“FOR CMS (MEDICARE) MEMBERS ONLY”

INTRODUCTION

Echocardiography is the ultrasonic examination of the heart. Transthoracic echocardiography (TTE) affords unique insight into cardiac structure and function. Two-dimensional (2D) imaging defines the configuration and changing dimensions of the chambers, dynamic cyclic variation in myocardial thickness, and the associated valvular motions throughout the cardiac cycle. The proximal great vessels and the pericardium can also be directly visualized, although transesophageal echocardiography (TEE) often permits better visualization of the thoracic aorta and great veins than does TTE. (ACC/AHA/ASE 2003 Guideline Update for the Clinical Application of Echocardiography [hereafter referred to as the "ACC/AHA/ASE Guideline Update"], pg. 41).

A Doppler examination is a valuable adjunct to a complete echocardiographic examination. The basic principle utilizes the changes in frequency when a transmitted ultrasound wave is reflected from moving surfaces (e.g., heart valves, red blood cells), allowing the capability of measuring normal and abnormal velocities of blood flow. Such data may lead to the calculation of valvular stenosis, valvular regurgitation, cardiac output, intracardiac pressures or intracardiac shunts.

Some cardiac ultrasound machines have become increasingly compact and portable. Certain "hand carried" scanners are "full featured" and permit a skilled examiner to image and record permanent records of all of the tomographic images and Doppler data (both color and spectral) needed to perform a complete transthoracic echocardiographic examination that may be quite comparable, in diagnostic value, to that obtained with a larger, "state of the art" instrument. In order to qualify as a valid echocardiographic service, the study must be done for an accepted clinical indication by a properly trained examiner and must include a permanent record of the findings, data sufficient to support the conclusions and an appropriate interpretation and written report. Such a study would meet the standards required for a complete echocardiographic examination, regardless of the size of the instrument used to perform the study.

All echocardiography services require a referral or an order from a treating physician.
This policy addresses the medically necessary and appropriate application of TTE, including stress echocardiography. Transesophageal echocardiography (TEE) is the subject of a separate policy statement.

**Indications:**

Echocardiography is indicated in the evaluation of derangements of valvular, myocardial and pericardial structure and function. The general applications for coverage include:

**A. Transthoracic Echocardiogram**

1. **Ventricular Function, Cardiomyopathies and Heart Failure**
   Changes in myocardial thickness (hypertrophy and thinning), in derived parameters of contractility, and in chamber volume and morphology, can be quantitated and charted over time by TTE. Cardiac responses to volume perturbations, chronic pressure excess and therapeutic interventions can be monitored. Recognition of the relative contributions of myocardial and valvular functional perturbations to a clinical presentation is facilitated. TTE aids in the recognition of myopathies and their classification into hypertrophic, dilated and restrictive types. Absent clinically documented, discrete (abrupt change in signs and symptoms) episodes of deterioration, it is not generally medically necessary to augment clinical assessments with TTE measurements at more frequent than annual examinations.

There is increasing data to support the prognostic value of diastolic function parameters in patients with systolic dysfunction. "When the etiology is in doubt, echocardiography can document or rule out the common cardiac causes of pulmonary congestion: left-sided valvular disease, depressed systolic or diastolic function, and cardiomyopathy. In this regard, echocardiography is the preferred initial diagnostic test when the history, physical examination, and routine laboratory tests suggest (or cannot eliminate) cardiac disease." (ACC/AHA/ASE 2003 Guideline Update, pg. 35) "Echocardiography is recommended for patients with edema with clinical signs of elevated central venous pressure when a potential cardiac etiology is suspected or when central venous pressure cannot be estimated with confidence and clinical suspicion of heart disease is high." TTE is also recommended for patients experiencing "dyspnea with clinical signs of heart disease." (ACC/AHA/ASE 2003 Guideline Update, pg. 37) "Echocardiography is not recommended in patients with edema when the jugular venous pressure does not appear to be elevated." (ACC/AHA/ASE 2003 Guideline Update, pg. 35).

2. **Hypertensive Cardiovascular Disease**
   "Echocardiography is the noninvasive procedure of choice in evaluating the cardiac effects of systemic hypertension, the most common cause of LV hypertrophy and congestive heart failure in adults." (ACC/AHA/ASE 2003 Guideline Update, pg. 42) Left ventricular hypertrophy (LVH) correlates with prognosis in hypertensive cardiovascular disease. However, "the usefulness of echocardiography in an individual patient with hypertension without suspected concomitant heart disease depends on the clinical relevance of the
assessment of LV mass or function in that patient. Thus, not every patient with hypertension should have resting LV function assessed (Class I), but if such an assessment is relevant, echocardiography is a well-documented and accepted method by which to achieve it. The value of repeated studies in asymptomatic hypertensive patients with normal LV function is not clearly established." (ACC/AHA 2003 Guideline Update, pg. 42).

Certain antihypertensive medications have been reported to stabilize and possibly contribute to the regression of left ventricular hypertrophy and the insidiously progressive development of left ventricular dysfunction and dilatation. In young individuals and in individuals with borderline hypertension, the decision to commit to long-term antihypertensive therapy may be determined by the presence of left ventricular hypertrophy and/or left ventricular mass calculation.

3. Acute Myocardial Infarction and Coronary Insufficiency
TTE can detect ischemic and infarcted myocardium. Regional motion, systolic thickening perturbations and mural thinning can be quantitated and global functional adaptation assessed. The relative contributions of right ventricular ischemia and/or infarction can be evaluated. Complications of acute infarction (e.g., mural thrombi, papillary muscle dysfunction and rupture, septal defects, true or false aneurysm and myocardial rupture) can be diagnosed and their contribution to the overall clinical status placed in perspective. Following an initial TTE in the setting of acute infarction, repetition frequency will typically be dictated by the acute clinical course. The medical record should document the medical necessity of the frequency for TTE assessment.

"Evaluation of chest pain in patients with suspected acute myocardial ischemia, when baseline ECG and other laboratory markers are nondiagnostic and when study can be obtained during pain or within minutes after its abatement" is recommended in the ACC/AHA/ASE 2003 Guideline Update. "The use of echocardiography for diagnosis of acute myocardial infarction provides the greatest amount of incremental information when the clinical history and ECG findings are nondiagnostic." (ACC/AHA/ASE 2003 Guideline Update, pg. 15) This application may be used as part of a thoughtful clinical evaluation, especially as a triage decision on chest pain syndrome.

4. Exposure to Cardiotoxic Agents (chemotherapeutic and external)
Measures of myocardial contractility, thinning and dilatation are important in the titration of therapeutic agents with known myocardial toxicity. When echocardiography is used to monitor cardiac toxicity of chemotherapeutic agents (e.g., degenerative cardiomyopathy produced by doxorubicin therapy), an initial complete TTE may be performed prior to first administration of the agent with the frequency of repeat studies determined by the patient's clinical course and the toxicity profile of the agent being administered, although tests performed bimonthly during chemotherapy and at six (6) months following therapy are generally considered medically appropriate.

5. Cardiac Transplant and Rejection Monitoring
TTE is an integral part of the cardiac donor-selection and donor-recipient matching process.
Evaluation focuses on analysis of ventricular function and valvular integrity. TTE is also incorporated into the management of allograft recipients. Myocardial thickness, refractile properties, contractile patterns and indices, restrictive hemodynamics, and the late development of pericardial fluid may alert the clinician to a rejection episode. None of these findings has achieved diagnostic sensitivity or specificity. Typically, TTE is performed weekly for the first four to eight (4-8) weeks following transplant, with decremental frequency over time. Absent acute rejection episodes, approximately two (2) TTE examinations are typically performed yearly in chronic transplant recipients. TTE of cardiac allografts is most appropriately serially performed at transplant centers by examiners with expertise in the management of cardiac allograft recipients. Uses in excess of the generally accepted frequency will be expected to have appropriate medical necessity documentation provided.

6. **Native Valvular Heart Disease**

TTE is well established as a technique of primary choice for the evaluation of valvular pathology and its effect upon global myocardial function. The relative severity of multi-valve pathologies can be quantified. Visualization of the valve and valvular apparatus facilitates therapeutic decisions when competing therapeutic options exist. For example, noninvasive TTE remains the study of choice for monitoring chronic aortic pathology with images suitable for serial quantitation. In some patients, Doppler echocardiography is the only noninvasive method capable of identifying the cause of a heart murmur. (ACC/AHA/ASE 2003 Guideline Update, pg. 7) Absent acute intervention, or a discrete change in otherwise stable clinical signs and symptoms, it is not medically necessary to repeat these examinations more frequently than annually. when the patient's clinical status shows evidence of change or the plan of care includes consideration for imminent valvular surgery, more frequent exams may be necessary.

7. **Prosthetic Heart Valves (Mechanical & Bioprostheses)**

TTE assessment soon after prosthetic valve implant is important in establishing a baseline structural and hemodynamic profile unique to the individual and the prosthesis. Size, position, underlying ventricular function and concomitant valve pathologies all impact this unique profile. Reassessment following convalescence (3-6 months) for establishment of a baseline is appropriate. Thereafter, re-evaluation of patients with suspected dysfunction, thrombosis or a change in clinical status or symptoms is indicated.

8. **Acute Endocarditis**

TTE can provide diagnostic information; larger vegetations may be directly visualized; and valvular anatomy and ventricular function directly assessed. The complications or sequelae of acute infective endocarditis can be detected and monitored over time. Examination frequency in the acute phase of illness is dictated by the individual clinical course. When the acute process has been stabilized, the frequency of serial TTE evaluation will be determined by the residual pathophysiology and discrete clinical events, analogous to the serial assessment of chronic valvular dysfunction and/or normally functioning prosthetic valves.
9. Pericardial Disease
Detection and quantitation of the amount of pericardial effusion were among the first, and remain important, applications of TTE. Pericardial fluid accumulations of as little as twenty (20) milliliters have been reliably diagnosed by TTE. Cardiac motion and blood flow patterns demonstrated by TTE characterize the hemodynamic consequences of pericardial fluid accumulation. A collage of TTE findings has been found to be reliable indices of cardiac tamponade. TTE can be a valuable adjunct during the removal of pericardial fluid and creation of pericardial windows. The acute clinical status will dictate examination frequency. In a patient with evolving pericardial pathology, a limited focused TTE exam may be appropriate. TTE and Doppler techniques are quite helpful in identifying pericardial constriction and differentiating it from restrictive myocardial disease.

10. Abnormalities of the Great Vessels
Aorta: TTE can provide valuable information when acute or chronic aortic pathology is present; however, the posterior window of TEE, coupled with the more posterior position of the thoracic aorta, has rendered TEE a more determinative study. Noninvasive TTE remains the study of choice for chronic aortic pathology when images suitable for serial quantitation can be obtained. Routine (yearly) evaluation is indicated in patients with severe aortic stenosis or regurgitation, in whom the information obtained will be used in determining or modifying the plan of care. In some individuals, such as those with ascending aortic dilatation or aneurysms, a focused limited follow-up exam (93308) to serially measure ascending aortic diameters may be indicated. Although TTE may visualize the intimal flap in patients with aortic dissection, TEE has proved to be a far more sensitive diagnostic procedure. TEE is the technique that is indicated in examination of the entire aorta, especially in emergency situation.

Pulmonary Artery: It is also indicated for visualization of the main pulmonary artery segment and the proximal right and left pulmonary arteries.

Venae Cavae: Echocardiography is indicated for visualizing the vena cavae and diagnosing various congenital and acquired abnormalities such as vena caval thrombosis, vena caval dilation, and thrombosis or extension of tumors from the inferior vena cava to the right-heart chambers.

11. Congenital Heart Disease
In children and small adults TTE provides accurate anatomic definition of most congenital heart diseases. Coupled with Doppler hemodynamic measurements, TTE usually provides accurate diagnosis and noninvasive serial assessment. A technically adequate TTE can obviate the need for preoperative catheterization in select individuals. When the disease process and therapy are stable, serial assessment by TTE requires contemporaneous medical necessity documentation, if the frequency exceeds an annual evaluation. In asymptomatic patients following repair of ASD, PFO, VSD or PDA follow up examination is only indicated within the first year after correction.

12. Suspected Cardiac Thrombi and Embolic Sources
TTE is indicated for the evaluation for cardiovascular source of embolic events (PFO/ASD,
atrial or ventricular thrombus, intracardiac tumor) in evaluation for patients with abrupt occlusion of a major peripheral or visceral artery or for with neurological events without evidence of cerebrovascular disease or other obvious cause. Limited visualization of atrial appendages and the more peripheral and superior portions of the atria render TTE less sensitive than TEE in the detection of atrial thrombus and potentially embolic material. In those instances where the precise diagnosis and localization of potentially embolic material is of paramount therapeutic importance and the information so obtained will potentially and substantively alter therapy, or the risk of anticoagulants is inordinately high, consideration should be given to TEE if TTE provides inadequate decisional information.

13. **Cardiac Tumors and Masses**
Infiltrative and ventricular tumors and masses can be visualized, their extent quantitated and their hemodynamic consequences assessed by TTE. Right atrial space-occupying masses are usually well visualized by TTE. TEE provides a more detailed view of the left atrium and is more sensitive in quantifying mass characteristics (solid, cystic, etc.), extensions and attachments. Serial TTEs may be medically necessary to monitor tumor size or tumor recurrence.

14. **Critically Ill and Trauma Patients**
There is a role for echocardiography in the management of critically ill patients and trauma victims. The diagnosis of suspect aortic or central pulmonary pathology, cardiac contusion, or a pericardial effusion may be confirmed. Perturbations of volume status may be more completely defined and management strategies modified. The frequency of these typically acute studies will be dictated by the exigencies of the clinical milieu.

15. **Arrhythmias and Palpitations**
Transthoracic echocardiography is useful in defining cardiac function in which arrhythmias occur, and may be useful in the management of cardiac arrhythmias. Some arrhythmias are frequently associated with underlying organic heart disease or may predispose the patient to hemodynamic deterioration. Atrial fibrillation and atrial flutter are examples of arrhythmias in which echocardiography may be appropriate to assess the underlying disorder. Echocardiographic studies are appropriate only when there is evidence of heart disease. Palpitations without evidence of arrhythmias, or minor arrhythmias (e.g., isolated APC's or VPC's) without evidence of heart disease, are not covered indications for transthoracic echocardiography.

16. **Syncope**
Determination of the etiology of syncopal episodes can be a difficult clinical problem. The origin may be cardiac, neurological, or due to other causes. Syncope due to cardiac origin is most commonly related to vasodepressor reflexes, bradyarrhythmias, or tachyarrhythmias. Syncope is less commonly caused by cardiac structural disorders. Patients with a structurally normal heart generally have a much more benign prognosis than those with underlying structural coronary artery disease or cardiomyopathic disease. Echocardiography is only appropriate as the initial evaluation, and when other findings are suggestive of valvular heart disease or obstructive cardiomyopathy.
17. **Pulmonary**
Pulmonary heart disease may result from acute changes in the pulmonary circulation (e.g., pulmonary embolus), or chronic changes produced by chronic hypoxia which may cause significant right ventricular dysfunction and hypertrophy. Echocardiography may assess right ventricular size and performance, and quantify the severity of pulmonary hypertension using Doppler interrogation of valvular flow signals. Indications include unexplained pulmonary hypertension, and pulmonary emboli with suspected right atrial or right ventricular sources of emboli.

18. **Contrast Echocardiography**
Contrast echocardiography is indicated when a conventional study has failed to provide adequate and critically needed information on left ventricular function. A contrast agent is considered medically necessary when it is used to improve the delineation of the left ventricular endocardial borders in a patient whose non-contrast study is inadequate or suboptimal, and for whom the LV function information is essential to the management of the patient. Contrast is indicated when more than two (2) contiguous segments of the left ventricular border are not visualized.

**LIMITATIONS:**
1. Echocardiography performed for screening purposes is not covered. Screening includes testing performed on patients who present with risk factors (including the risk factor as having a positive family history, e.g., familial history of Marfan's disease). A screening service for high-risk patients is considered good medical practice but is not covered by Medicare. When the result of the test is abnormal, subsequent services may be billed with the test-result diagnosis; however, the initial screening test must be listed as screening, even though the result of the screening test may be a covered condition.

**The following indications (#2-15) are deemed to be not medically necessary and are therefore not reimbursable:**

2. Routine (yearly) evaluation of asymptomatic patients with corrected ASD, VSD or PDA more than one year after successful correction.

3. Routine (yearly) re-evaluation of mitral valve prolapse in patients with no or mild mitral regurgitation and no change in clinical status.

4. Routine (yearly) re-evaluation of an asymptomatic patient with mild native aortic stenosis or mild-moderate native mitral stenosis and no change in clinical status.

5. Routine (yearly) re-evaluation of native valvular regurgitation in an asymptomatic patient with mild regurgitation, no change in clinical status and normal left ventricular size.

6. Routine (yearly) evaluation of a patient with a prosthetic valve in whom there is no
suspicion of valvular dysfunction and no change in clinical status.

7. Routine (yearly) re-evaluation of patients with heart failure (systolic or diastolic) in whom there is no change in clinical status.

8. Routine (yearly) evaluation of hypertrophic cardiomyopathy in a patient with no change in clinical status.

9. Patients who have isolated APC or VPC without other evidence of heart disease.

10. Evaluation of LV function with prior ventricular function within the past year with normal (such as prior echocardiogram, left ventriculogram, SPECT, cardiac MRI) in patients in whom there has been no change in clinical status.

11. Initial evaluation of patient with suspected pulmonary embolism in order to establish diagnosis.

12. Evaluation of native and/or prosthetic valves in patients with transient fever but without evidence of bacteremia or new murmur.

13. Re-evaluation of a patient with known hypertensive heart disease without a change in clinical status.

14. Routine evaluation of patients with systemic hypertension without suspected hypertensive heart disease.

15. Evaluation of a patient with atrial fibrillation/flutter for left atrial thrombus or spontaneous contrast when a decision has been made to anticoagulate and not to perform cardioversion.

[Items 2-15, see ACCF/ASE/ACEP/ASNC/SCAI/SCCT/SCMR 2007 Appropriateness Criteria for Transthoracic and Transesophageal Echocardiography, JACC 2007].

B. Follow-up Studies or Limited Studies

INDICATIONS AND LIMITATIONS

A complete study includes a full evaluation of all aspects of the heart, including the cardiac chambers, valves, blood flow, and great vessels. The images are reviewed, measured, analyzed and interpreted by the physician. A report is prepared for the patient's record. When a less than complete examination is performed for the purpose of evaluation of one specific cardiac problem, or region of the heart, the service performed is described by codes 93304, 93308 and 93321, follow-up or limited studies. When a limited service is performed, or the patient's condition requires only a limited examination, these codes must be used to indicate the appropriate service.
Examples of appropriate use of 93308: a follow-up study of a patient with pericardial effusion following heart surgery, to evaluate progression or resolution of the effusion; or a serial evaluation of left ventricular function during antineoplastic chemotherapy.

Examples of appropriate use of 93321: recording tricuspid regurgitant velocity in order to estimate pulmonary artery systolic pressure; or sequential evaluation of the transmitral velocity profile in a patient with mitral stenosis, in order to evaluate for a change in gradient or valve area.

C. Doppler Color Flow Velocity Mapping

INDICATIONS AND LIMITATIONS
Spectral Doppler echocardiography and Doppler color flow-velocity mapping (93320, 93321, 93325) may be necessary in addition to an echocardiogram when the examination could contribute significant information to the patient's condition or treatment plan (For Dates of service on or after 01/01/2009, code 93306 should be used when Doppler is combined with a complete echocardiogram). Typically, Doppler is indicated in the evaluation of some heart murmurs, valvular problems, shunts, suspected congenital heart disease, complications of myocardial infarction, or cardiomyopathy. Doppler should be medically necessary for the evaluation and management of the patient.

"Color/spectral Doppler may not be useful or appropriate in certain relatively small and well-defined patient populations when there is a recent comprehensive examination and the test is being ordered for re-evaluation of a limited problem." (ASE comment).

The use of the Doppler is inherent in the ultrasonic cardiac evaluation. However, if the test reports fail to document the use of this technique to assess these structures and function (e.g., measurement of valvular insufficiency or stenosis, myocardial diastolic function, etc. as described by the ASE), or if the medical records fail to document that the examination was "clinically necessary" (e.g., follow-up of pericardial effusion size) then the Doppler portion of the test may be considered medically unnecessary and denied.

D. Limited Capability Ultrasound Scanners

INDICATIONS AND LIMITATIONS

Some small scanners have more limited capabilities and lack either the permanent recording capabilities or some of the functional capabilities needed to perform a complete examination. Such a study may be quite useful as an extension of the physical examination. However, an examination that does not meet the standards required for a complete diagnostic echocardiographic examination – whether performed with a "conventional" scanner or a limited capability ultrasound scanner - will not be recognized as a valid echocardiographic service and will be non-covered.
E. Stress Echocardiography

Stress Echocardiography may be necessary when the evaluation could contribute significant information to the patient's condition or treatment plan. A nonimaging stress test focuses on the hemodynamic and electrocardiographic responses to stress. To enhance the diagnostic specificity, the stress test may be combined with echocardiographic imaging or scintigraphic imaging. A contrast agent may be used with echocardiographic imaging to enhance endocardial visualization and diagnostic accuracy. When two (or more) imaging studies (e.g., ultrasound and scintigraphy) are billed without a supporting clinical indication for each, one of the services will be denied as not medically necessary. This section addresses the echocardiographic imaging that is done in association with a stress test.

INDICATIONS

Stress echocardiography may be indicated in the care of patients with real or suspected ischemic heart disease in the following clinical settings:

1) To detect coronary artery disease in patients presenting with chest pains including atypical chest pains and exertional dyspnea when the suspicion of CAD is high.
2) To assess prognosis and functional capacity in patients following an acute myocardial infarction.
3) To evaluate the extent of exercise induced ischemia in patients who have had a revascularization procedure (PCTA, stent or coronary bypass) or patients who have known CAD disease.
4) In women, stress imaging has been recommended as the "initial test."
5) To evaluate a prior nondiagnostic or abnormal ECG exercise test as a substitute for a nuclear perfusion study.
6) To evaluate patients who are at high risk for myocardial infarction prior to a scheduled major surgical procedure (e.g., aneurysm, vascular surgery, surgeries with large volume shifts, etc) or transplant procedure.
7) To evaluate patients presenting with various arrhythmias (atrial and/or ventricular) or syncope (near or pre), when the suspicion of occult coronary artery disease is high.
8) To evaluate patients when an indicated standard exercise ECG is likely to be non-diagnostic, including patients with an abnormal resting ECG, orthostatic or hyperventilation induced ECG changes, non specific ST-T abnormalities due to ventricular hypertrophy drugs or associated intraventricular conduction defect.
9) To assess myocardial viability (hibernating myocardium) for planned revascularization or functional significance of coronary lesions (if not already known) in planning percutaneous transluminal coronary angioplasty.
10) To evaluate cardiomyopathy when the evaluation could reasonably be expected to contribute significant information regarding the patient's condition or treatment plan.
11) To evaluate ventricular dysfunction due to post-transplant rejection when the evaluation could reasonably be expected to contribute significant information regarding the patient's condition or treatment plan.
12) To evaluate congenital heart disease, when stress echocardiography helps to determine systemic and right ventricular function at rest and following stress and the presence of any other structural abnormalities, including valvular lesions that may be accentuated with stress.

13) Additionally, the test may be combined with Doppler intervention to evaluate exercise hemodynamics in patients with mitral stenosis, mitral regurgitation, pulmonary hypertension, aortic stenosis/regurgitation, prosthetic valves and other conditions where symptoms suggest a more severe impairment than the assessment done at rest.

14) Dobutamine stress echo may be indicated to detect low gradient, low output (aortic stenosis) or clinically silent transplant coronary disease.

**Limitations**

1) Stress echocardiography used as a screening test for ischemic heart disease in a patient without signs or symptoms is not covered.

2) "An echocardiographic study is not indicated when the pathology and/or systolic ventricular function have been adequately defined by other techniques, making the echocardiographic study redundant." (ACC/AHA/ASE 2003 Guideline Update, pg. 5) Since echocardiography, nuclear testing, magnetic resonance imaging (MRI), and positron emission tomography can yield overlapping if not identical information, often with similar or comparable accuracy, when two or more of these tests provide equivalent information, one (but not both/all) will be covered when medically necessary. Stress tests by multiple modalities (e.g. stress echocardiography, nuclear SPECT) for the same clinical event are covered only if the preceding test was inconclusive or uninterpretable.

3) Studies with or without contrast will be considered a single study, whether performed on the same or subsequent days.

4) Contrast echocardiography is not covered when used to evaluate perfusion. Contrast is not indicated unless more than two (2) contiguous segments of the left ventricular border are not visualized.

5) A stress test must be ordered by a physician or qualified non-physician provider.

6) The resting 12 lead EKG and rhythm strip are considered to be part of the stress test. These services are not separately reimbursable.

7) The initiation of an intravenous line and infusion of a pharmacological agent are considered to be a part of the test, and are not separately reimbursable. Stress testing should be conducted by well-trained personnel. Only technicians and physicians familiar with normal and abnormal responses during exercise are trained to recognize or prevent untoward events. Equipment, medications, and personnel trained to provide cardiopulmonary resuscitation (CPR) must be readily available.

F. 3-Dimensional Echocardiography

**Indications and Limitations**

New techniques for the 3-dimensional echocardiography have been reported. Initially these reports are mostly related to mitral valve dysfunction (stenosis and prolapse) and
measurement of left ventricular volumes. Three-dimensional echocardiography appears to be of clinical value in the pre-operative planning of mitral valve repair for prolapse, and the accurate calculation of mitral valve area. Although it provides improved calculation of volumetric studies when compared to 2D echocardiography, when compared to cardiac MRI, its value in affecting clinical outcomes is not yet proven. When performed in conjunction with transthoracic echocardiography (93303, 93304, 93306, 93307, 93308) it is indicated only for pre-operative planning in those patients in whom surgery is already planned and for monitoring the mitral valve area in patients with moderate to severe mitral stenosis.

G. Training Requirements

While it is not the Contractor's intention or jurisdiction to credential providers, Medicare does expect a satisfactory level of competence from providers who submit claims for services rendered. It is well known that substandard studies often lead to preventable repetition of studies and overutilization of services.

The acceptable levels of competence are outlined as follows:

For the technical portion, an acceptable level of competence is fulfilled when the image acquisition is obtained under any one of the following conditions:

1. The service is performed by a physician; or

2. The technical service is performed by an individual who is credentialed as either a Registered Diagnostic Cardiac Sonographer (RDCS) through the American Registry of Diagnostic Medical Sonographers or as a Registered Cardiac Sonographer (RCS) through the Cardiovascular Credentialing International; or

3. The service is performed at a laboratory (e.g. office, IDTF), credentialed by the Intersocietal Commission for the Accreditation of Echocardiography Laboratories (ICAEL). Any non-physician personnel used by an IDTF to perform tests must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met.

For the professional portion, an acceptable level of competence is fulfilled when the interpretation is performed by a physician meeting any one of the following requirements:

4. The physician is board certified in Cardiovascular Diseases; or

5. The physician has Level II training in transthoracic echocardiography, as defined by the American College of Cardiology/American Heart Association/American College of
Physicians Task Force on Clinical Competence in Echocardiography, or the equivalent of Level II training as set forth in that document.

For Facilities, quality requirements should encompass approved ACC/AHA/ASE training standards for physicians, accreditation by ICAEL for facilities, and certification of cardiac sonographers by recognized national credentialing organizations as the appropriate quality standards. The submission of claims for echocardiography will be considered an attestation that both the technical and professional components of the service were provided within the context of the above stated credentials.

CGS providers submitting claims for these services will be allowed a 2-year grace period (until 07/01/2011) to meet these standards.

Other Comments:

For claims submitted to the Part A MAC: this coverage determination also applies within states outside the primary geographic jurisdiction with facilities that have nominated CGS Administrators, LLC to process their claims.

Bill type codes only apply to providers who bill these services to the Part A MAC. Bill type codes do not apply to physicians, other professionals and suppliers who bill these services to the carrier or Part B MAC.

Limitation of liability and refund requirements apply when denials are likely, whether based on medical necessity or other coverage reasons. The provider/supplier must notify the beneficiary in writing, prior to rendering the service, if the provider/supplier is aware that the test, item or procedure may not be covered by Medicare. The limitation of liability and refund requirements do not apply when the test, item or procedure is statutorily excluded, has no Medicare benefit category or is rendered for screening purposes.

For dates of service prior to April 1, 2010, FQHC services should be reported with bill type 73X. For dates of service on or after April 1, 2010, bill type 77X should be used to report FQHC services.

For outpatient settings other than CORFs, references to "physicians" throughout this policy include non-physicians, such as nurse practitioners, clinical nurse specialists and physician assistants. Such non-physician practitioners, with certain exceptions, may certify, order and establish the plan of care as authorized by State law. (See Sections 1861[a][2] and 1862[a][14] of Title XVIII of the Social Security Act; 42 CFR, Sections 410.74, 410.75, 410.76 and 419.22; 58 FR 18543, April 7, 2000.)
Coding Information

Bill Type Codes:
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

011x Hospital Inpatient (Including Medicare Part A)
012x Hospital Inpatient (Medicare Part B only)
013x Hospital Outpatient
021x Skilled Nursing - Inpatient (Including Medicare Part A)
022x Skilled Nursing - Inpatient (Medicare Part B only)
023x Skilled Nursing - Outpatient
071x Clinic - Rural Health
073x Clinic - Freestanding
077x Clinic - Federally Qualified Health Center (FQHC)
085x Critical Access Hospital

Revenue Codes:
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

Revenue codes only apply to providers who bill these services to the Part A MAC. Revenue codes do not apply to physicians, other professionals and suppliers who bill these services to the carrier or Part B MAC.

Please note that not all revenue codes apply to every type of bill code. Providers are encouraged to refer to the FISS revenue code file for allowable bill types. Similarly, not all revenue codes apply to each CPT/HCPCS code. Providers are encouraged to refer to the FISS HCPCS file for allowable revenue codes.

All revenue codes billed on the inpatient claim for the dates of service in question may be subject to review.

0480 Cardiology - General Classification
0483 Cardiology - Echocardiology
0521 Free-Standing Clinic - Clinic Visit by Member to RHC/FQHC
0522 Free-Standing Clinic - Home Visit by RHC/FQHC Practitioner
0524 Free-Standing Clinic - Visit by RHC/FQHC Practitioner to a Member in a Covered Part A Stay at SNF
0525 Free-Standing Clinic - Visit by RHC/FQHC Practitioner to a Member in a SNF (not in a Covered Part A Stay) or NF or ICF MR or Other Residential Facility
0527 Free-Standing Clinic - Visiting Nurse Service(s) to a Member's Home when in a Home Health Shortage Area
CPT/HCPCS Codes

For dates of service on/after 1/1/2009, J2785 should be used to report regadenoson for Part A and Part B.

J3490 (Part B) should be used to report the stress agent, regadenoson for dates of services prior to 1/1/2009.

C9244 (Part A) should be used to report the stress agent, regadenoson for dates of services from 10/01/2008 through 12/31/2008. Prior to 10/01/2008, C9399 is used to report regadenoson for Part A.

Group 1 Codes:

- **76376**
  3D RENDERING WITH INTERPRETATION AND REPORTING OF COMPUTED TOMOGRAPHY, MAGNETIC RESONANCE IMAGING, ULTRASOUND, OR OTHER TOMOGRAPHIC MODALITY WITH IMAGE POSTPROCESSING UNDER CONCURRENT SUPERVISION; NOT REQUIRING IMAGE POSTPROCESSING ON AN INDEPENDENT WORKSTATION

- **76377**
  3D RENDERING WITH INTERPRETATION AND REPORTING OF COMPUTED TOMOGRAPHY, MAGNETIC RESONANCE IMAGING, ULTRASOUND, OR OTHER TOMOGRAPHIC MODALITY WITH IMAGE POSTPROCESSING UNDER CONCURRENT SUPERVISION; REQUIRING IMAGE POSTPROCESSING ON AN INDEPENDENT WORKSTATION

- **93303**
  TRANSTHORACIC ECHOCARDIOGRAPHY FOR CONGENITAL CARDIAC ANOMALIES: COMPLETE

- **93304**
  TRANSTHORACIC ECHOCARDIOGRAPHY FOR CONGENITAL CARDIAC ANOMALIES: FOLLOW-UP OR LIMITED STUDY

- **93306**
  WHEN PERFORMED, COMPLETE, WITH SPECTRAL DOPPLER ECHOCARDIOGRAPHY, AND WITH COLOR FLOW DOPPLER ECHOCARDIOGRAPHY

- **93307**
  ECHOCARDIOGRAPHY, TRANSTHORACIC, REAL-TIME WITH IMAGE DOCUMENTATION (2D), INCLUDES M-MODE RECORDING,
WHEN PERFORMED, COMPLETE, WITHOUT SPECTRAL OR COLOR DOPPLER ECHOCARDIOGRAPHY
ECHOCARDIOGRAPHY, TRANSTHORACIC, REAL-TIME WITH IMAGE DOCUMENTATION (2D), INCLUDES M-MODE RECORDING, WHEN PERFORMED, FOLLOW-UP OR LIMITED STUDY
DOPPLER ECHOCARDIOGRAPHY, PULSED WAVE AND/OR CONTINUOUS WAVE WITH SPECTRAL DISPLAY (LIST SEPARATELY IN ADDITION TO CODES FOR ECHOCARDIOGRAPHIC IMAGING): COMPLETE
DOPPLER ECHOCARDIOGRAPHY, PULSED WAVE AND/OR CONTINUOUS WAVE WITH SPECTRAL DISPLAY (LIST SEPARATELY IN ADDITION TO CODES FOR ECHOCARDIOGRAPHIC IMAGING)
DOPPLER ECHOCARDIOGRAPHY COLOR FLOW VELOCITY MAPPING (LIST SEPARATELY IN ADDITION TO CODES FOR ECHOCARDIOGRAPHY)
ECHOCARDIOGRAPHY, TRANSTHORACIC, REAL-TIME WITH IMAGE DOCUMENTATION (2D), INCLUDES M-MODE RECORDING, WHEN PERFORMED, DURING REST AND CARDIOVASCULAR STRESS TEST USING TREADMILL, BICYCLE EXERCISE AND/OR PHARMACOLOGICALLY INDUCED STRESS, WITH INTERPRETATION AND REPORT:
ECHOCARDIOGRAPHY, TRANSTHORACIC, REAL-TIME WITH IMAGE DOCUMENTATION (2D), INCLUDES M-MODE RECORDING, WHEN PERFORMED, DURING REST AND CARDIOVASCULAR STRESS TEST USING TREADMILL, BICYCLE EXERCISE AND/OR PHARMACOLOGICALLY INDUCED STRESS, WITH INTERPRETATION AND REPORT: INCLUDING PERFORMANCE OF CONTINUOUS ELECTROCARDIOGRAPHIC MONITORING, WITH SUPERVISION BY A PHYSICIAN OR OTHER QUALIFIED HEALTH CARE PROFESSIONAL
USE OF ECHOCARDIOGRAPHIC CONTRAST AGENT DURING STRESS ECHOCARDIOGRAPHY (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
SUPPLY OF INJECTABLE CONTRAST MATERIAL FOR USE IN ECHOCARDIOGRAPHY, PER STUDY
TRANSTHORACIC ECHOCARDIOGRAPHY WITH CONTRAST, OR WITHOUT CONTRAST FOLLOWED BY WITH CONTRAST, FOR CONGENITAL CARDIAC ANOMALIES: COMPLETE
TRANSTHORACIC ECHOCARDIOGRAPHY WITH CONTRAST, OR WITHOUT CONTRAST FOLLOWED BY WITH CONTRAST, FOR CONGENITAL CARDIAC ANOMALIES: FOLLOW-UP OR LIMITED STUDY
TRANSTHORACIC ECHOCARDIOGRAPHY WITH CONTRAST, OR WITHOUT CONTRAST FOLLOWED BY WITH CONTRAST, REAL-TIM
TIME WITH IMAGE DOCUMENTATION (2D), INCLUDES M-MODE RECORDING, WHEN PERFORMED, COMPLETE, WITHOUT SPECTRAL OR COLOR DOPPLER ECHOCARDIOGRAPHY

TRANSTHORACIC ECHOCARDIOGRAPHY WITH CONTRAST, OR WITHOUT CONTRAST FOLLOWED BY WITH CONTRAST, REAL-TIME WITH IMAGE DOCUMENTATION (2D), INCLUDES M-MODE RECORDING, WHEN PERFORMED, FOLLOW-UP OR LIMITED STUDY

TRANSTHORACIC ECHOCARDIOGRAPHY WITH CONTRAST, OR WITHOUT CONTRAST FOLLOWED BY WITH CONTRAST, REAL-TIME WITH IMAGE DOCUMENTATION (2D), INCLUDES M-MODE RECORDING, WHEN PERFORMED, DURING REST AND CARDIOVASCULAR STRESS TEST USING TREADMILL, BICYCLE EXERCISE AND/OR PHARMACOLOGICALLY INDUCED STRESS, WITH INTERPRETATION AND REPORT

TRANSTHORACIC ECHOCARDIOGRAPHY WITH CONTRAST, OR WITHOUT CONTRAST FOLLOWED BY WITH CONTRAST, REAL-TIME WITH IMAGE DOCUMENTATION (2D), INCLUDES M-MODE RECORDING, WHEN PERFORMED, COMPLETE, WITH SPECTRAL DOPPLER ECHOCARDIOGRAPHY, AND WITH COLOR FLOW DOPPLER ECHOCARDIOGRAPHY

TRANSTHORACIC ECHOCARDIOGRAPHY, WITH CONTRAST, OR WITHOUT CONTRAST FOLLOWED BY WITH CONTRAST, REAL-TIME WITH IMAGE DOCUMENTATION (2D), INCLUDES M-MODE RECORDING, WHEN PERFORMED, DURING REST AND CARDIOVASCULAR STRESS TEST USING TREADMILL, BICYCLE EXERCISE AND/OR PHARMACOLOGICALLY INDUCED STRESS, WITH INTERPRETATION AND REPORT: INCLUDING PERFORMANCE OF CONTINUOUS ELECTROCARDIOGRAPHIC MONITORING, WITH PHYSICIAN SUPERVISION

INJECTION, PERFLEXANE LIPID MICROSPHERES, PER ML
INJECTION, OCTAFLUOROPROPANE MICROSPHERES, PER ML
INJECTION, PERFLUTREN LIPID MICROSPHERES, PER ML

Group 2 Paragraph: Applicable to 93350, 93351, 93352
HCPCS code J0460 is deleted and replaced by code J0461, effective 01/01/2010.HCPCS J0152 is deleted and replaced with J0151 effective 01/01/2014.

Group 2 Codes:

UNCLASSIFIED DRUGS OR BIOLOGICALS
INJECTION, ADENOSINE, 1 MG (NOT TO BE USED TO REPORT ANY ADENOSINE PHOSPHATE COMPOUNDS)
INJECTION, AMINOPHYLLIN, UP TO 250 MG
INJECTION, ATROPINE SULFATE, 0.01 MG
INJECTION, DIPYRIDAMOLE, PER 10 MG
INJECTION, DOBUTAMINE HYDROCHLORIDE, PER 250 MG
Please refer to the CMS website for the ICD-10 Codes that Support Medical Necessity

Associated Information

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (See "Indications and Limitations of Coverage.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures, as well as reasons for repeat testing.

Each service requires a formal written report with interpretation. This report should be kept on file with copies of image documentation (paper or tape) for review if requested. All appropriate measurements should be included in the report.

At a minimum, a complete study should contain M mode and/or 2D measurements of LV end diastolic diameter, LV end systolic diameter, LV wall thickness, left atrial diameter, aortic valve excursion and a qualitative description of the LV function, whenever possible given any technical limitations in a particular case. Individual echocardiographic laboratories (providers) may choose valid substitutes for these parameters such as LV volumes, ejection fraction and mass measurements.

A Doppler interrogation should state the modes used and should give both qualitative and quantitative information.

Claims for contrast echocardiography services must be supported by documentation that conventional studies were inconclusive and there was a need for the contrast enhancement.

The medical record should clearly document the reasons for performing multiple tests, as well as prior data which has been reviewed. If specific prior test results were requested and not received, necessitating repeat or additional testing, then this should also be noted in the records.

In the case of disease processes that could preclude the performance of exercise stress testing, the medical documentation should clearly describe why the patient cannot perform exercise stress testing. The documentation must include (but is not limited to) history and physical exam findings demonstrating that the patient could not reasonably be expected to perform exercise stress testing.

Documentation of the qualifications of personnel performing tests, as described in the Indications section of the LCD, should be available on request.

In those instances in which repeat tests were denied, the physician must document a good
faith effort was made to identify them and to request copies of them from previous providers, in order for CGS to consider reimbursement for such tests on appeal.

Documentation must be available to Medicare upon request.

Not applicable

Repeat echocardiographic studies should be guided by the clinical status of the patient. The frequency of services is guided by the circumstances outlined in the Indications and Limitations section of this policy. Repeat studies are appropriate to monitor changes in cardiac structure or function when there are changes in the clinical status of the patient, or when disease progression is otherwise suspected.

Services performed in the Emergency Room and other emergency services are excluded from any frequency limitations on coverage for repeat testing. While Emergency Room services would be identified on the claim by the place of service code (23), emergency services provided at other sites would require post-pay review of the documentation provided in the medical record.

In those instances in which repeat tests were denied and a physician has documented a good faith effort to identify them and to request copies of them from previous providers, then CGS could reimburse such tests on appeal.

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