Molina Clinical Policy
Myocardial Strain Imaging: Policy No. 371

Last Approval: 8/9/2023
Next Review Due By: August 2024

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Myocardial strain imaging (MSI) 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) and 2-D or 3-D speckle tracking imaging (STI) or speckle-tracking echocardiography (STE). MSI 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 (Hayes 2020)

COVERAGE POLICY

MSI by TDI or 2-D and 3-D STI or STE **are considered experimental, investigational, and unproven** due to insufficient published evidence to assess the safety and/or impact on health outcomes.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

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.

Glikson et al. (2022) completed a prospective randomized controlled trial (RCT) to evaluate the benefit of speckle tracking radial strain imaging (STRSI) guided LV lead positioning in cardiac resynchronization therapy. Randomization occurred at a 2:1 ratio (2 participants randomized to STRSI for every 1 participant randomized to the control group).

The primary endpoint measured for the study was the comparison in the percent reduction in LV end-systolic volume at 6-months post-procedure compared to baseline. The secondary endpoints measured were the number of heart failure-related hospitalizations, deaths, improvement in additional echocardiographic measures, and quality of life during the follow-up period. A total of 172 participants were included in the study with 115 being included in the STRSI guided group and 57 being included in the control group. Implantation occurred in 169 of 172 patients with 9 patients either failing implantation or not being implanted. Of the 9 failing or not receiving implantation, 5 were in the STRSI group and 4 were in the control group. The average number of attempts to reach the final implantation location was higher in the STRSI group (n=1.5±0.84) compared to the control group (n=1.2±0.52). The median percent reduction in LV end-systolic volume was similar in both groups at -17%. The number of clinical events (secondary outcomes) at 6 months was 13% for the STRSI group and 5% for the control group. At 1-year follow-up, the number of clinical events was 22% for the STRSI group compared to 8% for the control group. There were 6 deaths in the STRSI group compared to 2 deaths in the control group. Researchers noted that STRSI does not improve the clinical or echocardiographic response compared to conventional implantation.

Thavendiranathan et al. (2021) completed a prospective multicenter RCT to determine if global longitudinal strain (GLS)-guided cardioprotective therapy prevented a reduction in LV ejection fraction (LVEF) and development of cancer therapy-related cardiac dysfunction (CTRCD) compared to EF-guided. CTRCD in the EF-guided group was considered a symptomatic drop of > 5% or asymptomatic drop of > 10% in LVEF compared to baseline. CTRCD in the GLS-guided group was considered a relative reduction of ≥ 12%. Cardioprotective therapy was initiated upon diagnosis of CTRCD and was an ACE inhibitor followed by a beta-blocker. Those that could not tolerate an ACE inhibitor were prescribed an angiotensin receptor blocker. A total of 331 participants were included in the study with 307 being included in data analysis due to 2 patients dying and 22 patients either withdrawing from the study or being lost to follow-up. Of the 307 included in data analysis, 153 were in the EF-guided group and 154 were in the GLS-guided group. Approximately 29% of patients had hypertension, 13% had diabetes mellitus, 21% had dyslipidemia, and 29% were current or former smokers. Approximately 278 patients had breast cancer with the rest having lymphomas or leukemias. All patients were treated with anthracycline-based chemotherapy and received subsequent therapy with trastuzumab. There were no significant differences in LVEF noted between either group at baseline. Median follow-up was 1.02 years following enrollment. EF-guided LVEF at baseline was 58% (range 57-59%) and 1-year follow-up was 55% (range 54-56%). GLS-guided LVEF at baseline was 59% (range 58-60%) and 1-year follow-up was 57% (range 56-58%). At 1-year follow-up, 20 patients in the EF-guided group and 7 patients in the GLS-guided group met criteria for CTRCD. Researchers noted that “results support the use of GLS in surveillance for CTRCD.”

A systematic review by Thavendiranathan, et al. (2014) 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.

National and Specialty Guidelines

The **European Society of Cardiology (ESC)** published guidelines for cardio-oncology in 2022 stating that “speckle tracking is recommended at baseline, using three apical views, particularly in moderate- and high-risk patients” to determine GLS (Lyon et al. 2022).

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 (Doherty et al. 2019). 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 who previously or is 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.

The **American Society of Clinical Oncology** published the clinical practice guideline on the *Prevention and Monitoring of Cardiac Dysfunction in Survivors of Adult Cancers* (Armenian et al. 2017). Measurement of strain has demonstrated some diagnostic and prognostic use in patients with cancer receiving cardiotoxic therapies. 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.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Code

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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

8/9/2023	Policy reviewed, no changes to coverage criteria. Updated Overview, Summary of Medical Evidence, and References sections. Grammatical edits to Disclaimer section and Documentation Requirements disclaimer. Supplemental Information section removed. IRO Peer Review on June 23, 2023, by a practicing, board-certified physician with a specialty in Cardiovascular Disease.
8/10/2022	Policy reviewed, no changes to coverage criteria. Updated Summary of Medical Evidence and Reference sections.
8/13/2021	Policy reviewed, no changes, updated references.
9/16/2020	New policy.

REFERENCES

1. Armenian SH, Lacchetti C, Barac A, et al. Prevention and Monitoring of Cardiac Dysfunction in Survivors of Adult Cancers: American Society of Clinical Oncology Clinical Practice Guideline. J Clin Oncol. 2017 Mar 10;35(8):893-911. doi: 10.1200/JCO.2016.70.5400. Epub 2016 Dec 5. PMID: 27918725.
2. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Accessed June 19, 2023. https://www.cms.gov/medicare-coverage-database/search.aspx.
3. Doherty JU, Kort S, Mehran R, et al. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS 2019 appropriate use criteria for multimodality imaging in the assessment of cardiac structure and function in nonvalvular heart disease: A report of the American College of Cardiology Appropriate Use Criteria Task Force, 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. J Thorac Cardiovasc Surg. 2019 Apr;157(4):e153-e182. doi: 10.1016/j.jtcvs.2018.12.061. Epub 2019 Jan 8. PMID: 30635178.
4. Hayes. Health technology assessment: Myocardial strain imaging by speckle-tracking echocardiography for evaluation of dilated cardiomyopathy. Available from Hayes. Published September 24, 2020. Updated November 2,October 7, 2022.1. Accessed June 19, 2023. https://evidence.hayesinc.com/.

5. Lyon AR, López-Fernández T, Couch LS, et al. 2022 ESC Guidelines on cardio-oncology developed in collaboration with the European Hematology Association (EHA), the European Society for Therapeutic Radiology and Oncology (ESTRO) and the International Cardio-Oncology Society (IC-OS). Eur Heart J. 2022 Nov 1;43(41):4229-4361. doi: 10.1093/eurheartj/ehac244. Erratum in: Eur Heart J. 2023 May 7;44(18):1621. PMID: 36017568.
6. Thavendiranathan P, Negishi T, Somerset E, et al. Strain-Guided Management of Potentially Cardiotoxic Cancer Therapy. J Am Coll Cardiol. 2021 Feb 2;77(4):392-401. doi: 10.1016/j.jacc.2020.11.020. Epub 2020 Nov 18. PMID: 33220426.
7. Thavendiranathan P, Poulin F, Lim KD, et al. Use of myocardial strain imaging by echocardiography for the early detection of cardiotoxicity in patients during and after cancer chemotherapy: a systematic review. J Am Coll Cardiol. 2014 Jul 1;63(25 Pt A):2751-68. doi: 10.1016/j.jacc.2014.01.073. Epub 2014 Apr 2. PMID: 24703918.