Molina Clinical Policy
Myocardial Strain Imaging: Policy No. 371

Last Approval: 8/10/2022
Next Review Due By: August 2023

OHIO MEDICAID: Ohio Medicaid prior auth reviews will not exclude code 64999 and requests will be reviewed for medical necessity on an individual basis

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 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 and 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. (Hayes, 2020; Hayes, 2018; Lopez-Candales, et al., 2017; Smiseth et al., 2016; Hartlage et al., 2015).

COVERAGE POLICY

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.

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 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 (den Boer et al., 2017). 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 (Lopez-Candales, et al., 2017; Hartlage et al., 2015).

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.

For (additional) peer-reviewed studies used in the development and update of this policy, please see the *Reference* section.

National and Specialty 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 (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.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Code

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

HCPCS Codes – None.

ICD-10 Codes – Any / All.

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

8/10/2022	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

Government Agency

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Available from CMS. Accessed June 22, 2022.

Peer Reviewed Publications

1. Hartlage GR, Kim JH, et al. The prognostic value of standardized reference values for speckle-tracking global longitudinal strain in hypertrophic cardiomyopathy. Int J Cardiovasc Imaging. 2015 Mar;31(3):557-65. doi: 10.1007/s10554-015-0590-5. Accessed June 22, 2022.
2. Lopez-Candales A, Hernandez-Suarez DF. Strain imaging echocardiography: What imaging cardiologists should know. Curr Cardiol Rev. 2017;13(2):118129. doi:10.2174/1573403X12666161028122649. Accessed June 22, 2022.
3. Smiseth OO, Torp HH, Opdahl AA, Haugaa KK, Urheim SS. Myocardial strain imaging: how useful is it in clinical decision making? Eur Heart J. 2016 Apr 14;37(15):1196-207. doi: 10.1093/eurheartj/ehv529. Accessed June 22, 2022.
4. den Boer SL, du Marchie Sarvaas GJ, et al. Distribution of strain patterns in children with dilated cardiomyopathy. Echocardiography. 2017 Jun;34(6):881-887. doi: 10.1111/echo.13548. Accessed June 22, 2022.
5. Thavendiranathan PP, Poulin FF, Lim KK, Plana JJ, Woo AA, Marwick TT. 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. Accessed June 22, 2022.

National and Specialty Organizations

1. Armenian SS, 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. Accessed June 22, 2022.
2. Doherty JJ, Kort SS, Mehran RR, 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 Am Coll Cardiol. 2019 Feb 5;73(4):488-516. doi: 10.1016/j.jacc.2018.10.038. Accessed June 22, 2022.

Evidence Based Reviews and Publications

1. 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, 2021. Accessed June 22, 2022. Registration and login required.
2. Hayes. Evidence analysis research brief: Myocardial strain imaging for prediction of chemotherapy-induced cardiotoxicity. Available from Hayes. Published September 2018. Updated November 2, 2021. Accessed June 22, 2022. Registration and login required.

Other Peer Reviewed and National Organization Publications (used in the development of this policy)

1. American Society of Echocardiography. Echocardiographic myocardial strain imaging for early detection of cardiotoxicity in patients receiving potentially cardiotoxic chemotherapy. Published December 2015. Accessed June 22, 2022.

2. Bulten BF, Verberne HJ, et al. Relationship of promising methods in the detection of anthracycline-induced cardiotoxicity in breast cancer patients. Cancer Chemother Pharmacol. 2015;Nov;76(5):957-967. doi: 10.1007/s00280-015-2874-9. Accessed June 22, 2022.
3. Candan O, Gecmen C, et al. Mechanical dispersion and global longitudinal strain by speckle tracking echocardiography: Predictors of appropriate implantable cardioverter defibrillator therapy in hypertrophic cardiomyopathy. Echocardiography. 2017 Jun;34(6):835-842. Available here. Accessed June 22, 2022.
4. Charbonnel C, Convers-Domart R, et al. Assessment of global longitudinal strain at low-dose anthracycline-based chemotherapy for the prediction of subsequent cardiotoxicity. Ann Cardiol Angeiol (Paris). 2016 Nov;65(5):380. doi: 10.1016/j.ancard.2016.09.033. Accessed June 22, 2022.
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10. Narayan HK, Wei W, Feng Z, et al. Cardiac mechanics and dysfunction with anthracyclines in the community: Results from the PREDICT study. Open Heart. 2017;4(1):e000524. Available here. Accessed June 22, 2022.
11. Negishi TT, et al. Rationale and design of the strain surveillance of chemotherapy for improving cardiovascular outcomes: The SUCCOUR trial. JACC Cardiovasc Imaging. 2018 Aug;11(8):1098-1105. doi: 10.1016/j.jcmg.2018.03.019. Accessed June 22, 2022.
12. Qasem M, Utomi V, et al. A meta-analysis for the echocardiographic assessment of right ventricular structure and function in ARVC: A study by the Research and Audit Committee of the British Society of Echocardiography. Echo Res Pract. 2016 Sep 29;3(3):95-104. doi: 10.1530/ERP-16-0028. Accessed June 22, 2022.
13. Réant P, Hauer AD, et al. Epicardial myocardial strain abnormalities may identify the earliest stages of arrhythmogenic cardiomyopathy. Int J Cardiovasc Imaging. 2016 Apr;32(4):593-601. doi: 10.1007/s10554-015-0813-9. Accessed June 22, 2022.
14. Safi JM, Picard MH. Expert analysis: Echocardiographic strain has limited clinical utility. https://www.acc.org/. Published June 26, 2017. Accessed June 22, 2022.
15. Tigen K, Sunbul M, et al. Left ventricular and atrial functions in hypertrophic cardiomyopathy patients with very high LVOT gradient: a speckle tracking echocardiographic study. Echocardiography. 2014 Aug;31(7):833-41. doi: 10.1111/echo.12482. Accessed June 22, 2022.
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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

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