Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Acoustic Cardiography

Policy #: 179
Latest Review Date: December 2022
Category: Medicine
ARCHIVED EFFECTIVE 11/1/2023

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 December 13, 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
0716T	Cardiac acoustic waveform recording with automated analysis and generation of coronary artery disease risk score

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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.
Medical Policy Group, December 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, November 2023: Archived effective 11/1/2023.
