



BlueCross BlueShield  
of Alabama

---

**Name of Blue Advantage Policy:**  
**Acoustic Cardiography**

Policy #: 179

Latest Review Date: January 2022

Category: Medicine

---

**BACKGROUND:**

*Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational\*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
  - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
  - *Furnished in a setting appropriate to the patient's medical needs and condition;*
  - *Ordered and furnished by qualified personnel;*
  - *One that meets, but does not exceed, the patient's medical need; and*
  - *At least as beneficial as an existing and available medically appropriate alternative.*

*\*Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare** for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

## **POLICY:**

**Blue Advantage** will treat **acoustic cardiography** and **correlated audio-electric cardiography** as a **non-covered** benefit and as **investigational**.

*Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

## **DESCRIPTION OF PROCEDURE OR SERVICE:**

Acoustic cardiography, or correlated audio-electric cardiography, describes the synchronization of EKG tracings with acoustic heart sounds and provides an assessment of the mechanical and electrical function of the heart via computer analysis. There are several FDA approved devices for acoustic cardiography.

## **KEY POINTS:**

A literature search was conducted through January 14, 2022.

### **Summary of Evidence**

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 combined with standard clinical workup for heart failure such as physical exam findings, laboratory testing, and routine imaging studies. 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.

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; therefore, acoustic cardiography when used for optimization of CRT therapy is considered not medically necessary.

There is a lack of evidence for utilizing acoustic cardiography for detecting CAD. The current studies are small and with potential bias. One study failed to show non-inferiority and other

studies have been inconclusive. Acoustic cardiography for detecting CAD is considered investigational.

**KEY WORDS:**

Acoustic heart sound recording, correlated audioelectric cardiography, Audicor, Acarix, CADScor System

**APPROVED BY GOVERNING BODIES:**

Audicor (Inovise Medical, Inc) received 510(k) approval from the FDA on November 3, 2003, and was specifically for correlated audio-electric cardiography. According to the FDA label, the intended use is as follows: “The Audicor Upgrade System, when used with Audicor Sensors in the V3 and V4 positions on the chest wall, is intended for use in acquiring, analyzing and reporting ECG and heart sounds (phonocardiograph) data and to provide interpretation of the data for consideration by physicians.”

Zargis Acoustic Cardioscan (ZAC) received 510k clearance in May 2004. It is described as an electronic auscultatory device, intended to provide support to physicians in the evaluation of heart sounds in patients. The product will acquire and record the acoustic signals of the heart and analyze these signals. The analysis procedure will identify specific heart sounds that may be present. Identified sounds include S1, S2, and suspected murmurs. The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis. Interpretations of heart sounds offered by the Zargis Acoustic Cardioscan are only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data. (FDA, Indications for Use).

CADence received 510k clearance in August 2017. It is described as a “digital stethoscope used to record cardiac sounds, with integrated sensors used to record electrical activity of the heart (ECG)...” The indications go on to state that, “The CADence system is not intended to be a stand-alone diagnostic device. It does not supersede the judgment of the clinician.”

**BENEFIT APPLICATION:**

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

**CURRENT CODING:**

**CPT codes:**

93799	Unlisted cardiovascular service or procedure
-------	--

**REFERENCES:**

1. Arand P, Burton D, Myers R, et al. Diagnostic performance of a computerized algorithm for augmenting the ECG with acoustical data. *J Electrocardiol* 2003; 36 Suppl: 169.
2. Azimpour F, Caldwell E, Tawfik P, et al. Audible Coronary Artery Stenosis. *Am J Med.* 2016 May;129 (5):515-521.
3. Bertini M, Delgado V, Bax JJ et al. Why, how and when do we need to optimize the setting of cardiac resynchronization therapy? *Europace* 2009; 11:v46-57.
4. Blue Cross Blue Shield Association. *Correlated Audioelectric Cardiography. Medical Policy Reference Manual, September 2008.*
5. Chan W, Woldeyohannes M, Colman R et al. Haemodynamic and structural correlates of the first and second heart sounds in pulmonary arterial hypertension: an acoustic cardiography cohort study. *BMJ Open* 2013; 3(4).
6. Collins Sean P, Lindsell Christopher J, et al. The effect of treatment on the presence of abnormal heart sounds in emergency department patients with heart failure. *American Journal of Emergency Medicine* 2006; 24: 25-32.
7. Erne P. Beyond auscultation – acoustic cardiography in the diagnosis and assessment of cardiac disease. *Swiss Med Wkly* 2008; 138:439-52.
8. FDA. Audiocor System. Available at:  
[https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start\\_search=1&productcode=DPS&knumber=&applicant=INOVISE%20MEDICAL%2C%20INC](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=DPS&knumber=&applicant=INOVISE%20MEDICAL%2C%20INC).
9. FDA. CADence System. Available at:  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K170928>
10. FDA. CADence System. Available at:  
[https://www.accessdata.fda.gov/cdrh\\_docs/pdf17/K170928.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf17/K170928.pdf)
11. FDA. Zargis Acoustic Cardioscan. Available at:  
[https://www.accessdata.fda.gov/cdrh\\_docs/pdf3/K031517.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf3/K031517.pdf).
12. Hasan A, Abraham WT, Quinn-Tate L et al. Optimization of cardiac resynchronization devices using acoustic cardiography: a comparison to echocardiography. *Congest Heart Fail*, 2006; 12(suppl 1):25-31.
13. IOM (Institute of Medicine). 2011. *Clinical Practice Guidelines We Can Trust.* Washington, DC: The National Academies Press.
14. Kobza R, Roos M, Toggweiler S, et al. Recorded heart sounds for identification of ventricular tachycardia. *Resuscitation*, November 2008; 79(2): 265-272.
15. Kosmicki DL, Collins SP, Kontos MC et al. Noninvasive prediction of left ventricular systolic dysfunction in patients with clinically suspected heart failure using acoustic cardiography. *Congest Heart Fail* 2010; 16:249-53.

16. Maisel AS, Peacock WF, Shah KS et al. Acoustic cardiography S3 detection use in problematic subgroups and B-type natriuretic peptide “gray zone”: secondary results from the Heart failure and Audicor technology for Rapid Diagnosis and Initial Treatment Multinational Investigation. *Am J Emerg Med* July 12, 2010. [Epub ahead of print]
17. Michaels AD, Khan FU, Moyers B. Experienced clinicians improve detection of third and fourth heart sounds by viewing acoustic cardiography. *Clin Cardiol* 2010; 33:E36-E42.
18. Moyers B, Shapiro M, Marcus GM, et al. Performance of phonoelectrocardiographic left ventricular systolic time intervals and B-type natriuretic peptide levels in the diagnosis of left ventricular dysfunction. *Ann Noninvasive Electrocardiol*, April 2007; 12(2): 89-97.
19. Shitara J, Kasai T, Murata N, et al. Temporal changes of cardiac acoustic biomarkers and cardiac function in acute decompensated heart failure. *ESC Heart Fail*. 2021 Oct; 8(5): 4037-4347.
20. Taha N, Zhang J, Ranjan R et al. Biventricular pacemaker optimization guided by comprehensive echocardiography-preliminary observations regarding the effects on systolic and diastolic ventricular function and third heart sound. *J Am Soc Echocardiogr* 2010; 23:857-66.
21. Tavel Morton E and Katz Hart. Usefulness of a new sound spectral averaging technique to distinguish an innocent systolic murmur from that of aortic stenosis. *American Journal of Cardiology*, April 2005, Vol. 95, pp. 902-904.
22. Thomas JL, Ridner M, Cole JH, et al. The clinical evaluation of the CADence device in the acoustic detection of coronary artery disease. *Int J Cardiovasc Imaging*. 2018 Dec; 34(12):1841-1848.
23. Toggweiler S, Odermatt Y, Brauchlin A et al. The clinical value of echocardiography and acoustic cardiography to monitor patients undergoing anthracycline chemotherapy. *Clin Cardiol* 2013; 36(4):201-6.
24. Toggweiler S, Zuber M, Kobza R et al. Improved response to cardiac resynchronization therapy through optimization of atrioventricular and interventricular delays using acoustic cardiography: a pilot study. *J Card Fail* 2007; 13:637-42.
25. U.S. Food and Drug Administration (FDA). Zargis Acoustic Cardioscan (ZAC). 510(k) Summary of Safety and Effectiveness. [www.fda.gov/cdrh/pdf6/K060197.pdf](http://www.fda.gov/cdrh/pdf6/K060197.pdf)
26. Wang S, Fang F, Liu M et al. Rapid bedside identification of high-risk population in heart failure with reduced ejection fraction by acoustic cardiography. *Int J Cardiol* 2013; 168(3):1881-6.
27. Wang S, Lam YY, Liu M et al. Acoustic cardiography helps to identify heart failure and its phenotypes. *Int J Cardiol* 2012. [Epub ahead of print]
28. Wen YN, Lee APW, Fang F, et al. Beyaon auscultation: Acoustic cardiography in clinical practice. *International Journal of Cardiology*. 2014 April 1;172(3):548-560.
29. Yancy CW, Jessup M, Bozkurt B et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation* 2013; 128(16):e240-e327.

30. Zhang FW, Zhang YX, Si LY, et al. Value of acoustic cardiography in the clinical diagnosis of coronary heart disease. Clin Cardiol. 2021 Oct; 44(10): 1386-1392.
31. Zuber M, Erne P. Acoustic cardiography to improve detection of coronary artery disease with stress testing. World J Cardiol. 2010 May 26;2(5):118-24.
32. Zuber M, Toggweiler S, Quinn-Tate L et al. A comparison of acoustic cardiography and echocardiography for optimizing pacemaker settings in cardiac resynchronization therapy. Pacing Clin Electrophysiol 2008; 31:802-11.
33. Zuber M, Toggweiler S, Roos M et al. Comparison of different approaches for optimization of atrioventricular and interventricular delay in biventricular pacing. Europace, 2008; 10:367-73.

## **POLICY HISTORY:**

Adopted for Blue Advantage, March 2005

Available for comment May 1-June 14, 2005

Medical Policy Group, June 2006

Medical Policy Group, June 2007

Medical Policy Group, June 2009

Medical Policy Group, June 2011

Available for comment July 6 through August 22, 2011

Medical Policy Group, June 2012

Medical Policy Group, August 2013

Medical Policy Group, August 2014

Medical Policy Group, December 2015

Medical Policy Group, December 2020

Medical Policy Group, January 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.

Medical Policy Group, June 2022: Quarterly Coding Update. Added CPT code 0716T to Current Coding and added Key Words Acarix, CADScr System.

---

*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*