



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Correlated Audioelectric
Cardiography**

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Microvolt T-Wave Alternans
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Analysis

INSTRUCTIONS FOR USE

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Coverage Policy

CIGNA does not cover correlated audioelectric cardiography because it is considered experimental, investigational or unproven.

General Background

Correlated audioelectric cardiography is a noninvasive diagnostic tool designed to be used in the evaluation of cardiac conditions such as left ventricular hypertrophy (LVH), acute and age-undetermined myocardial infarction (MI), cardiac arrhythmias, and detection of S3 and S4 heart sounds. An S3 heart sound may be associated with heart failure in patients over age 40. Correlated audioelectric cardiology is intended to augment physician auscultation, since S3 and S4 heart sounds may be difficult to hear in some patients. The device acquires, displays, and analyzes 12-lead electrocardiogram (ECG) and heart sound data (Collins et al., 2006; Kobza et al., 2008; Wagner et al., 2002; Warner et al., 2002).

Traditional diagnostic methods include physical examination and auscultation, 12-lead ECG laboratory examinations, measurement of biomarkers of cardiac damage, and imaging.

U.S. Food and Drug Administration (FDA)

The Eli 200+ Audicor (Mortara Instrument, Inc., Milwaukee, WI) is an interpretive electrocardiograph device designed to acquire, record and store cardiac data. The device uses Audicor Correlated Audioelectric Cardiography (COR) technology (Inovise Medical, Inc., Newberg, OR) to simultaneously acquire both 12-lead

electrocardiogram (ECG) and heart sound data. The Eli 200+ Audicor received U.S. Food and Drug Administration (FDA) clearance to market as a Class II device through the 510(k) process on July 25, 2003. The device was considered a technology evolution and substantially equivalent to the ELI 200, Inovise's Cardiovisc Interpretive Software, and Hewlett Packard's 1514A ECG/Phono System.

The FDA 510(k) notification of clearance to market the Eli 200+ Audicor included the following indications for use:

- The device is indicated for use to acquire, analyze, display and print ECG and heart sound data (COR).
- The device is indicated for use to provide interpretation of the data for consideration by physicians.
- The device is indicated for use in a clinical setting by a physician or by trained personnel and is not intended as a sole means of diagnosis.
- The interpretations of ECG and heart sound data (COR) offered by the device are only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.
- The device is intended for use on adult populations, typically symptomatic.
- The device is not intended to be used as a vital signs physiological monitor.
- The device is indicated for evaluation of cardiac conditions such as left ventricular hypertrophy (LVH), acute and age-undetermined myocardial infarction (MI), and detection of S3 and S4 heart sounds.

On October 31, 2003, the Audicor Upgrade System received FDA clearance as a Class II device through the 510(k) process. The Audicor Upgrade System is an add-on device used with Audicor Sensors in the V3 and V4 positions on the chest wall. The system consists of a pocket personal computer (PC) with proprietary software and can be used with several models of existing electrocardiographs to allow physicians access to the COR report, including graphical display of MI and LVH conditions, display of heart sound waveforms, and identification of S3 and S4 heart sounds.

The Zargis Acoustic Cardioscan (Zargis Medical Corporation, Princeton, NJ) received FDA approval through the 510(k) process on May 26, 2004. The system is an electronic auscultatory device intended to acquire, record, and analyze heart sounds. The system consists of an electronic stethoscope, notebook computer, software, printer and an isolation transformer. According to the FDA indications for use, the device acquires and records the acoustic signals of the heart and analyses these signals. The analysis procedure will identify specific heart sounds that may be present, including S1, S2, and suspected murmurs. The approval lists the Audicor system as a predicate device.

Literature Review

Published studies have evaluated the use of Cardiovisc diagnostic software, a predicate device and component of the Audicor System, for the detection of acute and prior MI (Wagner, et al., 2002; Andresen, et al., 2002). Published studies involving the Audicor system or correlated audioelectric cardiography are limited.

Collins et al. (2009) conducted a multisite study to evaluate the effect of an S3 captured by acoustic cardiography on diagnostic accuracy and confidence in the diagnosis of acute decompensated heart failure in patients presenting to the emergency department (ED) with dyspnea (n=995). The study also evaluated the impact on patient prognosis. ED physicians who were initially blinded to all laboratory and acoustic cardiography results estimated the probability of acute decompensated heart failure on a scale of 0% to 100% on a visual analog scale. The visual analog scale was repeated after acoustic cardiography results were provided. Patients were followed for 90 days to determine the relationship of the S3 to adverse events. The initial sensitivity, specificity, and accuracy for acute decompensated heart failure as a possible diagnosis were 89.0%, 58.2%, and 71.0%, respectively. Sensitivity, specificity, and accuracy for acoustic cardiography were 40.2%, 88.5%, and 68%, respectively. The authors concluded that acoustic cardiography S3 was specific to acute decompensated heart failure, but did not improve diagnostic accuracy, primarily because of the low sensitivity. In addition, the acoustic cardiography S3 provided no significant independent prognostic information.

Kobza et al. conducted a case series to test the hypothesis that recorded digital cardiac acoustical data reflect hemodynamic changes that can be used for ventricular tachycardia (VT) detection (n=57). Acoustic cardiography using the Audicor device was performed during electrophysiological (EP) testing for known or suspected cardiac arrhythmias. The researchers evaluated the ability of S1 intensity and variability to discriminate between VT and supraventricular rhythm. The 57 patients had 17 episodes of VT and 76 episodes

of supraventricular rhythm. VT had a lower S1 intensity and higher S1 variability than supraventricular rhythm. The authors concluded that electronic recording and digital processing of digital heart sound data is useful for identifying VT and may facilitate the differential diagnosis of clinically important tachyarrhythmias, particularly when advanced techniques such as EP studies are not available.

Collins et al. (2006) evaluated the use of an S3 heart sound combined with B-type natriuretic peptide (BNP) levels in the diagnosis of emergency room patients with dyspnea. The author concluded that an S3 sound is highly specific for heart failure and is ideally suited for use in combination with BNP to improve diagnostic accuracy. The sensitivity, specificity, positive and negative predictive value, and diagnostic accuracy of the electronic S3 for primary heart failure were 34%, 93%, 66%, 7%, and 70%, respectively. The values obtained by physician auscultation were 16%, 97%, 84%, 3%, and 66%, respectively. The addition of an Audicor S3 to intermediate BNP levels improved the positive likelihood ratio from 1.3 to 2.9 and improved the positive predictive value from 53% to 80%. The overall ER misdiagnosis rate was 14%. Of the 48 cases, 44 were a failure to diagnose heart failure when it was present. If the Audicor had been used as the sole diagnostic tool among these 44 ultimately considered to have primary HF, 15 would have been correctly diagnosed. Similarly, if the Audicor tool had been used as the sole diagnostic tool, 14 of the 206 patients correctly diagnosed as nonprimary HF would have been incorrectly diagnosed as primary HF. Although the evaluation of S3 heart sounds in combination with BNP testing may improve diagnostic accuracy in patients with dyspnea of unclear etiology, this study does not demonstrate that the Audicor system provides a benefit, when used alone or in combination with other tests, in terms of improved clinical outcomes.

Marcus et al. (2006) conducted a prospective study to determine the diagnostic test characteristics of the S3 and S4 heart sounds for prediction of left ventricular dysfunction using the Audicor system in patients undergoing elective left-sided heart catheterization (n=90). Patients underwent computerized heart sound phonocardiographic analysis (Audicor system) for assessment of S3/S4 heart sounds, cardiac catheterization for assessment of left ventricular end-diastolic pressure (LVEDP), transthoracic echocardiography for evaluation of left ventricular ejection fraction (LVEF), and blood sampling for BNP. Mean LVEDP was significantly elevated; LVEF was reduced; and median BNP was elevated in those with an S3, S4, or both, compared to patients without a diastolic heart sound. The sensitivities of these heart sounds to detect an elevated LVEDP, reduced LVEF, or elevated BNP were 41%, 52%, 32% for an S3, and 46%, 43%, and 40% for an S4, respectively. The authors concluded that neither the phonocardiographic S3 nor the S4 is a sensitive marker of left ventricular dysfunction. The absence of an S3 or S4 using phonocardiographic testing (Audicor system) is therefore not sufficient to exclude ventricular dysfunction. If present, the phonocardiographic S3 and S4 are specific for an elevated LVEDP, depressed LVEF, and elevated BNP level.

Professional Societies/Organizations

The American College of Cardiology/American Heart Association (ACC/AHA) Guidelines for the Management of Patients with ST-Elevation Myocardial Infarction (Antman, et al., 2004) and the ACC/AHA Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult (Hunt, et al., 2005), make no mention of correlated audioelectric cardiography or acoustic heart sounds as a diagnostic tool. In addition, this technology is not mentioned in AHA/ACC Recommendations for the Standardization and Interpretation of the Electrocardiogram, Part I (Kligfield, et al., 2007) and II (Mason, et al., 2007).

Summary

Correlated audioelectric cardiography has been proposed as a more accurate method for the detection of acute myocardial infarction (MI); the detection, sizing and location of prior MI; detection of left ventricular hypertrophy (LVH); cardiac arrhythmias, and identification of S3 and S4 heart sounds. There is insufficient evidence in the published medical literature to demonstrate that the diagnostic accuracy of correlated audioelectric cardiography is equal or superior to traditional diagnostic tools, including physical examination and auscultation, 12-lead electrocardiogram, laboratory examinations, measurement of biomarkers of cardiac damage, and imaging, or that the use of this technology results in improved clinical outcomes.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

CPT Codes*	Description
93799	Unlisted cardiovascular service or procedure
0223T	Acoustic cardiography, including automated analysis of combined acoustic and electrical intervals; single, with interpretation and report
0224T	Acoustic cardiography, including automated analysis of combined acoustic and electrical intervals; multiple, including serial trend analysis and limited reprogramming of device parameters, AV or VV delays only, with interpretation and report
0225T	Acoustic cardiography, including automated analysis of combined acoustic and electrical intervals; multiple, including serial trend analysis and limited reprogramming of device parameters, AV and VV delays, with interpretation and report
0068T	Acoustic heart sound recording and computer analysis; with interpretation and report (code deleted 01/01/2010)
0069T	Acoustic heart sound recording and computer analysis; acoustic heart sound recording and computer analysis only (code deleted 01/01/2010)
0070T	Acoustic heart sound recording and computer analysis; interpretation and report only (code deleted 01/01/2010)

ICD-9-CM Diagnosis Codes	Description
	All codes

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	02/15/2008	0435	Correlated Audioelectric Cardiography

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