

Comments and Responses Regarding Draft Local Coverage Determination: Transesophageal Echocardiography (TEE)

As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Transesophageal Echocardiography LCD. The official notice period for the final LCD begins on April 15, 2009, and the final determination will become effective on July 1, 2009.

Comment:

The following comments were received from the American Society of Echocardiography. Many providers submitted identical comments in part or in total.

1. *"While ASE supports several provisions of the Draft TEE LCD, we are extremely concerned about a number of aspects of this document. For example, TTE cannot be done during cardiac surgery and thus the indications for TEE for diagnostic purposes in the operating room before and after open heart surgery are more extensive than those listed. Approved indications should include, but not be limited to, patients with heart failure and valvular dysfunction. "*
2. *"Missing from the indications are indications:*
 - *Using TEE to assess etiology of mitral regurgitation;*
 - *Using TEE to assist in the decision of mitral valve repair vs. replacement;*
 - *Using TEE to assess the size of the aortic root in the setting of aortic stenosis or aortic regurgitation, which may be necessary to determine if aortic root needs to be replaced in addition to aortic valve.*
 - *Under "critically ill," the LCD should specifically spell out that this includes patients who exhibit hemodynamic instability after heart and vascular surgery.*
 - *TEE has value in assessing function of circulatory support devices such as LVAD and percutaneous assist devices in advanced heart failure and in determining the response to weaning from devices.*
 - *TEE has value in the assessment of the young patient with stroke in addition to the specific items listed such as intracardiac clot. Specifically, this includes valve tumors.*

3. *“Second, we have a number of concerns about the section of the Draft TEE LCD related to 3D echo. For example, the section on 3D echo should include complex congenital heart disease on the list of indications, as 3D helps clarify the spatial relationships of lesions within the heart.*

“In addition, while the Draft TEE LCD indicates that 3-D echo has not shown clinical value in comparison with cardiac MRI, in fact, a recent study indicates that 3-D echo measurements are comparable to those by MRI. Jenkins et al, European Heart J 2009; 30:98-106.

4. *“Third, while we applaud the decision to include Training Requirements in the Draft TEE LCD, we would suggest the following changes:*

- In the section on technical component training requirements, please note that TEE cannot be performed by a sonographer. This bullet should be removed. The physician should be required to meet training requirements (Level II and 25 esophageal intubations) listed in the ACC\AHA Clinical Competence Statement on Echocardiography. J Am Coll Cardiology 2003; 41:687-708.*
- In the section on professional component training requirements, we would suggest that the language of the second bullet (Level II training) be clarified to make it clear that Level II training requirements must be met for both performance and interpretation.*

5. *“Finally we strongly believe that the utilization limits should be removed from the draft LCD. We do not believe that diagnostic TEE is a substantial source of frequent repeat testing. Moreover, the draft LCD does not address the crucial question of how a physician (or hospital or other provider) is to know whether or not two TEEs were conducted within the prior year through a different provider or hospital, since patients are often unreliable sources of this type of information. In the absence of an established process for determining the nature and results of prior diagnostic testing, it is quite likely that, if the Draft TEE LCD is adopted without modifications, physicians who perform TEEs will routinely provide Medicare patients with Advance beneficiary Notification (ABN) to enable physicians to recover the costs of providing the service in the event that the patient had two TEEs within the prior year.*

“Also, there are situations where more than two TEEs in a one year period would be necessary. For example, a patient with mitral valve prolapse and new shortness of breath will need an initial TEE to determine if the valve can be repaired, and then a second TEE will be performed in the operating room to determine if the repair was adequate. In the post-operative period if the patient exhibits hemodynamic instability, a third TEE will be required to insure there is no pericardial hematoma or that the repair has been disrupted. There is also the chance that this patient might develop fevers and bacteremia in the ensuing year and would need a TEE to assess for endocarditis.

“At a minimum, the coverage limit of two TEEs/year should be modified so that it applies to a specific indication only. For example, in the patient above, the third TEE is medically appropriate for endocarditis (a different indication than the first two TEEs performed for mitral regurgitation). Please note, too, that endocarditis with complications, such as fistula or abscess in some situations will require more than four TEEs in a year.”

Response:

We appreciate the effort performed by the ASE in developing this response to this draft LCD. We note that multiple earlier versions of this LCD did not generate such a response, and consequently there are issues addressed herein that although present in previous versions have not been addressed before.

1. We agree that TTE is not available intraoperatively for cardiac surgery patients. The LCD specifically states that it is indicated for:
 - Intraoperative evaluation to assess prosthetic or repaired/reconstructed valve function, or the integrity/function of complex congenital heart repairs;
 - Only TEE done for specific *diagnostic* purposes may be separately payable during intraoperative use (TEE used for monitoring purposes is not separately payable).

As a specific diagnostic test, and when clinically indicated intraoperative TEE may be necessary to assess the presence and/or severity of outflow tract obstruction or the presence/repair of an intracardiac shunt. It is unclear that TEE, as a diagnostic test to assess wall motion abnormalities is superior to the direct observation of the heart in a patient with an open chest. However, once the chest has been closed, the TEE may then be needed to assess wall motion abnormalities in the case of acute deterioration in the patient's status. The results of the test should be needed and used in making the management decisions on the patient's intraoperative treatment. The TEE must be specifically diagnostic and not just intraoperative monitoring which is included in the anesthesia care. We will revise the LCD to reflect these additional indications.

2. The draft LCD includes in the abstract section of this policy, the statement, *Transesophageal echocardiography (TEE) is performed by placing the ultrasound transducer in the esophagus achieving closer proximity to the anatomical structures of the heart, and improved image quality. This is particularly useful for posterior structures, such as the pulmonary veins, left atrium, and mitral valve. It also provides better visualization of the aortic root, valve and the ascending and descending aorta and arch.* We regret that this same information was inadvertently left out of the indications section of the LCD. We agree that TEE may be of great value in those instances when TTE does not provide sufficient information with which to make management decisions, especially in patients with mitral valve disease, left atrial abnormalities, and aortic root disease. We agree that TEE may be indicated in the assessment of mitral regurgitation and in the pre-operative planning for mitral surgery, but would only be indicated in those cases of aortic disease for which the TTE was inadequate for this assessment. We believe that the LCD already includes indications for TEE for identification of suspected cardiac masses, thrombi and aortic ulceration, atherosclerotic plaque and mural thrombotic material, and vegetations implicated in possible etiologies of stroke. We find that there is no reason not to enumerate valve tumors separately from other cardiac tumors. We will revise the LCD to reflect these additional indications.

We respectfully disagree with the ASE's comments regarding the use of TEE to assess hemodynamic instability after cardiac and vascular surgery. This is a rather broad category for which they do not identify the specific causes of such instability. TEE would be indicated for assessment of those conditions which might result in instability, and for which examination by TTE is inadequate. We believe that the LCD already supports these indications.

The recommendation that TEE be used to assess function of circulatory support devices such as LVAD and percutaneous assist devices in advanced heart failure and in determining the response to weaning from devices, was not supported by additional explanation or copies of articles from the literature. We believe that such use represents monitoring, rather than diagnostic testing, and is otherwise performed by other means. The use of TEE to evaluate specific myocardial function, valve dysfunction or shunt flow are already included among indications for TEE when TTE does not provide sufficient information and need not be redefined here. The use of transesophageal Doppler for the determination of cardiac output in such patients is a separate service that is already covered under an NCD (220.5), and is not included in this LCD.

3. The use of 3 dimensional echocardiography is an evolving technique. We have already included as covered indications its use for pre-operative planning for mitral valve and atrial septal defect surgery, as well as for interventional cardiac procedures such as transcatheter treatment of atrial shunts and paravalvular leaks, and intraoperative atrial ablations. We have reviewed the Jenkins article (January 2009) on left ventricular volume measurement, and note that in this small study limited to patients with past myocardial infarction it reports 3-D echo imaging measurements consistent with results obtained by MRI. However, the additive effect on patient outcomes, of the added accuracy above obtained by conventional methods is not documented. While the technique may provide more detailed images, it is unclear whether in doing so there is increased benefit to the patient; and whether its routine use to determine ventricular volumes is needed in all patient groups. We believe that further identification of those patients likely to benefit from its use is needed. In an editorial originally published in JACC (48:2152-2155; 2006), Dr. Pamela Douglas stated, "The evidence base supporting the clinical use or benefit of an imaging procedure is limited and problematic....At the core of the problem is the difficulty in connecting performance of an imaging test to a health-related outcome.... Creation of a robust body of clinical evidence regarding the value of imaging is long overdue. It is a necessary foundation for any quality improvement process, which can no longer be based on the educated guesses that inform our current consensus model." [quoted in NEJM 3/5/2009; 360 (10): 1030-1037].

4. We appreciate the ASE's recognition of this contractor's attempt to cover only quality testing.

The performance of a TEE is a physician service. However, while the physician performs the placement and manipulation of the probe accompanied by online interpretation, technician participation is included in the recording and acquisition of the images. The AMA RUC Direct Practice Expense Inputs for 2008 does include 49 minutes of sonographer (technician) time. The technician competency requirement is only to address these limited functions that have been identified in the technical component of the service.

We agree with the ASE's position that only those tests performed by physicians properly trained in the performance and interpretation of TEE should be reimbursed. The ACCF Training Statement Task statement on echocardiography (JACC 2008: 51: 361-367) specifies that Level II training is required for TEE, and indicates that practicing physicians should still be required to obtain equivalent training, usually in a mentoring relationship, and that the number of cases necessary to

achieve level II training would be the same as in a fellowship training program. We will revise the LCD accordingly.

5. We agree that frequency parameters may be problematic when applied across an entire spectrum of patients. However, the contractor is charged with the responsibility of ensuring that only services that are reasonable and necessary are reimbursed. Part of that process is the creation of frequency parameters which reflect the general use in the community. Claims data indicates that approximately 83% of TEEs are performed in a inpatient hospital stay. It is noteworthy that the ASE examples reflect hospital-based situations, and the LCD already specifically excludes TEEs performed during an in-patient hospital stay from these frequency edits. We will revise the utilization section to reflect that tests for which there is documentation that the tests were performed for clinical indications reflecting a change in the patients status or underlying cardiac condition, or due to a new unrelated condition/sign or symptom would be considered for reimbursement.

Comment:

Several providers submitted comments similar to those below:

1. "Under the draft LCD echocardiographic examinations ordered for high risk patients would be considered screening, regardless of the results of the study. This is a departure from the rules used for other diagnostic testing. Many times a test is ordered for one reason and an unexpected result is found that will greatly affect the patients care or prognosis. The purpose of a test is to obtain information that is not available to us prior to performing the test. It is generally allowed with all other diagnostic tests to code for a result of the test regardless of why the test was originally ordered.
2. The draft LCD will also preclude the ordering of Doppler studies unless specifically ordered for a particular indication. The failure to routinely allow for Doppler studies with echocardiography could result in potential misdiagnosis and cause harm to patients. For example a patient has a myocardial infarction and has an echocardiogram and because the Doppler is not covered the patient is not diagnosed with significant mitral regurgitation or a possible VSD is missed. This change in the draft LCD reflects a substantial change in the CMS considering Doppler studies to be an integral part of the echocardiographic examination and thus the "bundling" of Doppler studies in TTE and TEE.
3. The draft LCD also indicates that routine re-examination of common cardiac conditions are not covered. This is something that should follow the appropriateness guidelines set up by the ACC/ASE. The guidelines indicate that reexamination is appropriate if there is a change in clinical circumstances. It is unclear as to how the draft LCD will affect this. Even more important is how does a physician (or hospital) know whether or not a study was conducted within the last year since patients are not reliable sources of this type of information. This does not address problems that may arise where information is emergently needed and the results of a prior study are not available to the current treating physician or hospital. I truly believe that TTE and TEE with Doppler studies

are an integral part of patient evaluation and limiting services as proposed in the draft LCD may seriously harm patients by preventing them from having access to important diagnostic testing. This also may increase the cost of the patient's care by delaying appropriate treatment."

Response:

1. We respectfully disagree with the commenters' interpretation of screening tests. A screening test is one that is performed without signs or symptoms of disease. With the specific exceptions noted in Title XVIII, screening services are not covered or reimbursable under Medicare (see Social Security Act Title XVIII Section 1862(a)(7)). While the test may be diagnosis-coded based on the results, it does not change the reason why the test was performed which is the basis for the coverage.
2. The use of Doppler provides information that is used to identify abnormal flow characteristics related to native and prosthetic valve function and dysfunction, shunts, congenital defects, pulmonary vascular disease and cardiac hemodynamics. We agree with the commenters that Doppler has become an essential and major part of cardiac ultrasound, and for which there do exist many indications. This LCD does not preclude the use of Doppler when ultrasonically examining the heart, but specifically includes it, indicating that it is covered when there is a *clinical indication*. Some commenters have made a point that the new CPT codes even bundle the Doppler into a single code with the transthoracic study (CPT 93306). We also note that CPT has retained the transthoracic test without the Doppler and color-flow components which may not always be needed or performed. NGS claims history indicates a very high concordance for performance of the echocardiogram and these add-on codes, for which all are generally reimbursed. We agree that there is a very frequent indication for Doppler and color flow to accompany the transthoracic study, and do not envisage that there will be a significant change in this pattern of use based on this LCD. We believe that in those instances in which it is considered integral to the study, based on the anticipated information being sought, Doppler and color-flow would be judged to be medically necessary.

Nonetheless, we agree with the ASE that the purpose of the echocardiogram is to examine the heart so as to determine a complete evaluation of its anatomy and function, recognizing that it may not be possible to dissociate the multiple structures and pathophysiologic responses from the function of these structures and the overall function of the entire organ and patient.

We will revise the LCD to clarify that 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 documentation fails to document that the examination was "clinically necessary" as ASE has indicated (e.g., follow-up of pericardial effusion size) then the Doppler portion of the test may be considered medically unnecessary and denied.

3. We appreciate the commenters' recognition that the draft is consistent with the ACC/ASE Appropriateness Guidelines in identifying those conditions for which repeat examination is and is not indicated. We agree with this commenters that "*re-examination is appropriate if there is a change in*

clinical circumstances.” The utilization guidelines section of the LCD specifically states “Repeat studies are appropriate to monitor changes in cardiac structure or function when there are clinical changes in the status of the patient, or when disease progression is otherwise suspected. “

We agree that the tracking of previous tests by a patient or obtaining copies of records by other providers may be problematic. However, it is also not appropriate that the Medicare Program bear the sole burden of unnecessary repeat testing. It is not anticipated that this would be an issue in patients under the continuous care of a single physician or group, where such information and records should be readily available. Certainly in such instances the physician should be held to this standard. In those instances in which a physician has documented a good faith effort to identify previous tests performed and to request copies of them from previous providers, if repeat tests were denied then NGS could reimburse such tests on appeal.

Comment:

A New York Cardiologist provided us with a copy of the syllabus presentation from a conference on 3-D echocardiography.

Response:

We appreciate the material to help us in the understanding of the applications of this technology.

Comment:

The cardiology representative to the New York State Medical Society Interspecialty Committee had several comments on this LCD. He thought the LCD was reasonable, with the exception of the training requirements. The policy states that the service can be performed by a physician and a technician who is credentialed as either a registered diagnostic sonographer or a registered cardiac sonographer. The registered diagnostic sonographer would be registered through the American Registry of Diagnostic Medical Sonographers and the registered cardiac sonographer would be registered through the Cardiovascular Credentialing International.

Response:

We appreciate the ASE support on the quality requirements. Having staff privileges to interpret echocardiograms at a hospital that participates in the Medicare program is an outdated and insufficient sole criteria for determining quality, and should be deleted. We agree that 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 performance of a TEE is a physician service. However, while the physician performs the placement and manipulation of the probe accompanied by online interpretation, technician participation is included in the recording and acquisition of the images. The AMA RUC Direct Practice Expense Inputs for 2008 does include 49 minutes of sonographer (technician) time. The technician competency requirement is only to address these limited functions that have been identified in the technical component of the service.

Comment:

The cardiology representative to the Indiana CAC stated that he thinks that this is a good policy and that as 3D echo is an evolving technology the policy will have to be updated periodically.

Response:

We appreciate the commenter's review of the LCD and his support. We agree that emerging technologies represent a special problem for coverage and require periodic re-evaluation and updates.

Comment:

An IDTF provider asked that the LCD be clarified in relation to the training requirements for non-physician personnel in an IDTF setting. He would like the LCD to state that requirements in an IDTF are based on individual technician qualifications, and that technicians must be registered in this setting.

Response:

We agree that according to 42 CFR 410.33, non-physician personnel performing tests in an *IDTF 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 absence of a State licensing board, the technician must be certified by an appropriate national credentialing board.*

We will include this information in the final version of the LCD.
