or unable to exercise
- High pretest probability of CAD and regardless of ECG interpretability and ability to exercise

Stress Echocardiography for Detection of CAD/Risk Assessment: Symptomatic or Ischemic Equivalent Acute Chest Pain

- Possible ACS and ECG: no ischemic changes or with LBBB or electronically paced ventricular rhythm and low-risk TIMI score and negative troponin levels
- Possible ACS and ECG: no ischemic changes or with LBBB or electronically paced ventricular rhythm and low-risk TIMI score and peak troponin: borderline, equivocal, minimally elevated
- Possible ACS and ECG: no ischemic changes or with LBBB or electronically paced ventricular rhythm and high-risk TIMI score and negative troponin levels
- Possible ACS and ECG: no ischemic changes or with LBBB or electronically paced ventricular rhythm and high-risk TIMI score and peak troponin: borderline, equivocal, minimally elevated

Stress Echocardiography for Detection of CAD/Risk Assessment: Asymptomatic (Without Ischemic Equivalent) in Patient Populations With Defined Comorbidities New-Onset or Newly Diagnosed HF or LV Systolic Dysfunction

- No prior CAD evaluation and no planned coronary angiography

Stress Echocardiography for Detection of CAD/Risk Assessment: Asymptomatic (Without Ischemic Equivalent) in Patient Populations With Defined Comorbidities Arrhythmias

- Sustained Ventricular tachycardia (VT)
- Frequent premature ventricular contractions (PVCs), exercise-induced VT, or non-sustained VT

Stress Echocardiography for Detection of CAD/Risk Assessment: Asymptomatic (Without Ischemic Equivalent) in Patient Populations With Defined Comorbidities Syncope

- Intermediate or high global CAD risk

Stress Echocardiography for Detection of CAD/Risk Assessment: Asymptomatic (Without Ischemic Equivalent) in Patient Populations With Defined Comorbidities Elevated Troponin

- Troponin elevation without symptoms or additional evidence of ACS

Stress Echocardiography Following Prior Test Results Asymptomatic: Prior Evidence of Subclinical Disease

- Coronary calcium Agatston score >400

Stress Echocardiography Following Prior Test Results Coronary Angiography (Invasive or Noninvasive)

- Coronary artery stenosis of unclear significance

Stress Echocardiography Following Prior Test Results Treadmill ECG Stress Test

- Intermediate-risk treadmill score (e.g., Duke)
- High-risk treadmill score (e.g., Duke)

Stress Echocardiography Following Prior Test Results New or Worsening Symptoms

- Abnormal coronary angiography or abnormal prior stress imaging study

Stress Echocardiography Following Prior Test Results Prior Noninvasive Evaluation

- Equivocal, borderline, or discordant stress testing where obstructive CAD remains a concern

Stress Echocardiography for Risk Assessment: Perioperative Evaluation for Noncardiac Surgery Without Active Cardiac Conditions Vascular Surgery

- ≥ 1 clinical risk factor and poor or unknown functional capacity (<4 METs)

Stress Echocardiography for Risk Assessment: Within 3 Months of an ACS STEMI

- Hemodynamically stable, no recurrent chest pain symptoms, or no signs of HF and to evaluate for inducible ischemia and no prior coronary angiography since the index event

Stress Echocardiography for Risk Assessment: Within 3 Months of an ACS UA/NSTEMI

- Hemodynamically stable, no recurrent chest pain symptoms, or no signs of HF and to evaluate for inducible ischemia and no prior coronary angiography since the index event

Stress Echocardiography for Risk Assessment: Postrevascularization (PCI or CABG) Symptomatic

- Ischemic equivalent

Stress Echocardiography for Risk Assessment: Postrevascularization (PCI or CABG) Asymptomatic

- Incomplete revascularization and additional revascularization feasible

Stress Echocardiography for Assessment of Viability/Ischemia Ischemic Cardiomyopathy/Assessment of Viability

- Known moderate or severe LV dysfunction and patient eligible for revascularization and use of dobutamine stress only

ACC/AHA – Before Non-Cardiac Surgery: The ACC/AHA 2009 Guidelines on Perioperative Cardiovascular Evaluation and Care for Non-cardiac Surgery state under the subheading of Radionuclide Myocardial Perfusion Imaging, "stress nuclear myocardial perfusion imaging has a high sensitivity for detecting patients at risk for perioperative cardiac events. Perioperative cardiac risk appears to be directly proportional to the amount of myocardium at risk as reflected in the extent of reversible defects found on imaging. Because of the overall low positive predictive value of stress nuclear imaging, it is best used selectively in patients with a high clinical risk of perioperative cardiac events" (Fleisher, et al., 2009).

Recommendations for Preoperative Noninvasive Evaluation of Left Ventricular Function

- It is reasonable for patients with dyspnea of unknown origin to undergo preoperative evaluation of left ventricular (LV) function (CLASS IIa)
- It is reasonable for patients with current or prior heart failure with worsening dyspnea or other change in clinical status to undergo preoperative evaluation of LV function if not performed within 12 months (CLASS IIa)
- Reassessment of LV function in clinically stable patients with previously documented cardiomyopathy is not well established (CLASS IIb)
- Routine perioperative evaluation of LV function in patients is not recommended (CLASS III)

Recommendations for Noninvasive Stress Testing Before Noncardiac Surgery

- Patients with active cardiac conditions* in whom noncardiac surgery is planned should be evaluated and treated per published ACC/AHA guidelines before noncardiac surgery. (CLASS I)
- Noninvasive stress testing of patients with 3 or more clinical risk factors and poor functional capacity (less than 4 metabolic equivalents [METs]) who require vascular surgery** is reasonable if it will change management. (CLASS IIa)
- Noninvasive stress testing may be considered for patients with at least 1 to 2 clinical risk factors and poor functional capacity (less than 4 METs) who require intermediate-risk non-cardiac surgery if it will change management (CLASS IIb)
- Noninvasive stress testing may be considered for patients with at least 1 to 2 clinical risk factors and good functional capacity (greater than or equal to 4 METs) who are undergoing vascular surgery (CLASS IIb)
- Noninvasive testing is not useful for patients with no clinical risk factors undergoing intermediate-risk non-cardiac surgery (CLASS III)
- Noninvasive testing is not useful for patients undergoing low-risk non-cardiac surgery (CLASS III)

*Active Cardiac Conditions for Which the Patient Should Undergo Evaluation and Treatment Before Non-cardiac Surgery

- Unstable coronary syndromes Decompensated HF (NYHA functional class IV; worsening or new-onset HF)
- Significant arrhythmias
- Severe valvular disease

**Vascular surgery is defined by aortic and other major vascular surgery and peripheral vascular surgery.

ACC: The ACC/AHA guideline for assessment of cardiovascular risk in asymptomatic adults (Greenland, et al., 2010) recommends:

- Stress MPI may be considered for advanced cardiovascular risk assessment in asymptomatic adults with diabetes or asymptomatic adults with a strong family history of coronary heart disease (CHD) or when previous risk assessment testing suggests high risk of CHD, such as a CAC score of 400 or

greater (Class*IIb). See Appendix A for American College of Cardiology/American Heart Association (ACC/AHA) Definitions of Classification.

- Stress MPI is not indicated for cardiovascular risk assessment in low- or intermediate-risk asymptomatic adults (Exercise or pharmacologic stress MPI is primarily used and studied for its role in advanced cardiac evaluation of symptoms suspected of representing CHD and/or estimation of prognosis in patients with known CAD (Class III, No Benefit).

ACC/AHA – Myocardial Infarction: The 2004 ACC/AHA Guidelines for the Management of Patients with ST-Elevation Myocardial Infarction (Antman, et al., 2004) states the following re nuclear imaging:

Initial Recognition and Management in the Emergency Department, Initial Patient Evaluation:

SPECT radionuclide imaging should not be performed to diagnose STEMI in patients for whom the diagnosis of STEMI is evident on the ECG (*Class III). SPECT radionuclide imaging at rest is not routinely indicated to establish the diagnosis of MI in patients with STEMI, although it can provide valuable, accurate diagnostic and prognostic information in patients who present to the ED with symptoms suggestive of acute cardiac ischemia and a normal or nondiagnostic ECG (Klocke, et al., 2003). During the recuperative phase of hospitalization for STEMI, SPECT imaging can be used to study myocardial perfusion and to look for segmental abnormalities of LV wall motion.

Hospital Management, Estimation of Infarct Size:

The most comprehensive assessment of STEMI with radionuclide imaging was developed with the Technetium sestamibi SPECT approach (Gibbons, et al., 2000). This technique has been validated extensively and offers the opportunity for both early and late imaging to initially assess the area of ischemic risk as opposed to the ultimate infarct size. This approach is well delineated in the ACC/AHA/ASNC Guidelines on Cardiac Radionuclide Imaging (Klocke, et al., 2003). Radionuclide angiography with a variety of radiolabeled isotopes can also provide an estimate of regional and global LV function.

Hospital Management; Convalescence, Discharge, and Post-MI Care:

Dipyridamole or adenosine stress perfusion nuclear scintigraphy or dobutamine echocardiography before or early after discharge should be used in patients with STEMI who are not undergoing cardiac catheterization to look for inducible ischemia in patients judged to be unable to exercise (Class I)

Left ventricular ejection fraction should be measured in all STEMI patients (Class I) Assessment of LV function after STEMI has been shown to be one of the most accurate predictors of future cardiac events in both the prereperfusion and the reperfusion eras. The assessment can include such basic factors as clinical estimates based on patients' symptoms (e.g., exertional dyspnea, functional status), physical findings (e.g., rales, murmurs, elevated jugular venous pressure, cardiomegaly, S_3 gallop), and measurement of ejection fraction by contrast ventriculography, radionuclide ventriculography, and 2-dimensional echocardiography.

Myocardial perfusion imaging or dobutamine echocardiography is reasonable in hemodynamically and electrically stable patients 4 to 10 days after STEMI to assess myocardial viability when required to define the potential efficacy of revascularization (Class IIa)

The ACC/AHA 2009 Focused Update for the Management of Patients With ST-Elevation Myocardial Infarction (Kushner, et al., 2009) does not address imaging.

*See Appendix A for American College of Cardiology/American Heart Association (ACC/AHA) Definitions of Classification.

ACC/AHA – Chronic Stable Angina: The ACC/AHA 2002 Guideline Update for the Management of Patients with Chronic Stable Angina (Gibbons, et al., 2003) lists the following recommendations involving myocardial perfusion imaging:

Recommendations for Cardiac Stress Imaging as the Initial Test for Diagnosis in Asymptomatic Patients

*Class IIb

- Exercise perfusion imaging or exercise echocardiography in asymptomatic patients with severe coronary calcification on EBCT who are able to exercise and have one of the following baseline ECG abnormalities:
  - Pre-excitation (Wolff-Parkinson-White) syndrome
  - More than 1 mm of ST depression at rest
- Adenosine or dipyridamole myocardial perfusion imaging in asymptomatic patients with severe coronary calcification on EBCT but with one of the following baseline ECG abnormalities:
  - Electronically paced ventricular rhythm
  - Left bundle-branch block
- Adenosine or dipyridamole myocardial perfusion imaging or dobutamine echocardiography in patients with possible myocardial ischemia on ambulatory ECG monitoring or with severe coronary calcification on EBCT who are unable to exercise

Class III

- Exercise or dobutamine echocardiography in asymptomatic patients with left bundle-branch block
- Exercise myocardial perfusion imaging, exercise echocardiography, adenosine or dipyridamole myocardial perfusion imaging, or dobutamine echocardiography as the initial stress test in an asymptomatic patient with a normal rest ECG who is not taking digoxin
- Adenosine or dipyridamole myocardial perfusion imaging or dobutamine echocardiography in asymptomatic patients who are able to exercise and do not have left bundle-branch block or electronically paced ventricular rhythm

<u>Recommendations for Cardiac Stress Imaging After Exercise ECG Testing for Diagnosis in Asymptomatic Patients</u>

Class IIb

- Exercise myocardial perfusion imaging or exercise echocardiography in asymptomatic patients with an intermediate-risk or high-risk Duke treadmill score on exercise ECG testing
- Adenosine or dipyridamole myocardial perfusion imaging or dobutamine echocardiography in asymptomatic patients with a previously inadequate exercise ECG

Class III

- Exercise myocardial perfusion imaging, exercise echocardiography, adenosine or dipyridamole myocardial perfusion imaging, or dobutamine echocardiography in asymptomatic patients with a low-risk Duke treadmill score on exercise ECG testing

<u>Recommendations for Cardiac Stress Imaging as the Initial Test for Risk Stratification in Asymptomatic Patients</u>

Class IIb

- Exercise perfusion imaging or exercise echocardiography in asymptomatic patients with severe coronary calcification on EBCT who are able to exercise and have one of the following baseline ECG abnormalities:
  - Pre-excitation (Wolff-Parkinson-White) syndrome
  - More than 1 mm of ST depression at rest
- Adenosine or dipyridamole myocardial perfusion imaging in patients with severe coronary calcification on EBCT, but with one of the following baseline ECG abnormalities:
  - Electronically paced ventricular rhythm
  - Left bundle-branch block
- Adenosine or dipyridamole myocardial perfusion imaging or dobutamine echocardiography in patients with possible myocardial ischemia on ambulatory ECG monitoring or with severe coronary calcification on EBCT who are unable to exercise

Class III

- Exercise or dobutamine echocardiography in asymptomatic patients with left bundle-branch block
- Exercise myocardial perfusion imaging, exercise echocardiography, adenosine or dipyridamole myocardial perfusion imaging, or dobutamine echocardiography as the initial stress test in an asymptomatic patient with a normal rest ECG who is not taking digoxin
- Adenosine or dipyridamole myocardial perfusion imaging or dobutamine echocardiography in asymptomatic patients who are able to exercise

Recommendations for Cardiac Stress Imaging After Exercise ECG Testing for Risk Stratification in Asymptomatic Patients

Class IIb

- Exercise myocardial perfusion imaging or exercise echocardiography in asymptomatic patients with an intermediate-risk or high-risk Duke treadmill score on exercise ECG testing
- Adenosine or dipyridamole myocardial perfusion imaging or dobutamine echocardiography in asymptomatic patients with a previously inadequate exercise ECG

Class III

- Exercise myocardial perfusion imaging, exercise echocardiography, adenosine or dipyridamole myocardial perfusion imaging, or dobutamine echocardiography in asymptomatic patients with a low-risk Duke treadmill score on exercise ECG testing

Recommendations for Cardiac Stress Imaging as the Initial Test for Diagnosis in Patients With Chronic Stable Angina Who Are Able to Exercise

Class I

- Exercise myocardial perfusion imaging or exercise echocardiography in patients with an intermediate pretest probability of CAD who have one of the following baseline ECG abnormalities:
  - Pre-excitation (Wolff-Parkinson-White) syndrome.
  - More than 1 mm of ST depression at rest.
- Exercise myocardial perfusion imaging or exercise echocardiography in patients with prior revascularization (either PCI or CABG).
- Adenosine or dipyridamole myocardial perfusion imaging in patients with an intermediate pretest probability of CAD and one of the following baseline ECG abnormalities:
  - Electronically paced ventricular rhythm.
  - Left bundle-branch block.

Class IIb

- Exercise myocardial perfusion imaging or exercise echocardiography in patients with a low or high probability of CAD who have one of the following baseline ECG abnormalities:
  - Pre-excitation (Wolff-Parkinson-White) syndrome.
  - More than 1 mm of ST depression.
- Adenosine or dipyridamole myocardial perfusion imaging in patients with a low or high probability of CAD and one of the following baseline ECG abnormalities:
  - Electronically paced ventricular rhythm.
  - Left bundle-branch block.
- Exercise myocardial perfusion imaging or exercise echocardiography in patients with an intermediate probability of CAD who have one of the following:
  - Digoxin use with less than 1 mm ST depression on the baseline ECG.
  - LVH with less than 1 mm ST depression on the baseline ECG.
- Exercise myocardial perfusion imaging, exercise echocardiography, adenosine or dipyridamole myocardial perfusion imaging, or dobutamine echocardiography as the initial stress test in a patient with a normal rest ECG who is not taking digoxin.
- Exercise or dobutamine echocardiography in patients with left bundle-branch block.

Recommendations for Cardiac Stress Imaging as the Initial Test for Diagnosis in Patients With Chronic Stable Angina Who Are Unable to Exercise

Class I

- Adenosine or dipyridamole myocardial perfusion imaging or dobutamine echocardiography in patients with an intermediate pretest probability of CAD.
- Adenosine or dipyridamole stress myocardial perfusion imaging or dobutamine echocardiography in patients with prior revascularization (either PCI or CABG).

Class IIb

- Adenosine or dipyridamole stress myocardial perfusion imaging or dobutamine echocardiography in patients with a low or high probability of CAD in the absence of electronically paced ventricular rhythm or left bundle-branch block.

- Adenosine or dipyridamole myocardial perfusion imaging in patients with a low or a high probability of CAD and one of the following baseline ECG abnormalities
  - Electronically paced ventricular rhythm.
  - Left bundle-branch block.
- Dobutamine echocardiography in patients with left bundle-branch block.

Recommendations for Cardiac Stress Imaging as the Initial Test for Risk Stratification of Patients With Chronic Stable Angina Who Are Able to Exercise

Class I
- Exercise myocardial perfusion imaging or exercise echocardiography to identify the extent, severity, and location of ischemia in patients who do not have left bundle-branch block or an electronically paced ventricular rhythm and who either have an abnormal rest ECG or are using digoxin
- Dipyridamole or adenosine myocardial perfusion imaging in patients with left bundle-branch block or electronically paced ventricular rhythm
- Exercise myocardial perfusion imaging or exercise echocardiography to assess the functional significance of coronary lesions (if not already known) in planning PCI

Class IIb
- Exercise or dobutamine echocardiography in patients with left bundle-branch block
- Exercise, dipyridamole, or adenosine myocardial perfusion imaging, or exercise or dobutamine echocardiography as the initial test in patients who have a normal rest ECG and who are not taking digoxin

Class III
- Exercise myocardial perfusion imaging in patients with left bundle-branch block
- Exercise, dipyridamole, or adenosine myocardial perfusion imaging, or exercise or dobutamine echocardiography in patients with severe comorbidity likely to limit life expectation or prevent revascularization.

Recommendations for Cardiac Stress Imaging as the Initial Test for Risk Stratification of Patients With Chronic Stable Angina Who Are Unable to Exercise

Class I
- Dipyridamole or adenosine myocardial perfusion imaging or dobutamine echocardiography to identify the extent, severity, and location of ischemia in patients who do not have left bundle-branch block or electronically paced ventricular rhythm
- Dipyridamole or adenosine myocardial perfusion imaging in patients with left bundle-branch block or electronically paced ventricular rhythm
- Dipyridamole or adenosine myocardial perfusion imaging or dobutamine echocardiography to assess the functional significance of coronary lesions (if not already known) in planning PCI.

Class IIb
- Dobutamine echocardiography in patients with left bundle-branch block.

Class III
- Dipyridamole or adenosine myocardial perfusion imaging or dobutamine echocardiography in patients with severe comorbidity likely to limit life expectation or prevent revascularization.

Recommendations for Echocardiography, Treadmill Exercise Testing, Stress Radionuclide Imaging, Stress Echocardiography Studies, and Coronary Angiography During Patient Follow-up:

Class I
- Chest X-ray for patients with evidence of new or worsening CHF
- Assessment of LV ejection fraction and segmental wall motion by echocardiography or radionuclide imaging in patients with new or worsening CHF or evidence of intervening MI by history or ECG
- Echocardiography for evidence of new or worsening valvular heart disease
- Treadmill exercise test for patients without prior revascularization who have a significant change in clinical status, are able to exercise, and do not have any of the ECG abnormalities listed below

- Stress radionuclide imaging or stress echocardiography procedures for patients without prior revascularization who have a significant change in clinical status and are unable to exercise or have one of the following ECG abnormalities:
  - Pre-excitation (Wolff-Parkinson-White) syndrome
  - Electronically paced ventricular rhythm
  - More than 1 mm of rest ST depression
  - Complete left bundle-branch block
- Stress radionuclide imaging or stress echocardiography procedures for patients who have a significant change in clinical status and required a stress imaging procedure on their initial evaluation because of equivocal or intermediate-risk treadmill results
- Stress radionuclide imaging or stress echocardiography procedures for patients with prior revascularization who have a significant change in clinical status
- Coronary angiography in patients with marked limitation of ordinary activity (CCS class III) despite maximal medical therapy

Class IIb

- Annual treadmill exercise testing in patients who have no change in clinical status, can exercise, have none of the ECG abnormalities listed above, and have an estimated annual mortality rate greater than 1%.

Class III

- Echocardiography or radionuclide imaging for assessment of LV ejection fraction and segmental wall motion in patients with a normal ECG, no history of MI, and no evidence of CHF
- Repeat treadmill exercise testing in less than three years in patients who have no change in clinical status and an estimated annual mortality rate less than 1% on their initial evaluation, as demonstrated by one of the following:
  - Low-risk Duke treadmill score (without imaging)
  - Low-risk Duke treadmill score with negative imaging
  - Normal LV function and a normal coronary angiogram
  - Normal LV function and insignificant CAD
- Stress imaging or echocardiography for patients who have no change in clinical status and a normal rest ECG, are not taking digoxin, are able to exercise, and did not require a stress imaging or echocardiographic procedure on their initial evaluation because of equivocal or intermediate-risk treadmill results
- Repeat coronary angiography in patients with no change in clinical status, no change on repeat exercise testing or stress imaging, and insignificant CAD on initial evaluation

The ACC/AHA 2007 Chronic Stable Angina Focused Update (Fraker, et al., 2007) does not address stress imaging.

*See Appendix A for American College of Cardiology/American Heart Association (ACC/AHA) Definitions of Classification.

ACC/AHA – Valvular Heart Disease: The 2008 Focused Update and 2006 Guidelines for the Management of Patients with Valvular Heart Disease states the following under the subheading of Diagnosis of Coronary Artery Disease: Limited data are available on the use of myocardial perfusion imaging with thallium-201 or technetium-99m perfusion agents in patients with severe valvular disease. Noninvasive imaging is useful when CAD is suspected in patients with mild valve stenosis or regurgitation and normal LV cavity size and wall thickness (Bonow, et al., 2008).

ACC/AHA – Congenital Heart Disease: The ACC/AHA 2008 Guidelines for the Management of Adults with Congenital Heart Disease (under the sub-heading of Left-Sided Heart Obstructive Lesions: Aortic Valve Disease, Subvalvular and Supravalvular Aortic Stenosis, Associated Disorders of the Ascending Aorta, and Coarctation), lists one recommendation for evaluation of the unoperated patient specific to myocardial perfusion imaging: Exercise testing, dobutamine stress testing, positron emission tomography, or stress sestamibi with adenosine studies can be useful to evaluate the adequacy of myocardial perfusion (Class IIa) (Warnes, et al., 2008).

ACC/AHA – Percutaneous Coronary Intervention (PCI): The ACC/AHA Guideline Update for Percutaneous Coronary Intervention states the following regarding 'Exercise Testing After PCI': Stress imaging is preferred to

evaluate symptomatic patients after PCI. If the patient's exertional capacity is significantly limited, coronary angiography may be more efficacious to evaluate symptoms of typical angina. Exercise testing after discharge is helpful for activity counseling and exercise training as part of cardiac rehabilitation. Neither exercise testing nor radionuclide imaging is indicated for the routine, periodic monitoring of asymptomatic patients after PCI without specific indications (Smith, et al., 2006). The ACC/AHA 2007 Focused Update (King, et al., 2008) specifically addresses stress radionuclide ventriculography, stress radionuclide myocardial perfusion imaging, as well as stress echocardiography. Regarding when pre-operative coronary angiography may be indicated, King et al states that coronary angiography is usually indicated in patients with UA/NSTEMI who either have recurrent symptoms or ischemia despite adequate medical therapy or are at high risk as categorized by clinical findings (HF, serious ventricular arrhythmias) or noninvasive test findings (significant LV dysfunction: ejection fraction less than 0.35, large anterior or multiple perfusion defects). The 2009 ACCF/AHA Focused Update (Kushner, et al., 2009) does not address nuclear imaging.

ACC/AHA/European Society of Cardiology – Ventricular Arrhythmias: The ACC/AHA/ESC 2006 Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death states:

Regarding left ventricular function and imaging, MRI, cardiac computed tomography (CT), or radionuclide angiography can be useful in patients with ventricular arrhythmias when echocardiography does not provide accurate assessment of LV and RV function and/or evaluation of structural changes. Myocardial perfusion SPECT using exercise or pharmacological agents is applicable for a selected group of patients who are suspected of having ventricular arrhythmias triggered by ischemia and who are unable to exercise or have resting ECG abnormalities that limit the accuracy of ECG for ischemia detection. Myocardial perfusion SPECT can also be used to assess viability in patients with LV dysfunction due to prior MI. Accurate quantification of LVEF is possible with gated radionuclide angiography (multiple gated acquisition scan) and thus this technique may be helpful in patients for whom this measurement is not available with echocardiography.

American Heart Association and the American College of Cardiology: In a statement for healthcare professionals from the AHA/ACC entitled 'Assessment of cardiovascular risk by use of multiple-risk-factor assessment equations', Grundy et al. (1999) lists the following risk factors in the assessment of cardiovascular risk:

<u>Major Independent Risk Factors</u>
Cigarette smoking
Elevated blood pressure
Elevated serum total (and LDL) cholesterol
Low serum HDL cholesterol
Diabetes mellitus
Advancing age

<u>Other Risk Factors</u>
Predisposing risk factors
- Obesity
- Abdominal obesity
- Physical inactivity
- Family history of premature coronary heart disease
- Ethnic characteristics
- Psychosocial factors

Conditional risk factors
- Elevated serum triglycerides
- Small LDL particles
- Elevated serum homocysteine
- Elevated serum lipoprotein
- Prothrombotic factors (e.g., fibrinogen)
- Inflammatory markers (e.g., C-reactive protein)

American College of Radiology (ACR): The ACR Practice Guideline for the performance of cardiac scintigraphy. (2009) states there are five major classes of cardiac scintigraphy included in their guideline: myocardial perfusion imaging (SPECT or planar, stress and/or resting, gated or ungated), gated cardiac blood-

pool imaging (resting and/or stress), first-pass cardiac imaging, myocardial infarction imaging, and shunt evaluation. Indications for these studies include, but are not limited to, the following:

A. Myocardial Perfusion Imaging
1. Detecting the presence, location, and extent of coronary artery disease.
2. Evaluating the physiologic significance or sequelae of coronary artery stenosis.
3. Monitoring the effects of treatment of coronary artery disease, including revascularization and medical therapy.
4. Detecting acute myocardial infarction.
5. Evaluating the viability of dysfunctional myocardium.
6. Stratifying risk of myocardial events.
7. Evaluating ventricular function (using gated images).
8. Determining prognosis after myocardial infarction.
9. Preoperative stratification of risk for adverse cardiovascular events during noncardiac surgery.

B. Gated Cardiac Blood-Pool Imaging
1. Quantifying parameters of ventricular function (e.g., ejection fraction, wall motion, ventricular volume, cardiac output, diastolic function).
2. Detecting the presence, location, and extent of coronary artery disease.
3. Assessing whether congestive heart failure is due to ischemic or nonischemic causes.
4. Evaluating and monitoring potential cardiotoxic effects of cancer chemotherapy.
5. Evaluating the effects of valvular abnormalities.

C. First-Pass Cardiac Imaging
1. Calculating left and right ventricular ejection fractions.
2. Assessing wall motion abnormalities.
3. Quantifying left-to-right cardiac shunts.
4. Measuring cardiac output and absolute ventricular chamber volumes.

D. Myocardial Infarction Imaging
Diagnosing and assessing the location and extent of acutely infarcted myocardium.

E. Right-to-Left Shunt Evaluation
Detecting and quantifying right-to-left shunts using radiolabeled particles (ACR, 2009).

National Institute for Clinical Excellence (NICE, United Kingdom): NICE Clinical Guideline Chest Pain of Recent Onset discusses SPECT under the subheading People presenting with stable chest pain, use of non-invasive functional testing for myocardial ischemia. NICE states “When offering non-invasive functional imaging for myocardial ischemia use: myocardial perfusion scintigraphy with single photon emission computed tomography (MPS with SPECT) or stress echocardiography or first-pass contrast-enhanced magnetic resonance (MR) perfusion or MR imaging for stress-induced wall motion abnormalities.” NICE notes “Use adenosine, dipyridamole or dobutamine as stress agents for MPS with SPECT and adenosine or dipyridamole for first-pass contrast-enhanced MR perfusion” (2010).

SPECT/CT Imaging
Consistent with trends in PET/CT systems, hybrid SPECT systems have evolved, combining SPECT and CT systems for combined functional and anatomic information. It is proposed that hybrid imaging with sequential acquisition of structural and functional data in the same imaging session without alteration in patient position overcomes many of the shortcomings and enables more accurate co-registration. There is insufficient data in the peer-reviewed, scientific literature to support the use of combined SPECT/CT imaging. Studies vary widely regarding what diagnosis or body area is best examined with SPECT/CT. Small case series and cohort studies are promising, but do not yet demonstrate that this technique yields improved patient outcomes.

Society of Nuclear Medicine (SNM): SNM Procedure Guideline for SPECT/CT Imaging (May, 2006) states that indications for SPECT/CT include but are not limited to imaging of the following:
- tumors
- thyroid disorders
- parathyroid disorders

- skeleton disorders
- inflammation or infection
- lymphatic system
- heart disorders
- brain disorders
- other organs

American Society of Nuclear Cardiology (ASNC): ASNC Computed Tomographic Imaging within Nuclear Cardiology (2005) states "From a review of the current evidence and future possibilities of cardiac CT, there appears to be substantial promise for the complementary role for CT imaging with PET or SPECT. Current developments in the field of CT imaging will allow for multiple new indications for noninvasive imaging that span a spectrum of cardiac applications resulting in further added value to the field of nuclear cardiology."

Summary
Evidence in the published, peer-reviewed scientific literature, textbooks, and current clinical practice support cardiac nuclear imaging, including planar and single-photon emission computed tomography (SPECT) and multigated acquisition (MUGA) (i.e., equilibrium gated radionuclide angiography [ERNA], radionuclide ventriculography [RVG] or gated blood pool imaging) as proven and well-established imaging modalities. However, due to patient safety concerns regarding exposure to radiation, there are specific indications when SPECT is appropriate (for example in known diabetes mellitus or known coronary artery disease).

Hybrid SPECT/CT imaging studies have not yet demonstrated the therapeutic impact SPECT/CT imaging has on patient outcomes.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Planar or single-photon emission computed tomography (SPECT) cardiac nuclear imaging, **covered when medically necessary:**

CPT®* Codes	Description
78451	Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)
78452	Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection
78453	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)
78454	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection
78466	Myocardial imaging, infarct avid, planar; qualitative or quantitative
78468	Myocardial imaging, infarct avid, planar; with ejection fraction by first pass technique
78469	Myocardial imaging, infarct avid, planar; tomographic SPECT with or without quantification

ICD-9-CM Diagnosis Codes	Description

250.00 – 250.93	Diabetes Mellutus
398.91	Rheumatic heart failure (congestive)
401.0-401.9	Essential hypertension
402.00-402.91	Hypertensive heart disease
403.00-403.91	Hypertensive chronic kidney disease
404.00-404.93	Hypertensive heart and chronic kidney disease
410.00-410.92	Acute myocardial infarction
411.0-411.89	Other acute and subacute forms of ischemic heart disease
412	Old myocardial infarction
413.9	Other and unspecified angina pectoris
414.00-414.9	Other forms of chronic ischemic heart disease
420.0-420.99	Acute pericarditis
421.0-421.9	Acute and subacute endocarditis
422.0-422.99	Acute myocarditis
423.0-432.9	Other disease of the pericardium
424.0-424.99	Other diseases of endocardium
425.0-425.9	Cardiomyopathy
426.0-426.9	Conduction disorders
427.0-427.9	Cardiac dysrhymias
428.0-428.9	Heart Failure
429.0-429.9	Ill-defined descriptions and complications of heart disease
745.0-745.9	Bulbus cordis anomalies and anomalies of cardiac septal closure
746.00-746.9	Other congenital anomalies of heart
747.0	Patent ductus arteriosus
747.1	Coarctation of aorta
747.2	Other anomalies of aorta
747.3	Anomalies of pulmonary artery
747.4	Anomalies of great veins
780.2	Syncope and collapse
780.4	Dizziness and giddiness
785.0-785.3	Symptoms involving the cardiovascular system
785.9	Other symptoms involving cardiovascular system
786.05	Shortness of breath
786.50	Chest pain, unspecified
786.51	Precordial pain
786.52	Painful respiration
786.59	Other chest pain
794.30	Abnormal cardiovascular function study, unspecified
794.31	Abnormal electrocardiogram
794.39	Abnormal cardiovascular, other
796.4	Other abnormal clinical finding (Serum creatinine >2mg/dL)
V12.53	Personal history of sudden cardiac arrest
V12.54	Personal history of transient ischemic attack [TIA], and cerebral infarction without residual deficits
V45.01	Cardiac pacemaker status
V45.81	Postprocedural aortocoronary bypass status
V45.82	Postprocedural percutaneous transluminal coronary angioplasty status
V72.60	Laboratory examination, unspecified
V72.81	Pre-operative cardiovascular examination
V72.83-V72.84	Pre-operative examination

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
	All other codes

Multigated acquisition (MUGA) (i.e., equilibrium gated radionuclide angiography [ERNA], radionuclide ventriculography [RVG] or gated blood pool imaging) cardiac nuclear imaging, **Covered when medically necessary:**

CPT®* Codes	Description
78472	Cardiac blood pool imaging, gated equilibrium; planar, single study at rest or stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without additional quantitative processing
78473	Cardiac blood pool imaging, gated equilibrium; multiple studies, wall motion study plus ejection fraction, at rest and stress (exercise and/or pharmacologic), with or without additional quantification
78481	Cardiac blood pool imaging, (planar), first pass technique; single study, at rest or with stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without quantification
78483	Cardiac blood pool imaging, (planar), first pass technique; multiple studies, at rest and with stress (exercise and/ or pharmacologic), wall motion study plus ejection fraction, with or without quantification
78494	Cardiac blood pool imaging, gated equilibrium, SPECT, at rest, wall motion study plus ejection fraction, with or without quantitative processing
78496	Cardiac blood pool imaging, gated equilibrium, single study, at rest, with right ventricular ejection fraction by first pass technique (List separately in addition to code for primary procedure)
78499	Unlisted cardiovascular procedure, diagnostic nuclear medicine

ICD-9-CM Diagnosis Codes	Description
398.91	Rheumatic heart failure (congestive)
402.00-402.91	Hypertensive heart disease
403.00-403.91	Hypertensive chronic kidney disease
404.00-404.93	Hypertensive heart and chronic kidney disease
410.00-410.92	Acute myocardial infarction
411.0-411.89	Other acute and subacute forms of ischemic heart disease
412	Old myocardial infarction
413.9	Other and unspecified angina pectoris
414.00-414.9	Other forms of chronic ischemic heart disease
420.0-420.99	Acute pericarditis
421.0-421.9	Acute and subacute endocarditis
422.0-422.99	Acute myocarditis
423.0-432.9	Other disease of the pericardium
424.0-424.99	Other diseases of endocardium
425.0-425.9	Cardiomyopathy

426.0-426.9	Conduction disorders
427.0-427.9	Cardiac dysrhymias
428.0-428.9	Heart Failure
429.0-429.9	Ill-defined descriptions and complications of heart disease
745.0-745.9	Bulbus cordis anomalies and anomalies of cardiac septal closure
746.00-746.9	Other congenital anomalies of heart
747.0	Patent ductus arteriosus
747.1	Coarctation of aorta
747.2	Other anomalies of aorta
747.3	Anomalies of pulmonary artery
747.4	Anomalies of great veins
780.2	Syncope and collapse
780.4	Dizziness and giddiness
785.0-785.3	Symptoms involving the cardiovascular system
785.9	Other symptoms involving cardiovascular system
786.05	Shortness of breath
786.50	Chest pain, unspecified
786.51	Precordial pain
786.52	Painful respiration
786.59	Other chest pain
V12.53	Personal history of sudden cardiac arrest
V45.01	Cardiac pacemaker status
V49.83	Awaiting organ transplant status
V58.11	Encounter for antineoplastic chemotherapy

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	**Description**
	All other codes

References

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APPENDIX A

American College of Cardiology/American Heart Association (ACC/AHA) Definitions of Classification used:

Class I:	Conditions for which there is evidence for and/or general agreement that the procedure or treatment is beneficial, useful, and effective.
Class II:	Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/ efficacy of a procedure or treatment.
Class IIa:	Weight of evidence/opinion is in favor of usefulness/efficacy.
Class IIb:	Usefulness/efficacy is less well established by evidence/opinion.
Class III:	Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	10/15/2008	0169	Nuclear Imaging including Single-Photon Emission Computed Tomography (SPECT