BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 2.02.31 Myocardial Strain Imaging

Effective Policy Date: October 1, 2022

Original Policy Date: July 1, 2019

Related Policies:

None

Myocardial Strain Imaging

Description

Description

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 development of symptoms and irreversible myocardial dysfunction.

OBJECTIVE

The objective of this evidence review is to evaluate whether myocardial strain imaging improves the net health outcome.

POLICY STATEMENT

Myocardial strain imaging in individuals who have exposure to medications or radiation that could result in cardiotoxicity is **investigational**.

Myocardial strain imaging is **investigational** in all other situations.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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 EchoInsight 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.

Table 1. Examples of Software That Have Received FDA Clearance

Brand Name	Manufacturer	510(k) Number	FDA Product Code	Clearance Date
Myostrain	Myocardial Solutions	K182756	LNH	02/14/2019
Vivid	GE	K181685	IYN	10/25/2018
Aplio	Toshiba	K173090	IYN	01/11/2018
2D CARDIAC PERFORMANCE ANALYSIS	Tomtec	K120135	LLZ	04/13/2012
EchoInsight	Epsilon Imaging	K110447	LLZ	05/27/2011
Q-lab	Phillips	K023877	LLZ	12/23/2002

FDA: Food and Drug Administration.

RATIONALE

Summary of Evidence

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 an 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. 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. 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Cardiology et al

In 2019, 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 appropriate use criteria for multimodality imaging in the assessment of cardiac structure and function in nonvalvular heart disease (Table 2).[2,]

Using a modified Delphi approach, the panel rated indications as "appropriate", "may be appropriate", and "not appropriate".[7,] The specific studies that formed the basis of the American College of Cardiology guidelines are not cited, however, they note that they used American College of Cardiology/American Heart Association clinical practice guidelines whenever possible.

Of 81 indications considered for strain rate imaging, the panel rated only 4 as "appropriate" (Table 2). Three of the 4 concerned evaluation (initial or follow-up) in patients prior to and following exposure to potentially cardiotoxic agents. The other indication was follow-up testing to clarify initial diagnostic testing for patients with suspected hypertrophic cardiomyopathy. The guidelines 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 "may be appropriate" (Table 2). 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.[7,]

Table 2. Summary of ACC Appropriate Use Criteria for Myocardial Strain Imaging

Clinical Scenario and Indication	Rating
Initial evaluation in an asymptomatic patient:	
- Initial evaluation prior to exposure to medications/radiation that could result in cardiotoxicity/heart failure	Appropriate
- Initial cardiac evaluation of a known systemic, congenital, or acquired disease that could be associated with structural heart disease	May be appropriate
- Screening evaluation for structure and function in first-degree relatives of a patient with an inherited cardiomyopathy	May be appropriate
- Preparticipation assessment of an asymptomatic athlete with 1 or more of the following: abnormal examination, abnormal ECG, or definite (or high suspicion for) family history of inheritable heart disease)	May be appropriate
Initial evaluation of a patient with clinical signs and/or symptoms of heart disease:	

- Initial evaluation when symptoms or signs suggest heart disease	May be appropriate
- Arrhythmias or conduction disorders: Newly diagnosed LBBB; Nonsustained VT	May be appropriate
- Palpitations/presyncope/syncope: Clinical symptoms or signs consistent with a cardiac diagnosis known to cause presyncope/syncope (including but not limited to hypertrophic cardiomyopathy and heart failure)	May be appropriate
- Respiratory failure/exertional shortness of breath: Exertional shortness of breath/dyspnea or hypoxemia of uncertain etiology	May be appropriate
- HF/cardiomyopathy: Initial evaluation of known or suspected HF (systolic or diastolic) based on symptoms, signs, or abnormal test results to assess systolic or diastolic function and to assess for possible etiology (CAD, valvular disease); Suspected inherited or acquired cardiomyopathy (eg, restrictive, infiltrative, dilated, hypertrophic)	May be appropriate
- Device therapy: Known implanted pacing/ICD/CRT device with symptoms possibly due to suboptimal device settings	May be appropriate
- Cardiac transplantation: Monitoring for rejection or coronary arteriopathy in a cardiac transplant recipient	May be appropriate
- Other: Suspected pericardial diseases	May be appropriate
Sequential or follow-up testing to clarify initial diagnostic testing:	
- Evaluation of suspected hypertrophic cardiomyopathy	Appropriate
- Re-evaluation (1 y) in a patient previously or currently undergoing therapy with potentially cardiotoxic agents	Appropriate
- Periodic reevaluation in a patient undergoing therapy with cardiotoxic agents and worsening symptoms	Appropriate
- Pulmonary hypertension in the absence of severe valvular disease	May be appropriate
- Comprehensive further evaluation of undefined cardiomyopathy	May be appropriate
- Evaluation of suspected cardiac amyloidosis	May be appropriate
Sequential or follow-up testing: new or worsening symptoms or to guide therapy	
Re-evaluation of known structural heart disease with change in clinical status or cardiac examination or to guide therapy	May be appropriate
Re-evaluation of known cardiomyopathy with a change in clinical status or cardiac examination or to guide therapy	May be appropriate
Re-evaluation of known HF (systolic or diastolic) with a change in clinical status or cardiac examination without a clear precipitating change in medication or diet	May be appropriate
Re-evaluation for CRT device optimization in a patient with worsening HF	May be appropriate

ACC: American College of Cardiology; CAD: coronary artery disease; CRT: cardiac resynchronization therapy: ECG: electrocardiogram; HF: heart failure; ICD: implantable cardioverter-defibrillator; LBBB: left bundle branch block; VT: ventricular tachycardia.

Source: Adapted from Doherty et al (2019).[2,]

American Society of Clinical Oncology

In 2017, 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.[8,] 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.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

1. Smiseth OA, Torp H, Opdahl A, et al. Myocardial strain imaging: how useful is it in clinical decision making?. Eur Heart J. Apr 14 2016; 37(15): 1196-207. PMID 26508168
2. 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 Am Soc Echocardiogr. May 2019; 32(5): 553-579. PMID 30744922
3. Trivedi SJ, Altman M, Stanton T, et al. Echocardiographic Strain in Clinical Practice. Heart Lung Circ. Sep 2019; 28(9): 1320-1330. PMID 31064715
4. Yingchoncharoen T, Agarwal S, Popovic ZB, et al. Normal ranges of left ventricular strain: a meta-analysis. J Am Soc Echocardiogr. Feb 2013; 26(2): 185-91. PMID 23218891
5. 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. Jul 01 2014; 63(25 Pt A): 2751-68. PMID 24703918
6. Thavendiranathan P, Negishi T, Somerset E, et al. Strain-Guided Management of Potentially Cardiotoxic Cancer Therapy. J Am Coll Cardiol. Feb 02 2021; 77(4): 392-401. PMID 33220426
7. Hendel RC, Lindsay BD, Allen JM, et al. ACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. J Am Coll Cardiol. Feb 27 2018; 71(8): 935-948. PMID 29471942
8. Armenian SH, Lacchetti C, Lenihan D. Prevention and Monitoring of Cardiac Dysfunction in Survivors of Adult Cancers: American Society of Clinical Oncology Clinical Practice Guideline Summary. J Oncol Pract. Apr 2017; 13(4): 270-275. PMID 27922796

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2019	New policy	Policy created with literature review through January 12, 2019. Considered investigational.
June 2020	Replace policy	Policy updated with literature review through January 22, 2020; reference added. Investigational policy statement added to address cardiotoxicity.
June 2021	Replace policy	Policy updated with literature review through March 18, 2021. No references added. Policy statements unchanged.
September 2022	Replace policy	Policy updated with literature review through March 14, 2022; reference added. Policy statements unchanged.