Acoustic Cardiography
Archived Medical Policy

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

Based on review of available data, the Company considers acoustic cardiography for the diagnosis of heart failure and for the optimization of cardiac resynchronization therapy hemodynamic parameters to be **investigational.***

Background/Overview
Acoustic cardiography is a technique that simultaneously records the electrical and acoustical aspects of the heart. By integrating the acoustic and electric properties, acoustic cardiography is intended to enhance the diagnostic ability of simple auscultation. The information from acoustic cardiography has also been used to optimize hemodynamic parameters for device placement, particularly with cardiac resynchronization therapy (CRT).

Acoustic cardiography utilizes three inputs: a single EKG lead from two standard electrodes, and two audio sensors placed at the usual V3 and V4 positions on the chest. These three channels synchronously record electrical and audio information. The audio information is processed using wavelet signal processing techniques and a diagnostic algorithm that filters out extraneous noise and uses time-frequency analysis to objectively define the heart sounds and the intervals between sounds. An analogue visual display of the audio data is then displayed and paired with the electrical data from the EKG recording.

Output from acoustic cardiography can generate numerous parameters, some of which may have clinical applicability. Three of these measures are: 1) S3 strength - a quantitative measure of the intensity of the S3 heart sound, which is an abnormal sound that is associated with systolic dysfunction. 2) Electromechanical activation time (EMAT) defined as the interval between the onset of the QRS complex and the closure of the mitral valve. EMAT is the main parameter that is used to optimize CRT therapy by choosing the interval that optimizes cardiac output. 3) Left ventricular systolic time (LVST) - the interval between mitral valve closure and aortic valve closure. This length of the LVST has been correlated with changes in ejection fraction.

Auscultation for an S3 is part of the physical exam when evaluating for presence of heart failure. The presence of an S3 indicates systolic dysfunction, and is a specific physical exam finding supporting systolic heart failure. The S3 is an indistinct sound that can be difficult to hear, and is not present in all patients with systolic dysfunction. Other components of the diagnostic evaluation for heart failure include a variety of

clinical symptoms and physical exam findings such as dyspnea, orthopnea, pulmonary rales, increased jugular venous pressure, and peripheral edema. Routine diagnostic evaluation for heart failure also includes measurement of brain natriuretic peptide (BNP), and other common laboratory measures, and a chest x-ray. A direct measure of ejection fraction by echocardiography, nuclear medicine imaging, or other imaging modalities is a crucial component of clinical evaluation for heart failure. Systolic dysfunction can be confirmed by echocardiography and/or other imaging modalities.

Optimization of CRT therapy is usually done using Doppler echocardiography. Optimization involves manipulation of the atrio-ventricular (AV) and interventricular (VV) pacer settings in order to maximize LV filling and stroke volume. Some evidence has reported that optimization improves overall clinical benefit, but this data is not uniform. Also, whether re-optimization should be performed following initial optimization is controversial, as is the timing of re-optimization if it is performed.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
The Audicor™‡† system and electrodes received 510(k) marketing clearances from the FDA for "use in acquiring, analyzing and reporting EGG and heart sounds (phonocardiograph) data and to provide interpretation of the data for consideration by physicians."

Rationale/Source

The majority of studies of acoustic cardiography identified in the literature evaluate the technology in two general areas. First, it has been used as an aid for the diagnosis of systolic function, primarily using S3 detection, or S3 strength, compared to auscultation alone. Other studies have used acoustic cardiography for optimization of CRT, utilizing the parameter of EMAT and comparing this method of optimization to Doppler echocardiography. These two categories of evidence are examined separately as follows.

In patients with suspected heart failure, does acoustic cardiography improve the ability to diagnose systolic dysfunction, compared with auscultation only?

Michaels et al. evaluated whether acoustic cardiography improved detection of S3 and S4 in 90 patients referred for angiography. A total of 35 subjects at various levels of clinical experience, from medical student to attending, listened to recordings of each patient's heart sounds using auscultation alone, and then using both auscultation and acoustic cardiography. The gold standard for the presence or absence of heart sounds was the consensus of 2 experienced readers who were blinded to other aspects of the study.

There was improvement in the ability to detect S3 in each cohort of clinical training, with overall accuracy improving by between 2-18%. The improvement in accuracy was statistically significant for more experienced trainees but not for medical students. For example, using auscultation alone, residents

detected an S3 correctly in 68% of patients. This improved to 85% when auscultation was combined with acoustic cardiography. For attending physicians, the accuracy of S3 detection was 72% with auscultation alone, and this was improved to 80% ($p<0.01$) with the addition of acoustic cardiography.

Maisel et al. evaluated the predictive ability of acoustic cardiography for acute heart failure in 995 patients older than 40 years who presented to the emergency department (ED) with dyspnea. The main parameter used was the strength of the S3 sound graded on a 0-10 scale. The gold standard for the diagnosis of acute heart failure (AHF) was consensus by 2 cardiologists who were blinded to the results of acoustic cardiography. For the entire population, the S3 strength was predictive of AHF in univariate analysis but was not an independent predictor in multivariate analysis. For the subpopulation of patients who were labeled as 'gray zone' patients based on an intermediate level of BNP (100-499 pg/mL), the information from acoustic cardiography improved the diagnostic accuracy of AHF from 47-69%. Another potentially problematic subgroup examined was obese patients (body mass index [BMI] >30), in whom auscultation is often more difficult. In this population, the sensitivity of S3 detection improved from 14-28% with the addition of acoustic cardiography, but the specificity decreased from 99-88%.

A second study compared the diagnostic accuracy of acoustic cardiography with brain natriuretic peptide (BNP) in 433 patients who had results from acoustic cardiography, BNP, and echocardiography. Echocardiography was used as the gold standard to diagnosis of systolic dysfunction. When compared to BNP alone, acoustic cardiography was more accurate in diagnosing systolic dysfunction (area under-the curve [AUC] 0.88 vs. 0.67, respectively; $p<0.0001$). When confined to patients with BNP levels in the indeterminate range, acoustic cardiography also outperformed BNP in diagnosing systolic dysfunction (AUC 0.89 vs. 0.64, respectively; $p<0.0001$).

Wang et al. evaluated the ability of acoustic cardiography to distinguish between patients who had heart failure with systolic dysfunction (n=89), heart failure with normal systolic function (n=94), and hypertension without clinical heart failure (n=109). All patients underwent acoustic cardiography and echocardiography, and the diagnostic accuracy of acoustic cardiography was compared to echocardiography. For distinguishing patients with hypertension from patients with heart failure and normal systolic function, the sensitivity of acoustic cardiography was 55%, the specificity was 90%, and the area under the curve was 0.83. For distinguishing heart failure and normal systolic function from heart failure with systolic dysfunction, the sensitivity of acoustic cardiography was 53%, the specificity was 91% and the area under the curve was 0.81. These values were not significantly different from echocardiography for any of the measures reported.
Conclusions. Acoustic cardiography may improve the accuracy of detection of an S3 heart sound, although this finding has not been consistent in all subgroups examined. Acoustic cardiography has not been demonstrated to be an independent predictor of the diagnosis of acute heart failure when combined with other relevant clinical information. In order to demonstrate an incremental benefit in the diagnosis of heart failure, the improvement in diagnostic accuracy with and without acoustic cardiography must be in the context of the entire spectrum of clinical information collected routinely in the workup of a patient with

suspected heart failure. For example, two studies report that acoustic cardiography improves the accuracy of heart failure diagnosis for patients with a "gray zone" BNP. However, a gray zone BNP does not necessarily mean the diagnosis of heart failure is uncertain when all clinical information is considered; therefore, this type of evidence is not sufficient to conclude that acoustic cardiography improves the diagnosis of heart failure.

In patients treated with a CRT device, does optimization of hemodynamic parameters by acoustic cardiography improve outcomes, compared to optimization by Doppler echocardiography?

Toggweiler et al. reported that optimization of CRT settings by EMAT resulted in improved measures of clinical and hemodynamic factors such as work capacity, maximum oxygen uptake, ejection fraction, and end-systolic volume. However, this study did not compare EMAT with Doppler echocardiography and thus does not offer relevant data on this question.

Zuber et al. reported the correlation of optimal AV and VV intervals, as determined by echocardiography and acoustic cardiography in 43 patients with a CRT device. There was a high correlation for the optimal AV delay intervals ($r=0.86$, $p<0.001$) and a moderate correlation for the VV delay intervals ($r=0.58$, $p<0.05$). These authors also reported that the test-retest reproducibility was higher for the EMAT method ($r=0.91$) than for echocardiography ($r=0.35$) and that the intraobserver variability was similar for EMAT versus echocardiography (9.9% vs. 8.5%, respectively).

In a similar study, Hasan et al. reported the correlation of acoustic cardiography and echocardiography for optimization of CRT in 22 subjects. The correlation between the overall values as determined by each method was high ($r=0.90$, $p<0.001$). In the majority of patients (77.3%), the values obtained from echocardiography and acoustic cardiography were within 20 msec of each other. The authors also reported that acoustic cardiography took less time to perform and was easier to interpret.

Taha et al. also evaluated the correlation of acoustic cardiography with echocardiography for optimization of CRT settings, using the parameter of S3 signal strength rather than EMAT. There was a high correlation between the 2 parameters for optimization of AV delay ($r=0.86$, $p<0.001$) and a somewhat lower correlation for optimization of VV delay ($r=0.64$, $p<0.001$). For VV delay, the optimal intervals were identical in 56% of patients, and for VV delay the optimal intervals were identical in 75% of patients.

Zuber et al. evaluated the agreement in optimal AV and VV values using a number of different optimization methods in 20 patients treated with a CRT device. The different methods included various sequencing of Doppler echocardiography and EMAT parameters. There was poor agreement between the different methods of optimization, and there was not one method that was clearly preferable to the others.

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Conclusions. There is a high correlation between optimization of CRT settings by Doppler echocardiography and acoustic cardiography using EMAT values. EMAT may be simpler and easier to perform compared to Doppler echocardiography. However, it is extremely unlikely that clinical centers performing CRT optimization would not have expertise in performing echocardiography for this purpose. There is no evidence that health outcomes are improved when using acoustic cardiography for optimization compared to echocardiography.

Summary

Acoustic cardiography is a technique that integrates electric and acoustic information in order to enhance the ability to detect and characterize heart sounds. Published literature has evaluated the use of acoustic cardiography in two areas: 1) as an aid in the diagnosis of heart failure, and 2) for optimization of hemodynamic parameters in patients with a CRT device.

A number of published articles support that acoustic cardiography improves the detection of an S3 compared to auscultation alone. However, there is no evidence that acoustic cardiography contributes independent predictive information when added to a standard clinical workup for heart failure that includes physical exam findings, laboratory testing, and routine imaging studies.

When used to optimize CRT settings, several studies report that acoustic cardiography has a high correlation with Doppler echocardiography. No studies have demonstrated that acoustic cardiography is superior to echocardiography for this purpose, and therefore, there is no evidence that acoustic cardiography improves outcomes when used for optimization of CRT therapy.

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Code Type	Code
CPT	0223T, 0224T, 0225T
HCPCS	No code
ICD-9 Diagnosis	All diagnoses
ICD-9 Procedure	No code

Policy History

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B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
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