This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

### Populations
Individuals:
- With an indication for a transthoracic echocardiogram

### Interventions
Interventions of interest are:
- Myocardial strain imaging

### Comparators
Comparators of interest are:
- Left ventricular ejection fraction

### Outcomes
Relevant outcomes include:
- Symptoms
- Morbid events
- Quality of life
- Treatment-related mortality
- Treatment-related morbidity

**DESCRIPTION**

Myocardial strain refers to the deformation (shortening, lengthening, or thickening) of the myocardium through the cardiac cycle. Myocardial strain can be measured by tissue Doppler imaging or, more recently, speckle-tracking echocardiography. Speckle-tracking echocardiography uses imaging software to assess the movement of specific markers in the myocardium that are detected in standard echocardiograms. It is proposed that a reduction in myocardial strain may indicate sub-clinical impairment of the heart and can be used to inform treatment before development of symptoms and irreversible myocardial dysfunction.

**SUMMARY OF EVIDENCE**

For individuals who have an indication for a transthoracic echocardiogram who receive myocardial strain imaging (MSI), the evidence includes a systematic review of observational studies. The relevant outcomes include symptoms, morbid events, quality of life, treatment-related mortality, and treatment-related morbidity. A systematic review of 13 studies with 384 patients treated for cancer suggests that MSI with tissue Doppler imaging or speckle-tracking echocardiography may be able to identify changes in myocardial deformation that precede changes in left ventricle ejection fraction. Although MSI may detect sub-clinical myocardial changes, the value of these changes in predicting clinical outcomes or guiding therapy is uncertain. No studies were identified that compared MSI to left ventricle ejection fraction. A study that will compare clinical outcomes when therapy is guided by MSI or left ventricle ejection fraction is in progress, and will provide direct evidence on the clinical utility of MSI. The evidence is insufficient to determine the effects of the technology on health outcomes.
POLICY

Myocardial strain imaging is investigational.

BACKGROUND

The term strain indicates dimensional or deformational change under force. When used in echocardiography, the term ‘strain’ is used to describe the magnitude of shortening, thickening and lengthening of the myocardium through the cardiac cycle. The most frequent measure of myocardial strain is the deformation of the left ventricle (LV) in the long axis, termed global longitudinal strain (GLS). During systole, ventricular myocardial fibers shorten with movement from the base to the apex. GLS is used as a measure of global LV function, and provides a quantitative myocardial deformation analysis of each LV segment. Myocardial strain imaging is intended to detect subclinical changes in left ventricle function in patients with a preserved LV ejection fraction, allowing for early detection of systolic dysfunction. Since strain imaging can identify LV dysfunction earlier than standard methods, this raises the possibility of heart failure prophylaxis and primary prevention before the patient develops symptoms and irreversible myocardial dysfunction.

MYOCARDIAL STRAIN IMAGING

Myocardial strain can be measured by either tissue Doppler imaging or by speckle-tracking echocardiography (STE). Tissue Doppler strain imaging has been in use since the 1990’s but has limitations that include angle dependency and significant noise. Smiseth et al (2016), reported that the most widely used method of measuring myocardial strain at the present time is STE. In STE, natural acoustic markers generated by the interaction between the ultrasound beam and myocardial fibers form interference patterns (speckles). These markers are stable, and STE analyzes the spatial dislocation (tracking) of each point (speckle) on routine 2-dimensional sonograms. Echocardiograms are processed using specific acoustic-tracking software on dedicated workstations, with offline semi-automated analysis of myocardial strain. The 2-dimentional displacement is identified by a search with image processing algorithms for similar patterns across two frames. When tracked frame-to-frame, the spatiotemporal displacement of the speckles provides information about myocardial deformation across the cardiac cycle. GLS provides a quantitative analysis of each LV segment, which is expressed as a percentage. In addition to GLS, STE allows evaluation of LV rotational and torsional dynamics.

REGULATORY STATUS

A number of image analysis systems have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Examples of these are shown in Table 1. For example, the Echolnsoft software system (Epsilon Imaging) “enables the production and visualization of 2D tissue motion measurements (including tissue velocities, strains, strain rates) and cardiac structural measurement information derived from tracking speckle in tissue regions visualized in any Bmode (including harmonic) imagery loops as captured by most commercial ultrasound systems” (K110447). The FDA determined that this device was substantially equivalent to existing devices (e.g., syngo US Workplace, Siemens, K091286) for analysis of ultrasound imaging of the human heart.

Table 1. FDA Clearances

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Manufacturer</th>
<th>510(k) Number</th>
<th>FDA Product Code</th>
<th>Clearance Date</th>
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<td>Myostrain</td>
<td>Myocardial Solutions</td>
<td>K182756</td>
<td>LNH</td>
<td>02/14/2019</td>
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<td>2D CARDIAC PERFORMANCE ANALYSIS</td>
<td>Tomtec</td>
<td>K120135</td>
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<td>Echolnsoft</td>
<td>Epsilon Imaging</td>
<td>K110447</td>
<td>LLZ</td>
<td>05/27/2011</td>
</tr>
</tbody>
</table>
Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


