

DRAFT Medical Coverage Policy | Myocardial Strain Imaging



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OVERVIEW

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 the development of symptoms and irreversible myocardial dysfunction.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Myocardial strain imaging in individuals who have exposure to medications or radiation that could result in cardiotoxicity is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Myocardial strain imaging in all other situations is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

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 in the long axis, termed global longitudinal strain. During systole, ventricular myocardial fibers shorten with movement from the base to the apex. Global longitudinal strain is used as a measure of global left ventricle function and provides a quantitative myocardial deformation analysis of each left ventricle segment. Myocardial strain imaging is intended to detect subclinical changes in left ventricle function in patients with a preserved left ventricle ejection fraction, allowing for early detection of systolic dysfunction. Since strain imaging can identify left ventricle 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. Potential applications of speckle-tracking echocardiography are coronary artery disease, ischemic cardiomyopathy, valvular heart disease, dilated

cardiomyopathy, hypertrophic cardiomyopathies, stress cardiomyopathy, and chemotherapy-related cardiotoxicity.

Myocardial Strain Imaging

Myocardial strain can be measured by cardiac magnetic resonance imaging (MRI), tissue Doppler imaging, or by speckle-tracking echocardiography. Tissue Doppler strain imaging has been in use since the 1990s but has limitations that include angle dependency and significant noise. In 2016, Smiseth et al reported that the most widely used method of measuring myocardial strain is speckle-tracking echocardiography. In speckle-tracking echocardiography, natural acoustic markers generated by the interaction between the ultrasound beam and myocardial fibers form interference patterns (speckles). These markers are stable, and speckle-tracking echocardiography 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 semiautomated analysis of myocardial strain. The 2-dimensional displacement is identified by a search with image processing algorithms for similar patterns across 2 frames. When tracked frame-to-frame, the spatiotemporal displacement of the speckles provides information about myocardial deformation across the cardiac cycle. Global longitudinal strain provides a quantitative analysis of each left ventricle segment, which is expressed as a percentage. In addition to global longitudinal strain, speckle-tracking echocardiography allows evaluation of left ventricle 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 Echolnsight® software system (Epsilon Imaging) "enables the production and visualization of 2-dimensional tissue motion measurements (including tissue velocities, strains, strain rates) and cardiac structural measurement information derived from tracking speckle in tissue regions visualized in any B mode (including harmonic) imagery loops as captured by most commercial ultrasound systems" (K110447). The FDA determined that this device was substantially equivalent to existing devices (eg, syngo® US Workplace, Siemens, K091286) for analysis of ultrasound imaging of the human heart.

For individuals who have exposure to medications or radiation that could result in cardiotoxicity who receive myocardial strain imaging, the evidence includes systematic reviews of observational studies and a randomized controlled trial (RCT). 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 myocardial strain imaging 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. Two recently published observational studies reported conflicting evidence at 6 months post-radiotherapy on whether longitudinal strain reduction was associated with radiotherapy dose. Although myocardial strain imaging may detect sub-clinical myocardial changes, the value of these changes in predicting clinical outcomes or guiding therapy is uncertain. In the Strain Surveillance of Chemotherapy for Improving Cardiovascular Outcomes (SUCCOUR) RCT, left ventricle surveillance with global longitudinal strain was associated with an increased use of cardioprotective therapy and a lower incidence of cancer-therapy-related cardiac dysfunction as compared to left ventricular ejection fraction surveillance. However, no difference in the primary endpoint of final left ventricular ejection fraction at 1-year follow-up was observed between the groups and interpretation of findings was limited by important design and relevance limitations. At 3-year follow-up, despite the increase in the use of cardioprotective therapies in the global longitudinal strain-guided group, there were minimal differences in the change in left ventricular ejection fraction between groups. Additional studies are indicated to better define the threshold for cardioprotective therapy and assess whether a global longitudinal strain-guided approach to cardioprotective therapy reduces the long-term risk of heart failure and improves clinical outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

The following code(s) are considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

- 93356** Myocardial strain imaging using speckle tracking-derived assessment of myocardial mechanics (List separately in addition to codes for echocardiography imaging)
- C9762** Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging
- C9763** Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging

RELATED POLICIES

Not applicable

PUBLISHED

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