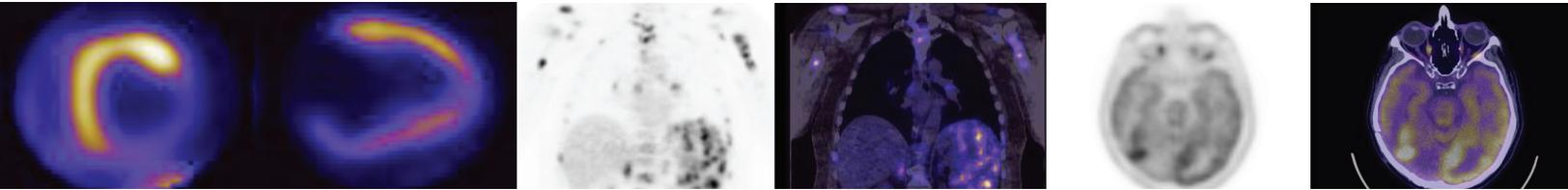


PET PROS

PET Professional Resources and Outreach Source



Cardiac PET and PET/CT Imaging Practice Guidelines

A summary of the recommendations and practice guidelines of professional groups

Background:

The SNM PET/CT Utilization Task Force (UTF) was formed in 2007 to review the current status of PET/CT utilization in the United States, and to identify ways to increase appropriate utilization based on medical evidence. The UTF had its first meeting in Chicago IL on January 15, 2008.

The PET/CT Utilization Task Force has four working groups: Referring Physician, Nuclear Medicine Physicians and Radiologists, Research, and Practice Guidelines.

Goals of the Practice Guideline Working Group

The first year goals are to:

1. Collect and review existing practice guidelines
2. Distribute, revise, develop guidelines for Cardiac PET and PET/CT
3. Develop educational materials describing best practices
4. Develop educational activities

Practice Guidelines List

The recommendations and practice guidelines of professional organizations regarding the use of Rubidium-82, Nitrogen-13 Ammonia, and F-18 fluorodeoxyglucose for cardiac PET and PET/CT imaging are summarized on the following pages for indications approved by the Centers for Medicare and Medicaid Services (CMS):

1. Perfusion of the heart using Rubidium-82 tracer
2. Perfusion of the heart using Ammonia N-13 tracer
3. Myocardial Viability

The summary is intended to serve as an educational tool for referring physicians, as well as nuclear medicine physicians and radiologists. The summary may not include all published guidelines. The summary is current as of December 2008. Practice guidelines are revised and updated periodically, and new guidelines are written. Readers are advised to check the websites of professional organizations as well as published literature for current information.

Practice Guidelines: Cardiac PET Imaging – Executive Summary

Practice guidelines and Appropriate Use Criteria of SNM, ACCF, ASNC and other professional groups are summarized for Cardiac PET imaging currently covered by Medicare.

Perfusion of the heart using Rubidium-82 tracer/ Perfusion of the heart using Ammonia N-13 tracer

PET or PET/CT scans performed at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical Rubidium 82 (Rb 82) or using the FDA-approved radiopharmaceutical ammonia N-13 are covered, provided the requirements below are met:

1. The PET scan, whether at rest alone, or rest with stress, is performed in place of, but not in addition to, a single photon emission computed tomography (SPECT); or
2. The PET scan, whether at rest alone or rest with stress, is used following a SPECT that was found to be inconclusive. In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient. (For purposes of this requirement, an inconclusive test is a test(s) whose results are equivocal, technically uninterpretable, or discordant with a patient's other clinical data and must be documented in the beneficiary's file.)

Cardiac PET: Myocardial Perfusion Imaging- Appropriate Use Criteria

1. Detection of CAD in the symptomatic patient:
 - a. Evaluation of Ischemic Equivalent (Non-Acute)
 - b. Acute Chest Pain
 - c. Acute chest pain (rest imaging only)
2. Detection of CAD/Risk Assessment without Ischemic Equivalent
 - a. Asymptomatic- High CHD Risk (ATP III Risk Criteria)
 - b. New-Onset or Newly diagnosed Heart Failure with LV Systolic Dysfunction without Ischemic Equivalent
 - c. Ventricular Tachychardia
 - d. Syncope with Intermediate or High CHD risk (ATP III Risk Criteria)
 - e. Troponin elevation without additional evidence of acute coronary syndrome
3. Risk Assessment with prior test results and/or known chronic stable CAD
 - a. Equivocal, borderline or discordant stress testing where obstructive CAD remains a concern
 - b. New or worsening symptoms- Abnormal coronary angiography OR abnormal prior stress imaging study
 - c. Coronary stenosis or anatomic abnormality of uncertain significance

- d. Asymptomatic, High CHD risk, Agatston score between 100-400
 - e. Asymptomatic, Agatston score greater than 400
 - f. Asymptomatic, Intermediate-Risk Duke Treadmill Score
 - g. Asymptomatic, High-Risk Duke Treadmill Score
4. Risk Assessment: Preoperative Evaluation for Non-Cardiac Surgery without Active Cardiac Conditions*
 - a. Intermediate-Risk Surgery
 - b. Vascular Surgery
 5. Risk Assessment: Within 3 months of an Acute Coronary Syndrome
 - a. STEMI
 - b. UA/NSTEMI
 6. Risk Assessment: Post Revascularization (PCI or CABG)
 - a. Symptomatic
 - b. Asymptomatic- Incomplete Revascularization or greater than or equal to 5 years post CABG
 7. Assessment of Viability/Ischemia
 - a. Ischemic Cardiomyopathy
 - b. Assessment of Viability for patient eligible for revascularization
 8. Evaluation of Left Ventricular Function
 - a. In absence of recent reliable diagnostic information from another imaging modality
 - b. Baseline and serial measures after key therapeutic milestones or evidence of toxicity from potentially cardiotoxic therapy

Cardiac PET: Myocardial Viability

The applications for Cardiac Viability Imaging with FDG PET are:

1. The identification of patients with partial loss of heart muscle movement or hibernating myocardium is important in selecting candidates with compromised ventricular function to determine appropriateness for revascularization.
2. Distinguish between dysfunctional but viable myocardial tissue and scar tissue in order to affect management decisions in patients with ischemic cardiomyopathy and left ventricular dysfunction.

Medicare covers FDG PET for the determination of:

1. Myocardial viability as a primary or initial diagnostic study prior to revascularization, or following an inconclusive SPECT. Studies performed by full and partial ring scanners are covered.
2. Limitations: In the event a patient receives a SPECT test with inconclusive results, a PET scan may be covered. However, if a patient receives a FDG PET study with inconclusive results, a follow up SPECT test is not covered.

Practice Guidelines – Perfusion of the heart using Rubidium-82 tracer/ Perfusion of the heart using Ammonia N-13 tracer

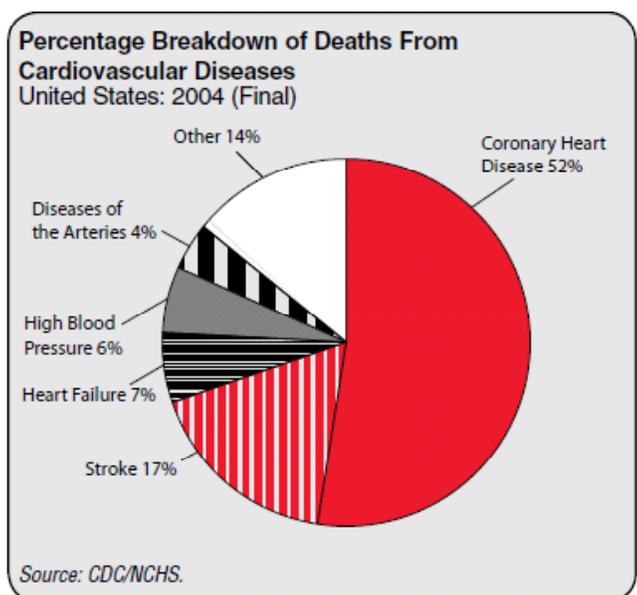
An estimated 80,700,000 American adults (one in three) have one or more types of cardiovascular disease (CVD), of whom 38,200,000 are estimated to be age 60 or older. Total CVD includes diseases in the bullet points below except for congenital CVD:

- High blood pressure (HBP)—73,000,000. (Defined as systolic pressure of 140 mm Hg or greater and/or diastolic pressure of 90 mm Hg or greater, taking antihypertensive medication or being told at least twice by a physician or other health professional that you have high blood pressure.)
- Coronary heart disease (CHD)—16,000,000.
 - Myocardial infarction (MI, or heart attack) — 8,100,000.
 - Angina pectoris (AP, or chest pain)—9,100,000.
- Heart failure (HF)—5,300,000.
- Stroke—5,800,000.
- Congenital cardiovascular defects—650,000–1,300,000.

In every year since 1900, except 1918, CVD accounted for more deaths than any other single cause or group of causes of death in the United States. (NCHS; http://www.nhlbi.nih.gov/resources/docs/shs_db.pdf)

Nearly 2,400 Americans die of CVD each day, an average of one death every 37 seconds. CVD claims about as many lives each year as cancer, chronic lower respiratory diseases, accidents and diabetes mellitus combined. (NCHS. *Compressed mortality file: underlying cause of death, 1979 to 2004*; <http://wonder.cdc.gov/mortSQL.html>)

The estimated direct and indirect cost of CVD in the United States for 2008 is \$448.5 billion.



From: American Heart Association. *Heart Disease and Stroke Statistics — 2008 Update*. Dallas, Texas: American Heart Association; 2008. c2008,

American Heart Association.

The applications of Cardiac PET and PET/CT Perfusion include:

1. Perfusion of the heart using Rubidium-82 tracer
2. Perfusion of the heart using Ammonia N-13 tracer

PET scans performed at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical Rubidium 82 (Rb 82) or using the FDA-approved radiopharmaceutical ammonia N-13

CMS Publication 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 4, Section 220.6 available at

http://www.cms.hhs.gov/manuals/downloads/ncd103c1_part4.pdf

Professional organizations with practice guidelines or recommendations that include PET or PET/CT in patients with known or suspected coronary artery disease are listed below.

SNM 2008

H. William Strauss, D. Douglas Miller, Mark D. Wittry, Manuel D. Cerqueira, Ernest V. Garcia, Abdulmassi S. Iskandrian, Heinrich R. Schelbert, Frans J. Wackers, Helena R. Balon, Otto Lang, and Josef Machac. Procedure Guideline for Myocardial Perfusion Imaging 3.3 J Nucl Med. 2008 Sept;36(3):155-161.

<http://interactive.snm.org/docs/155.pdf>

1. Perfusion imaging identifies areas of relatively reduced myocardial blood flow associated with ischemia or scar. The relative regional distribution of perfusion can be assessed at rest, during cardiovascular stress, or both.
2. Recording myocardial perfusion data with electrocardiographic (ECG) gating permits calculation of global and regional ventricular function and assessment of the relationship of perfusion to regional function

ASNC 2006

Josef Machac, MD, Stephen L. Bacharach, PhD, Timothy M. Bateman, MD, Jeroen J. Bax, MD, Robert Beanlands, MD, Frank Bengel, MD, Steven R. Bergmann, MD, PhD, Richard C. Brunken, MD, James Case, PhD, Dominique Delbeke, MD, Marcelo F. DiCarli, MD, Ernest V. Garcia, PhD, Richard A. Goldstein, MD, Robert J. Gropler, MD, Mark Travin, MD, Randolph Patterson, MD, Heinrich R. Schelbert, MD. Positron emission tomography myocardial perfusion and glucose metabolism imaging. J Nucl Cardiol 2006; 13:e121-51.

Vasken Dilzizian (chair), Stephen L. Bacharach, PhD Robert L. Beanlands, MD, Steven R. Bergmann, MD, PhD, Dominique Delbeke, MD, PhD, Robert J. Gropler, MD, Juhani Knuuti, MD, PhD, Heinrich R. Schelbert, MD, PhD,

Nagara Tamaki, MD, PhD, Mark I. Travin, MD: **ASNC guidelines for PET myocardial perfusion and metabolism clinical imaging.** April 2009, approved by ASNC board of director for publication in J Nucl Cardiol.

<http://www.asnc.org/imageuploads/Imaging%20Guidelines%20PET.pdf>

1. Assess myocardial perfusion, left ventricular (LV) function

ACC/AHA/ASNC 2003

Klocke FJ, Baird MG, Bateman TM, Berman DS, Carabello BA, Cerqueira MD, DeMaria AN, Kennedy JW, Lorell BH, Messer JV, O'Gara PT, Russell RO Jr., St. John Sutton

MG, Udelson JE, Verani MS, Williams KA. ACC/AHA/ASNC guidelines for the clinical use of cardiac radionuclide imaging: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/ASNC Committee to Revise the 1995 Guidelines for the Clinical Use of Radionuclide Imaging). (2003). American College of Cardiology Web Site.

<http://www.acc.org/qualityandscience/clinical/guidelines/radio/index.pdf>

1. A number of studies, involving a total of several hundred patients, indicate that perfusion imaging with PET using dipyridamole and either rubidium-82 or N-13-ammonia is a sensitive and specific clinical method to diagnose CAD.

2. Recommendations: Cardiac Stress Myocardial Perfusion PET:
 - a. Recommendations for Diagnosis of Patients With an Intermediate Likelihood of CAD and/or Risk Stratification of Patients With an Intermediate or High Likelihood of CAD
 - i. Class I*

Adenosine or dipyridamole myocardial perfusion PET in patients in whom an appropriately indicated myocardial perfusion SPECT study has been found to be equivocal for diagnostic or risk stratification purposes. (*Level of Evidence: B*)

*** Note: CMS will cover PET in place of or after an inconclusive SPECT**
 - ii. Class IIa
 1. Adenosine or dipyridamole myocardial perfusion PET to identify the extent, severity, and location of ischemia as the initial diagnostic test in patients who are unable to exercise. (*Level of Evidence: B*)
 2. Adenosine or dipyridamole myocardial perfusion PET to identify the extent, severity, and location of ischemia as the initial diagnostic test in patients who are able to exercise but have LBBB or an electronically-paced rhythm. (*Level of Evidence: B*)

ACCF/ASNC/ACR/AHA/ASE/SCCT/SCMR/SNM 2009

Robert C. Hendel, MD (Chair); Daniel S. Berman, MD; Marcelo F. Di Carli, MD; Paul A. Heidenreich, MD; Robert E. Henkin, MD; Patricia A. Pellika MD; Gerald M. Pohost, MD, Kim A. Williams, MD. **ACCF/ASNC/ACEP/ACR/AHA/ASE/SCCT/SCMR/SNM. Appropriate use** criteria for cardiac radionuclide imaging. www.acc.org. JACC2009;53 (23) (in press)

Practice Guidelines – Myocardial Viability

Data from the NHLBI's Framingham Heart Study indicate that (*Circulation*.2002;106:3068–3072) . .

- Heart failure (HF) incidence approaches 10 per 1,000 population after age 65.
- Seventy-five percent of HF cases have antecedent hypertension.
- About 22 percent of male and 46 percent of female heart attack (MI) victims will be disabled with HF within six years.
- At age 40, the lifetime risk of developing HF for both men and women is one in five.
- At age 40, the lifetime risk of HF occurring without antecedent MI is one in nine for men and one in six for women.
- The lifetime risk doubles for people with blood pressure greater than 160/90 mm Hg compared to those with blood pressure less than 140/90 mm Hg.
- A study conducted in Olmsted County, Minnesota, showed that the incidence of HF (ICD9/428) has not declined during two decades, but survival after onset has increased overall, with less improvement among women and elderly persons. (*JAMA*. 2004;292:344–350.)

In 2004, HF total mention mortality was 284,365 (see glossary for definition of “total mention mortality”). HF was listed as the underlying cause (see glossary for “underlying cause”) in 57,120 of those deaths.

The estimated direct and indirect cost of HF in the United States for 2008 is \$34.8 billion.

movement or hibernating myocardium is important in selecting candidates with compromised ventricular function to determine appropriateness for revascularization.

4. Distinguish between dysfunctional but viable myocardial tissue and scar tissue in order to affect management decisions in patients with ischemic cardiomyopathy and left ventricular dysfunction.

FDG PET is approved by the Centers for Medicare and Medicaid Services (CMS) for:

1. Myocardial viability as a primary or initial diagnostic study prior to revascularization, or following an inconclusive SPECT. Studies performed by full and partial ring scanners are covered.
2. Limitations: In the event a patient receives a SPECT test with inconclusive results, a PET scan may be covered. However, if a patient receives a FDG PET study with inconclusive results, a follow up SPECT test is not covered.

CMS Publication 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 4, Section 220.6). Available at

http://www.cms.hhs.gov/manuals/downloads/ncd103c1_part4.pdf

Professional organizations with practice guidelines or recommendations that include Cardiac Viability are listed below.

SNM 2008

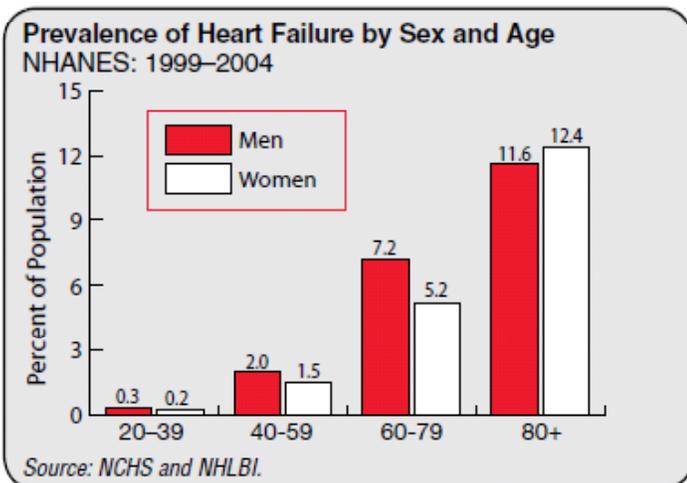
Fletcher JW, Djulbegovic B, Soares HP, Siegel BA, Lowe VJ, Lyman GH, Coleman RE, Wahl R, Paschold JC, Avril N, Einhorn LH, Suh WW, Samson D, Delbeke D, Gorman M, Shields AF. Recommendations on the use of 18F-FDG PET in oncology. *J Nucl Med*. 2008 Mar;49(3):480-508.

<http://jnm.snmjournals.org/cgi/reprint/49/3/480.pdf>

1. FDG PET with PET MPI compares the regional distribution of myocardial glucose use to regional myocardial perfusion. Two sets of images are recorded. The first is with 18F-FDG administered under conditions of glucose loading to determine the regional myocardial use of glucose, and the second is regional myocardial perfusion determined at rest (with 13N-ammonia or 82Rb). The regional distribution of perfusion and that of 18F-FDG are compared.

ASNC 2006

Josef Machac, MD, Stephen L. Bacharach, PhD, Timothy M. Bateman, MD, Jeroen J. Bax, MD, Robert Beanlands, MD, Frank Bengel, MD, Steven R. Bergmann, MD, PhD, Richard C. Brunken, MD, James Case, PhD, Dominique Delbeke, MD, Marcelo F. DiCarli, MD, Ernest V. Garcia, PhD, Richard A. Goldstein, MD, Robert J. Gropler, MD, Mark Travin, MD, Randolph Patterson, MD, Heinrich R. Schelbert, MD. Positron emission tomography myocardial perfusion and glucose metabolism imaging. *J Nucl Cardiol*



From: American Heart Association. *Heart Disease and Stroke Statistics — 2008 Update*. Dallas, Texas: American Heart Association; 2008. c2008, American Heart Association.

The applications for Cardiac Viability Imaging with FDG PET are:

3. The identification of patients with partial loss of heart muscle

2006; 13:e121-51.

Vasken Dilzizian (chair), Stephen L. Bacharach, PhD Robert L. Beanlands, MD, Steven R. Bergmann, MD, PhD, Dominique Delbeke, MD, PhD, Robert J. Gropler, MD, Juhani Knuuti, MD, PhD, Heinrich R. Schelbert, MD, PhD, Nagara Tamaki, MD, PhD, Mark I. Travin, MD. **ASNC guidelines for PET myocardial perfusion and metabolism clinical imaging.** April 2009, approved by ASNC board of director for publication in J Nucl Cardiol.

<http://www.asnc.org/imageuploads/Imaging%20Guidelines%20PET.pdf>

1. Cardiac positron emission tomography (PET) imaging is a well-validated, reimbursable means to assess myocardial perfusion, left ventricular (LV) function, and viability.

ACC/AHA/ASNC 2003

Klocke FJ, Baird MG, Bateman TM, Berman DS, Carabello BA, Cerqueira MD, DeMaria AN, Kennedy JW, Lorell BH, Messer JV, O’Gara PT, Russell RO Jr., St. John Sutton MG, Udelson JE, Verani MS, Williams KA. ACC/AHA/ASNC guidelines for the clinical use of cardiac radionuclide imaging: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/ASNC Committee to Revise the 1995 Guidelines for the Clinical Use of Radionuclide Imaging). (2003). American College of Cardiology Web Site.

<http://www.acc.org/qualityandscience/clinical/guidelines/radio/index.pdf>

1. In patients with chronic coronary disease and LV dysfunction, there exists an important subpopulation in which revascularization may significantly improve regional or global LV function, as well as symptoms and potentially natural history. The underlying pathophysiology involves reversible myocardial dysfunction (hibernation or stunning), which may exist independently or may coexist within the same patient. These states of potentially reversible LV dysfunction have in common preserved cell membrane integrity and sufficiently preserved metabolic activity to maintain cellular functions and cell membrane integrity in the absence of normal myocyte contractility secondary to resting ischemia or repetitive demand ischemia (“repetitive stunning”).

ACCF/ASNC/ACR/AHA/ASE/SCCT/SCMR/SNM 2009

Robert C. Hendel, MD (Chair); Daniel S. Berman, MD; Marcelo F. Di Carli, MD; Paul A. Heidenreich, MD; Robert E. Henkin, MD; Patricia A. Pellika MD; Gerald M. Pohost, MD, Kim A. Williams, MD. **ACCF/ASNC/ACEP/ACR/AHA/ASE/SCCT/SCMR/SNM. Appropriate use criteria for cardiac radionuclide imaging.** www.acc.org. JACC2009;53 (23) (in press).