2.02.31 Myocardial Strain Imaging

<table>
<thead>
<tr>
<th>Original Policy Date:</th>
<th>Effective Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 1, 2019</td>
<td>May 1, 2019</td>
</tr>
</tbody>
</table>

Section: 2.0 Medicine

Policy Statement

Myocardial strain imaging is considered investigational.

Policy Guidelines

The following category III CPT code is specific to myocardial strain imaging:

- **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)

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.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibit plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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 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 Bmode (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 1. FDA Clearances

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

FDA: Food and Drug Administration.

Rationale

Background
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. Since strain imaging can identify LV 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.

Myocardial Strain Imaging
Myocardial strain can be measured by either 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 semiautomated analysis of myocardial strain. The 2-dimensional 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.

Literature Review
Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.
Myocardial Strain Imaging to Detect Cardiotoxicity
Clinical Context and Test Purpose

The purpose of MSI in patients who have an indication for a transthoracic echocardiogram is to inform a decision whether to modify monitoring and/or treatment before the patient develops symptoms and irreversible myocardial dysfunction.

The American College of Cardiology, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Health Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and the Society of Thoracic Surgeons (2019) published appropriate use criteria for multimodality imaging in the assessment of cardiac structure and function in nonvalvular heart disease. The American College of Cardiology et al (2019) considered strain imaging by speckle or tissue Doppler appropriate for the following indications:

• 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.

The American College of Cardiology et al (2019) recommended that MSI "may be appropriate" for indications that are described in Table 2 in the Supplemental Information section.

The most developed evidence base on MSI is for cardiotoxicity, therefore, this evidence review will focus on clinical outcomes from use of strain imaging by speckle-tracking echocardiography (STE) or tissue Doppler imaging for the initial assessment and follow-up for cardiotoxicity.

Cardiovascular complications of cancer treatment can be either acute or chronic (early or delayed) and include heart failure, myocardial ischemia or infarction, hypertension, thromboembolism, and arrhythmias. Presymptomatic detection of cardiotoxicity may allow modification of cancer therapy combinations or use of cardioprotective agents.

The question addressed in this evidence review is does MSI improve the net health outcome in patients exposed to cardiotoxic agents?

The following PICOTS were used to select literature to inform this review.

Patients
For patients who are undergoing chemotherapy, current recommendations are to measure ejection fraction (EF) prior to chemotherapy, at completion of therapy, and six months later. It has been proposed that the measurement of myocardial strain in addition to EF will be helpful in cases when EF is in the lower normal range, and in these cases, the finding of subnormal strain should result in closer monitoring of cardiac function, modification of cancer therapy, and/or use of cardioprotective agents.

Interventions
The test being considered is myocardial strain imaging.

The most frequent measure of myocardial strain imaging is global longitudinal strain, which averages values over the length of the myocardial wall. Positive values indicate lengthening, thickening, or clockwise rotation. Greater deformation is indicated by lower strain values. Cardiac strain in a healthy individual is generally around 20%, indicated in echocardiography by a negative number (-20). In a meta-analysis of 24 studies (2597 healthy volunteers),
Yingchoncharoen et al (2013), reported that global longitudinal strain varied from -15.9% to -22.1% (mean -19.7%, 95% confidence interval -18.9% to -20.4%). Shortening of more than 20% is generally considered normal.

Comparators
The following tests are currently being used to make decisions about cardiac function. Tagged magnetic resonance imaging is considered the reference standard for MSI. However, its routine use is limited by high cost, limited availability, complexity of acquisitions, and time consuming image analysis. This evidence review will evaluate whether clinical outcomes are improved by myocardial strain imaging in comparison with EF.

Outcomes
The outcomes of interest are symptoms and signs of cardiotoxicity. Cardiotoxicity is typically defined as a decline in EF but there is little consensus regarding what level of decline in left ventricle(LVEF) constitutes cardiotoxicity.

The beneficial outcome of a true-positive test result would be an increase in monitoring or modification of treatment that would reduce cardiotoxicity.

The beneficial outcome of a true-negative test result would be avoiding unnecessary treatment.

A harmful outcome of a false-positive test result would be unnecessary therapy.

A harmful outcome of a false-negative test result would be failure to diagnose cardiotoxicity or progression of toxicity.

Timing
Cardiotoxicity may be measured by clinical symptoms and EF at six months and after one, two, and three years.

Setting
The setting is outpatient care in a echocardiography laboratory and specialist treatment in oncology.

Study Selection Criteria
For the evaluation of clinical validity of MSI, studies that meet the following eligibility criteria were considered:

- Reported on clinical outcomes
- Included a suitable reference standard (EF)
- Patient/sample clinical characteristics were described
- Patient/sample selection criteria were described

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid
Thavendiranathan et al (2014) conducted a systematic review of myocardial strain imaging for the early detection of cardiotoxicity in patients during and after cancer chemotherapy. Searches were conducted through November 2013. The reviewers included prospective or retrospective studies of at least ten patients that used echocardiographic-based myocardial deformation parameters as the primary method to detect cardiotoxicity. Studies had to provide data on changes in deformation parameters and LVEF during therapy. The authors focused the review on three clinical scenarios: 1) detection of early myocardial changes; 2) prediction of...
subsequent cardiotoxicity; and 3) detection of late consequences of therapy (>1 year posttreatment).

Detection of early myocardial changes: Thirteen single-center cohort studies (n=384) provided information on MSI parameters to detect early myocardial changes in patients treated with anthracycline-containing regimens. The earlier studies (n=7) used tissue Doppler imaging while more recent studies (n=6) used STE. There was heterogeneity regarding patient age, types of cancer, strain techniques, and timing of follow-up but all of the studies found that changes in myocardial deformation occurred earlier than changes in LVEF. In addition, reductions in myocardial deformation occurred at doses lower than those historically considered cardiotoxic.

Prognosis for early cardiotoxicity: Eight observational studies (n=452) included in the systematic review evaluated the prognostic value of MSI for subsequent cardiotoxicity (LVEF reduction or the development of heart failure). The studies differed in duration of follow-up (6 months, 12 to 15 months), treatment regimens, and other factors but used a similar definition of cardiotoxicity. The researchers found that an early fall in global longitudinal strain of 10% to 15% using STE predicted subsequent cardiotoxicity.

Prognosis for late cardiotoxicity: Nine case-control studies (n=436) were identified that compared findings in patients to controls. All of the studies used various myocardial deformation parameters to detect late subclinical cardiac injury but none provided data on subsequent cardiac events.

The authors identified the following areas for future research:
• Determination of whether strain-based approaches could be reliably implemented in multiple centers, including nonacademic settings
• Study in larger multicenter studies and in cancers other than breast cancer
• Need to determine the optimum sampling (single or multiple)
• Comparison with a traditional LVEF-based approach
• Understanding the long-term effect of strain changes that occur during therapy
• The use of vendor-neutral methods to measure strain
• The prognostic significance of strain abnormalities in survivors of cancer and those receiving radiation therapy
• Whether intervention would change the natural course of the cardiac disease

Section Summary: Clinical Validity
A systematic review of 13 studies with 384 patients treated for cancer suggests that MSI with tissue Doppler imaging or STE may be able to identify changes in myocardial deformation that precede changes in LVEF. Although MSI 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 MSI to LVEF.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

No direct evidence of the clinical utility of MSI is currently available. The Strain Surveillance of Chemo therapy for Improving Cardiovascular Outcomestrial, currently in progress, will be the first randomized controlled trial of MSI and will provide evidence to inform guidelines regarding the
place of MSI for surveillance for cardiotoxicity related to cancer chemotherapy. Preliminary descriptive results on the first 86 patients have been published.\textsuperscript{5}

**Chain of Evidence**

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Evidence is insufficient to determine the clinical validity of MSI

**Summary of Evidence**

For individuals who have an indication for a transthoracic echocardiogram who receive MSI, the evidence includes a systematic review of observational studies. The 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 MSI with tissue Doppler imaging or STE may be able to identify changes in myocardial deformation that precede changes in LVEF. Although MSI 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 MSI to LVEF. A study that will compare clinical outcomes when therapy is guided by MSI or LVEF is in progress, and will provide direct evidence on the clinical utility of MSI. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Supplemental Information**

**Practice Guidelines and Position Statements**

**American College of Cardiology et al.**

The ACC, 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 (2019) published appropriate use criteria for multimodality imaging in the assessment of cardiac structure and function in nonvalvular heart disease (see Table 2).\textsuperscript{2}

Using a modified Delphi approach, the panel rated indications as “appropriate”, “may be appropriate”, and “not appropriate”\textsuperscript{6} 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 2). Three of the four 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.\textsuperscript{6}

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

<table>
<thead>
<tr>
<th>Clinical Scenario and Indication</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial evaluation in an asymptomatic patient</td>
<td>Appropriate</td>
</tr>
<tr>
<td>Initial evaluation prior to exposure to medications/radiation that could result in cardiotoxicity/heart failure</td>
<td>May be appropriate</td>
</tr>
<tr>
<td>Initial cardiac evaluation of a known systemic, congenital, or acquired disease that could be associated with structural heart disease</td>
<td>May be appropriate</td>
</tr>
</tbody>
</table>
### Clinical Scenario and Indication

<table>
<thead>
<tr>
<th>Clinical Scenario and Indication</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening evaluation for structure and function in first-degree relatives of a patient with an inherited cardiomyopathy</td>
<td>Maybe appropriate</td>
</tr>
<tr>
<td>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</td>
<td>Maybe appropriate</td>
</tr>
</tbody>
</table>

### Initial evaluation of a patient with clinical signs and/or symptoms of heart disease:

<table>
<thead>
<tr>
<th>Clinical Scenario</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial evaluation when symptoms or signs suggest heart disease</td>
<td>Maybe appropriate</td>
</tr>
</tbody>
</table>
| Arrhythmias or conduction disorders  
  - Newly diagnosed LBBB  
  - Non-sustained VT | Maybe 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) | Maybe appropriate |
| Respiratory failure/exertional shortness of breath  
  - Exertional shortness of breath/dyspnea or hypoxemia of uncertain etiology | Maybe 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) | Maybe appropriate |
| Device therapy  
  - Known implanted pacing/ICD/CRT device with symptoms possibly due to suboptimal device settings | Maybe appropriate |
| Cardiac Transplantation  
  - Monitoring for rejection or coronary arteriopathy in a cardiac transplant recipient | Maybe appropriate |
| Other  
  - Suspected pericardial diseases | Maybe appropriate |

### Sequential or follow-up testing to clarify initial diagnostic testing:

<table>
<thead>
<tr>
<th>Clinical Scenario</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluation of suspected hypertrophic cardiomyopathy</td>
<td>Appropriate</td>
</tr>
<tr>
<td>Re-evaluation (1 year) in a patient previously or currently undergoing therapy with potentially cardiotoxic agents</td>
<td>Appropriate</td>
</tr>
<tr>
<td>Periodic re-evaluation in a patient undergoing therapy with cardiotoxic agents and worsening symptoms</td>
<td>Appropriate</td>
</tr>
<tr>
<td>Pulmonary hypertension in the absence of severe valvular disease</td>
<td>Maybe appropriate</td>
</tr>
<tr>
<td>Comprehensive further evaluation of undefined cardiomyopathy</td>
<td>Maybe appropriate</td>
</tr>
<tr>
<td>Evaluation of suspected cardiac amyloidosis</td>
<td>Maybe appropriate</td>
</tr>
</tbody>
</table>

### Sequential or follow-up testing: New or Worsening Symptoms or to Guide Therapy

<table>
<thead>
<tr>
<th>Clinical Scenario</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Re-evaluation of known structural heart disease with change in clinical status or cardiac examination or to guide therapy</td>
<td>Maybe appropriate</td>
</tr>
<tr>
<td>Re-evaluation of known cardiomyopathy with a change in clinical status or cardiac examination or to guide therapy</td>
<td>Maybe appropriate</td>
</tr>
<tr>
<td>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</td>
<td>Maybe appropriate</td>
</tr>
<tr>
<td>Re-evaluation for CRT device optimization in a patient with worsening HF</td>
<td>Maybe appropriate</td>
</tr>
</tbody>
</table>

### 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.
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 trials that might influence this review are listed in Table 3.

SUCCOUR is a randomized controlled trial 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 ACE 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.5

Table 3. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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</thead>
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<tr>
<td>ACTRN12614000341628</td>
<td>Strain Surveillance of Chemotherapy for Improving Cardiovascular Outcomes. The SUCCOUR Trial.</td>
<td>320</td>
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<tr>
<td>NCT03543228a</td>
<td>MyoStrain CMR for the Detection of Cardiotoxicity (Prefect)</td>
<td>50</td>
<td>Jun 2019</td>
</tr>
<tr>
<td>NCT03825224</td>
<td>Evaluation of MyoStrain in Clinical Practice</td>
<td>100</td>
<td>Feb 2020</td>
</tr>
<tr>
<td>NCT02286908</td>
<td>Global Strain and Mechanical Dispersion May Predict Death and Ventricular Anhythmias Better Than Ejection Fraction</td>
<td>3100</td>
<td>Dec 2021</td>
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<tr>
<td>NCT03297346</td>
<td>Early Detection of Cardiovascular Changes After Radiotherapy for Breast Cancer (EARLY-HEART)</td>
<td>250</td>
<td>May 2021</td>
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<tr>
<td>NCT02608567</td>
<td>Prognostic Impact of Myocardial Longitudinal Strain in Asymptomatic Aortic Stenosis: a Meta-Analysis</td>
<td>1000 (actual)</td>
<td>Dec 2017</td>
</tr>
</tbody>
</table>

ACTRN: NCT: national clinical trial.

References


Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

IE

The following services may be considered investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>0399T</td>
<td>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)</td>
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<tr>
<td>HCPCS</td>
<td>None</td>
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<tr>
<td>ICD-10 Procedure</td>
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<td></td>
</tr>
</tbody>
</table>

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.
Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements (as applicable to your plan)**

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.