Medical Policy

MP 2.02.31
Myocardial Strain Imaging

<table>
<thead>
<tr>
<th>BCBSA Ref. Policy: 2.02.31</th>
<th>Related Policies</th>
</tr>
</thead>
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<tr>
<td>Last Review: 03/21/2019</td>
<td>9.01.502 Experimental/Investigational Services</td>
</tr>
<tr>
<td>Effective Date: 06/14/2019</td>
<td>Section: Medicine</td>
</tr>
</tbody>
</table>

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POLICY

Myocardial strain imaging is investigational.

POLICY GUIDELINES

None.

BENEFIT APPLICATION

BlueCard/National Account Issues

State or federal mandates (eg, Federal Employee Program) may dictate that certain U.S. Food and Drug Administration approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only by their medical necessity.

BACKGROUND

SUDDEN CARDIAC ARREST

Sudden cardiac arrest (SCA) is the most common cause of death in patients with coronary artery disease.

Treatment

The implantable cardioverter defibrillator (ICD) has proven effective in reducing mortality for survivors of SCA and for patients with documented malignant ventricular arrhythmias. More recently, use of ICDs has been broadened by studies reporting a reduction in mortality for patients at risk for ventricular arrhythmias, such as patients with prior myocardial infarction and reduced ejection fraction.
ICDs consist of implantable leads, which are placed percutaneously in the heart, that are connected to a pulse generator placed beneath the skin of the chest or abdomen. ICD placement is a minor surgical procedure. Potential adverse events of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary counter shocks. See evidence review 7.01.44 for further information on ICDs.

The wearable cardioverter defibrillator (WCD) is an external device intended to perform the same tasks as an ICD, without invasive procedures. It consists of a vest worn continuously underneath the patient's clothing. Part of this vest is the “electrode belt” that contains the cardiac-monitoring electrodes and the therapy electrodes that deliver a counter shock. The vest is connected to a monitor with a battery pack and alarm module worn on the patient’s belt. The monitor contains the electronics that interpret the cardiac rhythm and determines when a counter shock is necessary. The alarm module alerts the patient to certain conditions by lights or voice messages, during which time a conscious patient can abort or delay the shock.

U.S. Food and Drug Administration (FDA)–labeled indications for the WCD are adults at risk for sudden cardiac arrest (SCA) and either are not candidates for or refuse an implantable ICD. Some experts have suggested that the indications for a WCD should be broadened to include other populations at high risk for SCA. The potential indications include:
- Bridge to transplantation (ie, the WEARIT study population)
- Bridge to implantable device or clinical improvement (ie, the BIROAD study population)
  - Post bypass with ejection fraction less than 30%
  - Post bypass with ventricular arrhythmias or syncope within 48 hours of surgery
  - Post myocardial infarction with ejection fraction less than 30%
  - Post myocardial infarction with ventricular arrhythmias within 48 hours
- Drug-related arrhythmias (during drug washout or after, during evaluation of long-term risk)
- Patients awaiting revascularization
- Patients too ill to undergo device implantation
- Patients who refuse device therapy.

REGULATORY STATUS

In 2001, the Lifecor WCD® 2000 system was approved by FDA through the premarket approval process for “adult patients who are at risk for cardiac arrest and are either not candidates for or refuse an implantable defibrillator.” The vest was renamed the Zoll LifeVest®.

In 2015, FDA approved the LifeVest® “for certain children who are at risk for sudden cardiac arrest, but are not candidates for an implantable defibrillator due to certain medical conditions or lack of parental consent.”

FDA product code: MVK.

RATIONALE

This evidence review was created in March 2019 with a search of the MEDLINE database through January 12, 2019.

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, Hearth 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 the 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 Chemotherapy for Improving Cardiovascular Outcomes trial, 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.

**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, Hearth 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).
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><strong>Initial evaluation in an asymptomatic patient:</strong></td>
<td></td>
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<tr>
<td>- Initial evaluation prior to exposure to medications/radiation that could result in cardiotoxicity/heart failure</td>
<td>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>
<tr>
<td>- Screening evaluation for structure and function in first-degree relatives of a patient with an inherited cardiomyopathy</td>
<td>May be appropriate</td>
</tr>
<tr>
<td>- 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</td>
<td>May be appropriate</td>
</tr>
<tr>
<td><strong>Initial evaluation of a patient with clinical signs and/or symptoms of heart disease:</strong></td>
<td></td>
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<tr>
<td>- Initial evaluation when symptoms or signs suggest heart disease</td>
<td>May be appropriate</td>
</tr>
<tr>
<td>o Arrhythmias or conduction disorders</td>
<td>May be appropriate</td>
</tr>
<tr>
<td>o Newly diagnosed LBBB</td>
<td>May be appropriate</td>
</tr>
<tr>
<td>o Nonsustained VT</td>
<td></td>
</tr>
<tr>
<td>o Palpitations/Presyncope/Syncope</td>
<td>May be appropriate</td>
</tr>
<tr>
<td>o Clinical symptoms or signs consistent with a cardiac diagnosis known to cause presyncope/syncope (including but not limited to hypertrophic cardiomyopathy and heart failure)</td>
<td>May be appropriate</td>
</tr>
<tr>
<td>- Respiratory failure/exertional shortness of breath</td>
<td>May be appropriate</td>
</tr>
<tr>
<td>o Exertional shortness of breath/dyspnea or hypoxemia of uncertain etiology</td>
<td>May be appropriate</td>
</tr>
<tr>
<td>- Heart failure cardiomyopathy</td>
<td>May be appropriate</td>
</tr>
<tr>
<td>o 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)</td>
<td>May be appropriate</td>
</tr>
<tr>
<td>o Suspected inherited or acquired cardiomyopathy (e.g., restrictive, infiltrative, dilated, hypertrophic)</td>
<td></td>
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</table>
MP 2.02.31  
Myocardial Strain Imaging

| - | Device therapy | May be appropriate |
| - | Known implanted pacing/ICD/CRT device with symptoms possibly due to suboptimal device settings |
| - | Cardiac Transplantation | May be appropriate |
| - | Monitoring for rejection or coronary arteriopathy in a cardiac transplant recipient |
| - | Other | May be appropriate |
| | Suspected pericardial diseases |

**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 2019²  
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.² 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**

Original Policy Date: March 2019
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 inhalation for surveillance for cardiotoxicity.\textsuperscript{2}

Table 3. Summary of key trials

<table>
<thead>
<tr>
<th>Study</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td><strong>Ongoing Studies</strong></td>
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<td></td>
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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>NCT03543228\textsuperscript{a}</td>
<td>MyoStrain CMR for the Detection of Cardiotoxicity (Prefect)</td>
<td>50</td>
<td>Jun 2019</td>
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<tr>
<td>NCT03825224</td>
<td>Evaluation of MyoStrain in Clinical Practice</td>
<td>100</td>
<td>Feb 2020</td>
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<tr>
<td>NCT02286908</td>
<td>Global Strain and Mechanical Dispersion May Predict Death and Ventricular Arrhythmias 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><strong>Unpublished</strong></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>
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</table>

\textsuperscript{a} Denotes industry-sponsored or cosponsored trial.

**ESSENTIAL HEALTH BENEFITS**

The Affordable Care Act (ACA) requires fully insured non-grandfathered individual and small group benefit plans to provide coverage for ten categories of Essential Health Benefits (“EHBs”), whether the benefit plans are offered through an Exchange or not. States can define EHBs for their respective state.

States vary on how they define the term small group. In Idaho, a small group employer is defined as an employer with at least two but no more than fifty eligible employees on the first day of the plan or contract year, the majority of whom are employed in Idaho. Large group employers, whether they are self-funded or fully insured, are not required to offer EHBs, but may voluntary offer them.

The Affordable Care Act requires any benefit plan offering EHBs to remove all dollar limits for EHBs.

**REFERENCES**


### CODES

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<th>Codes</th>
<th>Number</th>
<th>Description</th>
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<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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<td>HCPCS</td>
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<td>Per this policy, myocardial strain imaging is considered investigational</td>
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<td>ICD10-CM</td>
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<td>There is no PCS code specifically for myocardial strain imaging</td>
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<tr>
<td>Type</td>
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Service
Place  Inpatient/Outpatient
of Service

**POLICY HISTORY**

<table>
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<th>Date</th>
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<th>Description</th>
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<td>03/21/19</td>
<td>New policy – added to medicine section</td>
<td>Blue Cross of Idaho adopted policy, effective 06/14/2019. Policy created with literature review through January 12, 2019. Considered investigational.</td>
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