Anthem

Medical Policy

Subject: Myocardial Strain Imaging
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Description/Scope

This document addresses the use of myocardial strain imaging to detect subclinical cardiac dysfunction. Myocardial strain imaging is an additional analysis performed during conventional cardiac imaging (echocardiography or cardiac MRI). Myocardial strain imaging is theorized to be an improved sensitivity test over ejection fraction (EF) in monitoring ventricular function.

Notes:

- This document does not address cardiac imaging services including MRI. For criteria related to cardiac imaging, refer to applicable guidelines used by the plan.
- For more information on related topics, please see the following:
  - CG-MED-57 Cardiac Stress Testing with Electrocardiogram
  - MED.00134 Non-invasive Heart Failure and Arrhythmia Management and Monitoring System

Position Statement

Investigational and Not Medically Necessary:

Myocardial strain imaging in considered **investigational and not medically necessary** for all indications.

Rationale

Cancer therapy-related cardiac dysfunction (CTRCD)

A 2019 meta-analysis looked at the value of global longitudinal strain (GLS) in detecting early subclinical ventricular dysfunction. The meta-analysis focused on the prognostic role of GLS before or during chemotherapy for subsequent CTRCD. A total of 21 prospective and retrospective studies (n=1782) which reported on the prognostic or discriminatory performance of early GLS analysis and CTRCD development in individuals undergoing potentially cardiotoxic chemotherapy. The meta-analysis reported that a relative reduction in GLS from baseline or a lower absolute GLS value early during chemotherapy may be used to identify individuals at high risk for CTRCD development. There were limitations associated with this meta-analysis including heterogeneity within the studies and several sources of potential bias. None of the studies evaluated the clinical outcomes of GLS monitoring against EF monitoring.

In 2023, Kar and associates evaluated whether GLS computed from left ventricular (LV) MRI is an early prognostic factor of CTRCD in individuals with breast cancer who were treated with anthracyclines and trastuzumab (n=32). Individuals were evaluated at baseline, 3 months and 6 months. The study incorporated multiple contractile prognostic factors, including, but not limited to GLS, LVEF, blood pressure and heart rate. GLS was the only marker which did not revert to baseline at the 6-month follow-up. The authors concluded that the 3-month GLS was an early, independent prognosticator of incident CTRCD risk. The study contained several limitations including a single-center design in which 18% of eligible individuals did not participate. The study was limited to determining GLS strength for prognosticating CTRCD on a research basis.

The Strain Surveillance of Chemotherapy for Improving Cardiovascular Outcomes (SUCCOUR) trial is an international, multicenter, prospective, randomized controlled trial (RCT) to identify and evaluate global longitudinal strain (GLS) as a sensitive marker of LV dysfunction in individuals undergoing potentially cardiotoxic chemotherapy (Thavendiranathan; 2021). Individuals considered high risk for heart failure who were undergoing anthracycline therapy were included. Participants were monitored for myocardial dysfunction and allocated to one of two arms: monitoring based on GLS (n=166) or usual care, which is monitoring based on LVEF (n=165). CTRCD was defined as a symptomatic drop of > 5% or an asymptomatic drop of > 10% in LVEF or a ≥ 12% relative reduction in GLS. Once CTRCD was diagnosed in either group, cardioprotective therapy (CPT) was initiated. The primary study outcome was the difference in LVEF between the arms at one year follow-up. At baseline, there were no significant differences in LVEF or GLS between the groups. At one year follow-up, the final LVEF was similar between the groups (55 ± 7% versus 57 ± 6%, respectively; p = 0.050). The authors surmised that the lack of difference between the groups could be the result of an increase in LVEF at the final visit in individuals who did not develop CTRCD. An analysis limited to participants who were diagnosed with CTRCD and received CPT showed that individuals in the GLS-monitored group had a significantly lower reduction in LVEF from baseline compared to those in the usual care group.

The 3-year outcomes from the SUCCOUR trial were reported (Negishi, 2023). At the 3-year follow-up, 77% of the original group participated in the evaluation; 132/166 individuals in the GLS group and 123/165 individuals in the usual care group. CPT was initiated in a total of 18 individuals (14.6%) in the usual care group and 41 individuals (31%) in the GLS group. At 3 years, the mean EF and GLS had returned to baseline in both arms and the change in EF did not significantly differ between the groups (-0.03% ± 7.9% in the usual care group compared to -0.02% ± 6.5% in the GLS group). The authors concluded that the clinical outcomes did not show that GLS based monitoring was superior to EF monitoring.

Summary

The goal of myocardial strain imaging when used before or during chemotherapy is to identify individuals who might be at increased risk of developing CTRCD or to monitor for subclinical changes prior to EF changes. The current evidence does not show that the use of GLS to monitor for the need of cardioprotective therapies results in improved clinical outcomes.

Heart Failure (HF)

In an observational, prospective, single center cohort study, Tröbs and colleagues (2021) assessed the factors associated with GLS and its prognostic value in individuals with chronic HF. Individuals categorized with stages A through D heart failure were included (n=2186). GLS was measured during echocardiogram. Annual follow-up was done to obtain information about clinical outcomes including all-cause mortality and cardiac death. “Mean (SD) GLS worsened across AHA HF stages A (n=434; –19.44 [3.15%]), B (n=629; −18.01 [3.46%]), and C/D (n=1123; −15.52 [4.64%])". The authors concluded that in individuals with chronic HF "GLS is associated with clinical and cardiac status, reflects neurohormonal activation, and is associated with cardiac mortality independent of clinical and cardiac status. Thus, GLS may serve as a useful tool to improve risk stratification in patients with HF." The results of this study were not externally validated.

Summary

There are a number of studies focusing on myocardial strain imaging and the potential prognostic value of this imaging which suggest that myocardial strain, particularly GLS, might improve risk stratification in individuals with heart failure (Chen, 2022; Pellicori, 2014; Pozios, 2018; Tröbs, 2021; Vasquez, 2019). The results of these studies do not show how GLS testing will change management or improve clinical outcomes.

Other applications

Myocardial strain imaging, global and segmental strain, has been studied as a way to identify and localize scar tissue in ischemic and nonischemic cardiomyopathy (ICM and NICM). Several studies have reported a linear correlation between global and regional longitudinal strain and scar percentage is linear. Further validation is needed to confirm these results and to investigate whether there is a role for myocardial strain results to affect treatment and clinical outcomes (Amzulescu, 2019; Paiman, 2019; Trivedi, 2021; Trivedi, 2022).

Speckle-tracking echocardiography (STE) and GLS has been evaluated as a predictor of adverse outcomes in the general population. There appears to be some association between GLS values and cardiovascular outcomes. It appears that GLS might be a prognostic factor independent of conventional risk factors, such as LVEF. Risk factors, such as older age, hypertension and diabetes are also associated with changes in GLS in the absence of LVEF dysfunction (Al Saikhan, 2019).

Strain imaging has been proposed as a means of diagnosing or assessing multiple cardiac conditions including ischemic heart disease, hypertensive heart disease, dilated cardiomyopathy, hypertrophic cardiomyopathy, myocarditis, and infiltrative cardiomyopathies (Bjerregaard, 2023; Li, 2020; Neisius, 2019; Piella, 2010; Reichek, 2017). GLS has also been proposed as a prognostic tool for evaluating the risk of ventricular arrhythmias in individuals with hypertrophic cardiomyopathy (HCM). Cardiac conditions are typically diagnosed using a combination of modalities. Imaging can be a component used to diagnose or manage conditions. There is a paucity of evidence that supports that strain imaging is able to provide additional relevant clinical information when used in combination with other modalities and standard imaging. In 2019, Neisius and associates evaluated if GLS derived from cardiovascular magnetic resonance myocardial feature tracking (CMR-FT) could be used to differentiate between hypertensive heart disease and HCM. The authors concluded:

> GLS's diagnostic accuracy is similar to CMR markers of myocardial fibrosis and LVH. However GLS's discriminatory ability limits its clinical application and emphasizes the difficulty to differentiate the two diseases based on cardiac imaging alone.

Studies report that individuals with HCM showed reduced systolic function, as demonstrated by GLS, when compared to individuals without HCM, despite similar EF between the groups. GLS, along with other markers, such as mechanical dispersion or fibrosis may play a role in assessing individuals with HCM to provide additional information regarding risk of ventricular arrhythmias and sudden cardiac death. Further studies with larger populations for a longer period of time are needed to validate results and to determine clinical reference ranges (for example, normal and threshold ranges) which address clinical and technical variability (Biering-Sørensen, 2017; Haland, 2016; Ibrahim, 2020; Piella, 2010).

Guidelines and Recommendations

In 2017, the American Society of Clinical Oncology (ASCO) developed recommendations for the prevention and monitoring of cardiac dysfunction in individuals who survived adult-onset cancers (Armenian, 2016). In individuals with the clinical signs and symptoms of cardiac dysfunction during routine clinical assessment, multiple diagnostic techniques are listed, including the following:

- Serum cardiac biomarkers (troponins, natriuretic peptides) or echocardiography-derived strain imaging in conjunction with routine diagnostic imaging (Evidence based; benefits outweigh harms; Evidence quality: intermediate; Strength of recommendation: moderate)

At the time of recommendation publication, ASCO noted that there were no studies demonstrating that early intervention based on strain alone resulted in a clinically significant risk reduction, but noted that the SUCCOUR trial would provide insight when completed.

A 2019 Appropriate Use Criteria (AUC) document on imaging use in the assessment of cardiac structure and function in nonvalvular heart disease authored by multiple societies (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) lists scenarios and recommendations for multiple imaging modalities, including strain imaging and is based upon the 2014 American Society of Echocardiography (ASE) consensus report. The AUC considers strain/strain rate imaging by speckle or tissue doppler as appropriate for the following indications:

- Initial evaluation prior to exposure to medications/radiation that could result in cardiotoxicity/heart failure
- Evaluation of suspected hypertrophic cardiomyopathy
- Re-evaluation (<1 y) in a patient previously or currently undergoing therapy with potentially cardiotoxic agents
- Periodic re-evaluation in a patient undergoing therapy with cardiotoxic agents and worsening symptoms.

The American Society of Echocardiography and the European Association of Cardiovascular Imaging published an expert consensus report on imaging of adults during and after cancer therapy (Plana, 2014). The report includes the following key points:

Myocardial deformation (strain) can be measured using DTI or 2D STE. The latter is favored because of a lack of angle dependency.

- GLS is the optimal parameter of deformation for the early detection of sub-clinical LV dysfunction.
- Ideally, the measurements during chemotherapy should be compared with the baseline value. In patients with available baseline strain measurements, a relative percentage reduction of GLS of <8% from baseline appears not to be meaningful, and those >15% from baseline are very likely to be abnormal.
- When applying STE for the longitudinal follow-up of patients with cancer, the same vendor-specific ultrasound machine should be used.

The report also contains a list of strengths and weaknesses of GLS:

Strengths:	• Superiority in the prediction of all-cause mortality in the general population compared with LVEF • Improved risk stratification in patients with HF • Ability to recognize early LV dysfunction in patients undergoing cardiotoxic therapy and prognosticate subsequent CTRCD • Reproducible when performed by trained operators
Limitations	• Heavy dependence on the quality of the 2D echocardiographical images • Influenced by loading conditions • Lack of long-term randomized clinical trials evaluating the ability of GLS to predict persistent decreases in LVEF or symptomatic HF • Lack of data as to the reproducibility of GLS in non-academic centres or community hospital • Vendor and software specific

The 2022 American Society of Echocardiography, the American Society of Nuclear Cardiology, the Society for Cardiovascular Magnetic Resonance, and the Society of Cardiovascular Computed Tomography addresses strain imaging in the recommendations for imaging of individuals with hypertrophic cardiomyopathy (Nagueh, 2022). The guideline categorizes LV GLS as an emerging marker, noting that abnormal results are associated with a worse prognosis, but there is no clear threshold value. There is also a lack of standardization between platforms, further complicating the use of GLS values as an established prognostic tool.

The 2021 expert consensus statement on imaging for cardiac amyloidosis recommend speckle-tracking strain analysis in the diagnostic and prognostic phase and to monitor therapy (Dorbala, 2021). A comprehensive 2D echocardiography, which includes strain analysis (when available) is recommended as a diagnostic tool when there is a clinical suspicion of cardiac amyloidosis and unexplained LV wall thickening, as a prognostic tool and as a management tool whenever a speckle-tracking echocardiogram is performed. While an endomyocardial biopsy is considered the gold standard in diagnosing cardiac amyloidosis, the use of this test is limited by the inherent risks associated with an invasive procedure and the limited availability of providers to perform testing. Other modalities used to diagnose and manage cardiac amyloidosis are biomarkers and other imaging techniques including cardiac resonance imaging (CMR) and radionuclide imaging with bone-avid radiotracers. The guideline notes that when cardiac amyloidosis is present, abnormalities in several echocardiographic imaging parameters, such as left ventricular longitudinal strain, signal potential advanced disease. However, there are no formal staging systems using echocardiographic parameters. For this reason, the results of an echocardiogram should not be used in isolation to determine risk in an individual with cardiac amyloidosis. The authors note:

> Additional studies to assess the optimal risk-stratification algorithm that incorporates multiple echocardiographic parameters are needed. Moreover, further study is needed to demonstrate the incremental value of echocardiographic parameters over simple clinical markers (eg, New York Heart Association functional class, B-type natriuretic peptide, troponin, glomerular filtration rate) and radionuclide and CMR imaging findings.

The National Comprehensive Cancer Network® (NCCN) Clinical Practice Guideline (CPG) on systemic light chain amyloidosis recommend either echocardiogram with strain assessment to examine longitudinal strain or cardiovascular magnetic resonance (CMR) to evaluate for possible cardiac involvement in systemic light chain amyloidosis (V1.2024). There were no studies cited to support the recommendation regarding the use of an echocardiogram with strain imaging. When there is a clinical suspicion of cardiac amyloidosis, only CMR is recommended as an imaging modality.

Background/Overview

Myocardial strain is defined as the deformation (i.e., shortening, lengthening or thickening) within the myocardium during the cardiac cycle. Strain imaging has been proposed as an aid in diagnosis and prognosis of cardiac disease including coronary artery disease, ischemic cardiomyopathy, valvular heart disease, dilated cardiomyopathy, hypertrophic cardiomyopathies, stress cardiomyopathy, and chemotherapy-related cardiotoxicity. Similar to EF, strain imaging is intended to provide a load-dependent estimation of left ventricular function. However, unlike EF, strain imaging provides a more in-depth quantification of LV mechanics by providing information regarding the spatial components of contractile function in either longitudinal strain (LS), circumferential strain (CS), or radial strain (RS) directions, both globally and regionally. Myocardial deformation can be evaluated using either echocardiographic (2D or 3D) or cMR images.

The process begins by identifying the cardiac events (end-diastole [ED] and end-systole [ES]). The operator then defines and segments the region of interest to be tracked. The area of interest is then tracked throughout the cycle, and strain curves are calculated. There is an element of variability which is dependent upon user and segmentation algorithm. Strain rates are affected by a number of variables including afterload and preload at the myocyte level and intrinsic load-independent myocardial contractility and myocardial composition (Amzulescu, 2019; Reichek, 2017). Greater deformation is indicated by lower strain values.

Cardiotoxic chemotherapy regimens are associated with significant treatment related morbidity and mortality. Heart failure can occur during or after therapy. Anthracycline therapy decreases myocardial systolic function as quickly as 2 hours after the first dose (Plana, 2014). LVEF surveillance has traditionally been used to monitor cardiac function. Myocardial dysfunction identified by changes in LVEF typically has progressed to a stage where complete recovery is limited. Global strain has been proposed as a way to identify subclinical disease prior to permanent damage occurring (Thavendiranathan, 2021).

- The universal use of cardioprotection in patients at risk of CTRCD would be effective for the prevention of dysfunction, but even the most sensitive indicators of LV dysfunction show that it does not develop in 80% of cases. Evaluating an appropriate screening process is challenging when there is a low probability of developing disease, in this case significant LV dysfunction (Negishi, 2023).

Definitions

Cancer therapy–related cardiac dysfunction (CTRCD): Toxicity that affects the heart, including myocardium but also the pericardium, endocardium, and coronary vasculature. Previously known as cardiotoxicity.

Myocardial strain imaging: Non-invasive method of evaluating the function of the heart muscle by measuring myocardium deformation.

Myocardial Strain: The unitless measurement of local or regional shortening, thickening or lengthening of the myocardium during the cardiac cycle. The results are reported as a percentage (change in length as a proportion to baseline length).

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

When services are Investigational and Not Medically Necessary:
For the following procedure codes, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
93356	Myocardial strain imaging using speckle tracking-derived assessment of myocardial mechanics echocardiography [List separately in addition to codes for echocardiography imaging]
HCPCS	
C9762	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging
C9763	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging
ICD-10 Diagnosis	
	All diagnoses

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
New	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

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