



Louisiana

Myocardial Strain Imaging

Policy # 00672

Original Effective Date: 08/01/2019

Current Effective Date: 07/13/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers myocardial strain imaging in individuals who have exposure to medications or radiation that could result in cardiotoxicity to be **investigational**.*

Based on review of available data, the Company considers myocardial strain imaging in all other situations to be **investigational**.*

Background/Overview

The term strain indicates dimensional or deformational change under force. When used in echocardiography, the term 'strain' is used to describe the magnitude of shortening, thickening, and lengthening of the myocardium through the cardiac cycle. The most frequent measure of myocardial strain is the deformation of the left ventricle in the long axis, termed global longitudinal strain. During systole, ventricular myocardial fibers shorten with movement from the base to the apex. Global longitudinal strain is used as a measure of global left ventricle function and provides a quantitative myocardial deformation analysis of each left ventricle segment. Myocardial strain imaging is intended to detect subclinical changes in left ventricle function in patients with a preserved left ventricle ejection fraction, allowing for early detection of systolic dysfunction. Since strain imaging can identify left ventricle dysfunction earlier than standard methods, this raises the possibility of heart failure prophylaxis and primary prevention before the patient develops symptoms and irreversible myocardial dysfunction. Potential applications of speckle-tracking echocardiography are coronary artery disease, ischemic cardiomyopathy, valvular heart disease, dilated cardiomyopathy, hypertrophic cardiomyopathies, stress cardiomyopathy, and chemotherapy-related cardiotoxicity.

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Myocardial Strain Imaging

Myocardial strain can be measured by cardiac magnetic resonance imaging (MRI), tissue Doppler imaging or by speckle-tracking echocardiography. Tissue Doppler strain imaging has been in use since the 1990s but has limitations that include angle dependency and significant noise. In 2016, Smiseth et al reported that the most widely used method of measuring myocardial strain at the present time is speckle-tracking echocardiography. In speckle-tracking echocardiography, natural acoustic markers generated by the interaction between the ultrasound beam and myocardial fibers form interference patterns (speckles). These markers are stable, and speckle-tracking echocardiography analyzes the spatial displacement (tracking) of each point (speckle) on routine 2-dimensional sonograms. Echocardiograms are processed using specific acoustic-tracking software on dedicated workstations, with offline semiautomated analysis of myocardial strain. The 2-dimensional displacement is identified by a search with image processing algorithms for similar patterns across 2 frames. When tracked frame-to-frame, the spatiotemporal displacement of the speckles provides information about myocardial deformation across the cardiac cycle. Global longitudinal strain provides a quantitative analysis of each left ventricle segment, which is expressed as a percentage. In addition to global longitudinal strain, speckle-tracking echocardiography allows evaluation of left ventricle rotational and torsional dynamics.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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 Echolnsight 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
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Myostrain	Myocardial Solutions	K182756	LNH	02/14/2019
2D CARDIAC PERFORMANCE ANALYSIS	Tomtec	K120135	LLZ	04/13/2012
Echolnsight	Epsilon Imaging	K110447	LLZ	05/27/2011
Q-lab	Phillips	K023877	LLZ	12/23/2002
Vivid	GE	K181685	IYN	10/25/2018
Aplio	Toshiba		IYN	01/11/2018

FDA: U.S. Food and Drug Administration.

Rationale/Source

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.

For individuals who have exposure to medications or radiation that could result in cardiotoxicity who receive myocardial strain imaging, the evidence includes a systematic review of observational studies. 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. No studies were identified that compared the diagnostic accuracy of myocardial strain imaging to left ventricle ejection fraction. A study that will compare clinical outcomes when therapy is guided by myocardial strain imaging or left ventricle ejection fraction is in progress and will provide direct evidence on the clinical utility of myocardial strain imaging. The evidence is insufficient to determine the effects of the technology on health outcomes.

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Supplemental Information

Practice Guidelines and Position Statements

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 (see Table 2).

Using a modified Delphi approach, the panel rated indications as “appropriate”, “may be appropriate”, and “not appropriate” 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.

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

Clinical Scenario and Indication	Rating
<i>Initial evaluation in an asymptomatic patient:</i>	
- 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

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Clinical Scenario and Indication	Rating
- 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
<i>Initial evaluation of a patient with clinical signs and/or symptoms of heart disease:</i>	
- 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
- Heart failure/cardiomyopathy: Initial evaluation of known or suspected heart failure (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
<i>Sequential or follow-up testing to clarify initial diagnostic testing:</i>	
- Evaluation of suspected hypertrophic cardiomyopathy	Appropriate
- Re-evaluation (1 y) in a patient previously or currently undergoing therapy with potentially cardiotoxic agents	Appropriate

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Clinical Scenario and Indication	Rating
- 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).

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. 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.

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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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 3.

The Strain Surveillance of Chemotherapy for Improving Cardiovascular Outcomes (SUCCOUR) is a randomized controlled trial (RCT) that will evaluate clinical outcomes for patients who are monitored by myocardial strain imaging or conventional imaging. Patients with an abnormal test result will receive improved blood pressure and glucose control. Protective therapy with angiotensin-converting enzyme inhibitors and beta-blockers will be titrated to target dose. This will be the first trial to assess clinical outcomes based on myocardial strain imaging compared to conventional imaging (limited to evaluation of ejection fraction and valve disease). The SUCCOUR trial will provide evidence to inform guidelines regarding the place of global longitudinal strain for surveillance for cardiotoxicity.

Table 3. Summary of Key Trials

Study	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
ACTRN12614000341628	Strain Surveillance of Chemotherapy for Improving Cardiovascular Outcomes: The SUCCOUR Trial.	320	Aug 2021
NCT03825224	Evaluation of MyoStrain in Clinical Practice	100	Feb 2020
NCT02605512	Early Detection and Prediction of Cardiotoxicity in Radiotherapy-treated Breast Cancer Patients (BACCARAT)	120	Sep 2020

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Study	Trial Name	Planned Enrollment	Completion Date
NCT02286908	Global Strain and Mechanical Dispersion May Predict Death and Ventricular Arrhythmias Better Than Ejection Fraction	3100	Dec 2021
NCT03297346	Early Detection of Cardiovascular Changes After Radiotherapy for Breast Cancer (EARLY-HEART)	250	May 2021
<i>Unpublished</i>			
NCT02608567	Prognostic Impact of Myocardial Longitudinal Strain in Asymptomatic Aortic Stenosis: a Meta-Analysis	1000 (actual)	Dec 2017
NCT03543228 ^a	MyoStrain CMR for the Detection of Cardiotoxicity (Prefect)	50	Jun 2019

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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05/02/2019 Medical Policy Committee review

05/15/2019 Medical Policy Implementation Committee approval. New policy.

06/04/2020 Medical Policy Committee review

06/10/2020 Medical Policy Implementation Committee approval. Investigational policy statement added to address cardiotoxicity.

Next Scheduled Review Date: 06/2021

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Code Type	Code
CPT	Code 0399T deleted eff 1/1/2020 Code 93356 added eff 1/1/2020
HCPCS	Add codes eff 7/1/2020: C9762, C9763
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into

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standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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