

Subject: Myocardial Strain Imaging		Original Effective Date: 9/16/2020
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DISCLAIMER

This Molina clinical policy is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina clinical policy document and provide the directive for all Medicare members.¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Myocardial strain imaging is an echocardiographic imaging test used to detect left ventricular dysfunction. Strain or strain imaging is used in several clinical scenarios in cardiology. The most common uses are in hypertensive heart disease, coronary artery disease, left ventricular (LV) dysfunction caused by valvular heart disease, heart failure, and/or cardiomyopathy. Other uses include rejection in cardiac transplantation, chemotherapy induced cardiotoxicity, hypertrophic cardiomyopathy, cardiac amyloidosis, cardiac sarcoidosis, cardiac dyssynchrony and increased left ventricular wall thickness and mass with cavity dilatation known as athlete's heart.

In echocardiography, the term “strain” is used to describe local shortening, thickening and lengthening of the myocardium as a measure of regional LV function. Strain in the myocardium can be measured by tissue Doppler imaging (TDI) or by 2-D or 3-D speckle tracking imaging (STI) or speckle-tracking echocardiography (STE). Myocardial strain imaging is performed at the same time as doppler echocardiography and measures myocardial contractility and is purported to detect myocardial ischemia. A technique called speckle-tracking is used to view the myocardium, particularly the left ventricle, at various angles during the echocardiographic procedure and 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 in diagnosis, evaluation, prognosis, and treatment of cardiomyopathy and other cardiac diseases as a tool to inform treatment before development of symptoms and irreversible myocardial dysfunction.²⁻⁷

POSITION STATEMENT

Myocardial Strain imaging by tissue Doppler imaging (TDI) or 2-D and 3-D speckle tracking imaging (STI) or speckle-tracking echocardiography (STE) **are considered experimental, investigational and unproven** due to insufficient published evidence to assess the safety and/or impact on health outcomes.

SUMMARY OF MEDICAL EVIDENCE^{2-3,8-21}

At the current time the peer reviewed published evidence includes a systematic review of observational studies, prospective and retrospective comparative studies and prospective controlled and uncontrolled studies. There are no randomized controlled trials that compared myocardial strain imaging (MSI) to left ventricle ejection fraction. There are ongoing clinical trials for MSI in progress including a study that will compare clinical outcomes when therapy is guided by MSI or left ventricle ejection that will provide direct evidence on the clinical utility of MSI.¹¹ At the current time, the evidence is insufficient to determine the effects of MSI on health outcomes for diagnosis, evaluation, prognosis, and treatment of cardiomyopathy, chemotherapy induced cardiotoxicity and other cardiac diseases.

A systematic review by Thavendiranathan et al. (2013) identified 13 peer-reviewed publications, involving approximately 384 patients treated with anthracycline-containing regimens for cancer which assessed various echo-based myocardial deformation parameters to detect early myocardial changes without providing data on prognosis. The review suggests that myocardial strain imaging (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. According to the authors, the role of cardiovascular imaging continues to be studied for the identification and management of cardiotoxicity from cancer chemotherapy. Additional research is needed to determine whether strain-based approaches could be reliably implemented in multiple centers. The ability of strain changes to predict subsequent cardiotoxicity also needs to be examined in larger multicenter studies and in cancers other than breast cancer.

Professional Society Guidelines

The American College of Cardiology, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and the Society of Thoracic

Surgeons published guidance for the appropriate use of criteria for multimodality imaging in the assessment of cardiac structure and function in nonvalvular heart disease. The panel rated the following indications for strain imaging by speckle or tissue doppler as appropriate:

- Initial evaluation prior to exposure to medications/radiation that could result in cardiotoxicity/heart failure;
- Re-evaluation (one year) in a patient previously or currently undergoing therapy with potentially cardiotoxic agents;
- Periodic re-evaluation in a patient undergoing therapy with cardiotoxic agents with worsening symptoms; and
- Evaluation of suspected hypertrophic cardiomyopathy

The criteria did not separate imaging with speckle tracking and tissue doppler, nor were recommendations made related to the comparative effectiveness of these imaging modalities. The panel rated 14 other indications as “may be appropriate”. Interventions in this category should be performed depending on individual clinical patient circumstances and patient and provider preferences, including shared decision making.²²

The **American Society of Clinical Oncology** noted that measurement of strain has been demonstrated to have some diagnostic and prognostic use in patients with cancer receiving cardiotoxic therapies but that there have been no studies demonstrating that early intervention based on changes in strain alone can result in changes in risk and improved outcomes. The Society also notes that screening for asymptomatic cardiac dysfunction using advanced imaging could lead to added distress in cancer survivors.²³

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
93356	Myocardial strain imaging using speckle tracking-derived assessment of myocardial mechanics (List separately in addition to codes for echocardiography imaging)

HCPCS	Description
	N/A

ICD-10	Description
	Any/All

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Government Agency

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Professional Society Guidelines

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*NOTE: Policy reviewed in June 2020 by an Advanced Medical Reviews (AMR) practicing, board-certified physician(s) in the areas of Cardiovascular Disease and Interventional Cardiology.

REVISION/REVIEW HISTORY

9/16/2020	New policy.
8/13/2021	Policy reviewed, no changes, updated references.