Subject: Myocardial Strain Imaging		Original Effective Date: 9/16/20
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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.

Contents

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [7-8 15 24]

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.

RECOMMENDATION

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 [2-18]

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 "Much remains to be understood about the role of cardiovascular imaging in the identification and management of cardiotoxicity from cancer chemotherapy. Whether strain-based approaches could be reliably implemented in multiple centers, including nonacademic settings, needs to be studied. The ability of strain changes to predict subsequent cardiotoxicity needs to be examined in larger multicenter studies and in cancers other than breast cancer, where treatment with potentially cardiotoxic regimens is provided…" [17]

Professional Society Guidelines [19-24]

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 in 2019, appropriate use criteria for multimodality imaging in the assessment of cardiac structure and function in nonvalvular heart disease. According to the criteria, the panel rated the following four 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

It should be noted that the criteria did not separate out imaging with speckle tracking and tissue doppler and did not make recommendations related to the comparative effectiveness of these imaging modalities. The panel rated 14 other indications as "may be appropriate". According to the panel, interventions in this category should be performed depending on individual clinical patient circumstances and patient and provider preferences, including shared decision making. [21]

The American Society of Clinical Oncology (2017) 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 American Society of Clinical Oncology also notes that screening for asymptomatic cardiac dysfunction using advanced imaging could lead to added distress in cancer survivors. [22]

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: [For dates of service on or after 10/01/2015]

REFERENCES

Government Agency

1. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National coverage determination (NCD) Search. Accessed at: http://www.cms.gov/medicare-coverage-database/

Peer Reviewed Publications

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.
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.
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.
5. 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.
6. Farsalinos KE, Daraban AM, Ünlü S, Thomas JD, Badano LP, Voigt JU. Head-to-Head Comparison of Global Longitudinal Strain Measurements among Nine Different Vendors The EACVI/ASE Inter-Vendor Comparison Study. *J Am Soc Echocardiogr* 2015;28:1172-81,e2.
7. 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):557-565.
8. Hernandez-Suarez DF, López-Candales A. Strain Imaging Echocardiography: What Imaging Cardiologists Should Know. Curr Cardiol Rev. 2017 May; 13(2): 118–129. Accessed at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5452148/
9. Liu H, Pozios I et al. Role of global longitudinal strain in predicting outcomes in hypertrophic cardiomyopathy. Am J Cardiol. 2017 Aug 15;120(4):670-675.
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.
11. Negishi, TT, Thavendiranathan, PP et al. Rationale and Design of the Strain Surveillance of Chemotherapy for Improving Cardiovascular Outcomes: The SUCCOUR Trial. JACC Cardiovasc Imaging, 2018 Jun 18;11(8). PMID 29909105.
12. Tomoko Negishi TT, Thavendiranathan PP, Penicka M et al. Precision and Stability of Parameters for Assessment of Left Ventricular Systolic Function in Clinical Trials: Lessons from the Succour Trial. Journal of the American College of Cardiology. Volume 73, Issue 9 Supplement 1, March 2019. DOI: 10.1016/S0735-1097(19)32120-5
13. 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 Research and Practice 2016;3(3):95-104.
14. 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.

15. Smiseth, OO, Torp, HH, Opdahl, AA, Haugaa, KK, Urheim, SS. Myocardial strain imaging: how useful is it in clinical decision making? Eur. Heart J., 2015 Oct 29;37(15). PMID 26508168.
16. 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):833-841.
17. 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 Apr 8;63(25 Pt A). PMID 24703918. Accessed at: https://www.sciencedirect.com/science/article/pii/S073510971401660X?via%3Dihub
18. Yingchoncharoen, TT, Agarwal, SS, PopoviÄ‡, ZZ, Marwick, TT. Normal ranges of left ventricular strain: a meta-analysis. J Am Soc Echocardiogr, 2012 Dec 12;26(2). PMID 23218891.

Professional Society Guidelines and Statements

19. American Society of Echocardiography. Echocardiographic Myocardial Strain Imaging for Early Detection of Cardiotoxicity in Patients Receiving Potentially Cardiotoxic Chemotherapy. 2015. Accessed at: https://asecho.org/wp-content/uploads/2015/12/MLM-Revised-Strain-Code-11-12-15.pdf
20. ACC. Expert Analysis. Safi JM et al. Echocardiographic Strain Has Limited Clinical Utility. Accessed at: https://www.acc.org/latest-in-cardiology/articles/2017/06/26/08/15/echocardiographic-strain-has-limited-clinical-utility
21. ACC/AATS/AHA/ASE/ASNC/HRS/SCAI/SCCT/SCMR/STS. Doherty, JJ, Kort, SS, Mehran, RR, Schoenhagen et al. 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 Soc Echocardiogr, 2019 Feb 13. PMID 30744922. Accessed at: https://www.onlinejacc.org/content/accj/early/2019/01/02/j.jacc.2018.10.038.full.pdf?_ga=2.120864776.1406398001.1557605734-1828015168.1551206332
22. Armenian, SS, Lacchetti, CC, Lenihan, DD. Prevention and Monitoring of Cardiac Dysfunction in Survivors of Adult Cancers: American Society of Clinical Oncology Clinical Practice Guideline Summary. J Oncol Pract, 2016 Dec 7;13(4). PMID 27922796.
23. European Society of Cardiology. Clinical applications of speckle tracking. 2018. Accessed at: https://www.escardio.org/Education/Practice-Tools/EACVI-toolboxes/3D-Echo/clinical-applications-speckle-tracking

Other Resources

24. Hayes a TractManager Company. Winifred Hayes Inc., Lansdale, PA.
    - EARB. Echocardiography with Myocardial Strain Imaging for Evaluation Of Cardiomyopathy. May, 2019.

- EARB. Myocardial Strain Imaging for Prediction of Chemotherapy-Induced Cardiotoxicity. Sept, 2018. [Archived]

25. AMR Peer Review Network: Policy reviewed by practicing MD Board certified in Cardiovascular Disease, Interventional Cardiology. June 28, 2020. Additional References cited buy the reviewer:
    - Marwick TH1, Shah SJ2,3, Thomas JD2. Myocardial Strain in the Assessment of Patients With Heart Failure: A Review. JAMA Cardiol. 2019 Mar 1;4(3):287-294. doi: 10.1001/jamacardio.2019.0052.
    - 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

Revision/Review History:

9/16/20: New Policy