BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:
Myocardial Strain Imaging

Policy #: 726
Category: Radiology
Latest Review Date: September 2020
Policy Grade: C

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service January 1, 2020, and after:
Blue Advantage will treat **myocardial strain imaging** as a **noncovered benefit** and as **investigational.**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

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 (LV) in the long axis, termed global longitudinal strain (GLS). During systole, ventricular myocardial fibers shorten with movement from the base to the apex. GLS is used as a measure of global LV function, and provides a quantitative myocardial deformation analysis of each LV segment. Myocardial strain imaging is intended to detect subclinical changes in left ventricle function in patients with a preserved LV ejection fraction, allowing for early detection of systolic 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.

Myocardial Strain Imaging

Myocardial strain can be measured by either cardiac magnetic resonance imaging (MRI), tissue Doppler imaging or by speckle-tracking echocardiography (STE). Tissue Doppler strain imaging has been in use since the 1990's but has limitations that include angle dependency and significant noise. Smiseth et al (2016), reported that the most widely used method of measuring myocardial strain at the present time is STE. In STE, natural acoustic markers generated by the interaction between the ultrasound beam and myocardial fibers form interference patterns (speckles). These markers are stable, and STE analyzes the spatial dislocation (tracking) of each point (speckle) on

routine 2-dimensional sonograms. Echocardiograms are processed using specific acoustic-tracking software on dedicated workstations, with offline semi-automated analysis of myocardial strain. The 2-dimentional displacement is identified by a search with image processing algorithms for similar patterns across two frames. When tracked frame-to-frame, the spatiotemporal displacement of the speckles provides information about myocardial deformation across the cardiac cycle. GLS provides a quantitative analysis of each LV segment, which is expressed as a percentage. In addition to GLS, STE allows evaluation of LV rotational and torsional dynamics.

KEY POINTS:

This evidence review was developed using a search of the MEDLINE database through January . 22, 2020.

Summary of Evidence

For individuals who receive myocardial strain imaging, the evidence includes systematic reviews of observational studies. Relevant outcomes include symptoms, morbid events, quality of life, treatment-related mortality, and treatment-related morbidity. 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 compares 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.

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 1).

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 ACC guidelines are not cited, however, they note that they used ACC/American Heart Association clinical practice guidelines whenever possible.

Of 81 indications considered for strain rate imaging, the panel rated only 4 as “appropriate” (Table 1). Three of the four “appropriate indications”, 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 as "may be appropriate" (Table 1). 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 1. 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
Pre-participation 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 • Non-sustained 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 (e.g., 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

Clinical Scenario and Indication	Rating
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 year) 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

Source: Adapted from Doherty et al 2019

The American Society of Clinical Oncology
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.

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
Myocardial strain, cardiovascular, cardiac, Myostrain, 2D Cardiac Performance Analysis, EchoInsight, Echo1nsight, Q-lab, Vivid, Aplio

APPROVED BY GOVERNING BODIES:
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 2. For

example, the Echolnsight software system (Epsilon Imaging) "enables the production and visualization of 2D 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 (e.g., syngo US Workplace, Siemens, K091286) for analysis of ultrasound imaging of the human heart.

Table 2. FDA Clearances

Brand Name	Manufacturer	510(k) Number	FDA Product Code	Clearance Date
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: Food and Drug Administration.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

93356	Myocardial strain imaging using speckle tracking-derived assessment of myocardial mechanics (List separately in addition to codes for echocardiography imaging) **(Effective 01/01/20)**

PREVIOUS CODING:

CPT Codes

0399T	Myocardial strain imaging (quantitative assessment of myocardial mechanics using image-based analysis of local myocardial dynamics) (List separately in addition to code for primary procedure) **(Deleted 12/31/19)**

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POLICY HISTORY:

Adopted for Blue Advantage, January 1, 2020.
Medical Policy Group, September 2020

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.