Acoustic cardiography/heart sound recording

Clinical Policy ID: CCP.1495

Recent review date: 9/2024

Next review date: 1/2026

Policy contains: Acoustic cardiography, acoustic heart sound recording, electronic heart auscultation.

Keystone First VIP Choice has developed clinical policies to assist with making coverage determinations. Keystone First VIP Choice's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First VIP Choice, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First VIP Choice's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First VIP Choice's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First VIP Choice will update its clinical policies as necessary. Keystone First VIP Choice's clinical policies are not guarantees of payment.

Coverage policy

Acoustic cardiography, or heart sound recording, is investigational/not clinically proven and, therefore, not medically necessary for cardiovascular diagnosis.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Physical examination.
- Laboratory testing.
- Routine imaging studies.

Background

Auscultation by stethoscope presents limitations in accurate cardiovascular diagnosis, specifically the inability to recognize murmurs of aortic regurgitation (both diastolic and systolic, but especially diastolic). Hand-held pocket-size echocardiography, digital stethoscopes, and acoustic cardiography are examples of recent technologies that attempt to improve sensitivity (Montinari, 2019).

Acoustic cardiography, also referred to as acoustic heart sound recording, is a diagnostic method that combines the heart sound waves from auscultation with an electrocardiogram to generate detailed information on systolic and diastolic left ventricular function, followed by computer interpretation. It is less operator dependent than a phonocardiogram and faster than a 12-lead electrocardiogram. Recent technical advances allow for ambulatory monitoring and capturing respiratory events. Acoustic cardiography is proposed for diagnosing early heart failure and ischemic heart disease, as well as sleep apnea, constrictive pericarditis, ventricular fibrillation, and left ventricular hypertrophy fibrillation (Wen, 2014).

In 2004, the U.S. Food and Drug Administration granted pre-market approval to Zargis Medical Corporation to market the company's Zargis Acoustic Cardioscan®, an electronic auscultatory device designed to measure specific heart sounds, including S1/S2 (first and second heart sounds), and suspected murmurs. The notification specified not to use the device as a sole means of diagnosis (U.S. Food and Drug Administration, 2004).

In 2011, the U.S. Food and Drug Administration granted pre-market approval to Inovise Medical Inc. for the Audicor® Sensor 4.0 with adapter to aid in diagnosis and determine effects of treatment on electrocardiography and hemodynamics in adults over age 18. Three years later, the Administration modified approval to include sleep disordered breathing and snoring detection only as a screening device for obstructive or mixed apnea to evaluate the need for polysomnography (U.S. Food and Drug Administration, 2011, 2014).

Findings

Guidelines

The American College of Cardiology and American Heart Association did not mention either correlated audioelectric cardiography or acoustic sound recording in their guidelines on managing ST-elevation myocardial infarction and heart failure (Anbe, 2018; Heidenreich, 2022).

Evidence review

The relative ease of use and low cost of ambulatory acoustic cardiography, in particular, make it an attractive option for monitoring heart failure in hospital and home settings. However, small sample sizes, inadequate follow up, and confounders of diagnostic accuracy (e.g., noise and movement) limit interpretation of the collective evidence base and the ability to establish a clinical role for acoustic cardiography in the management of patients with heart failure.

A systematic review and meta-analysis of 19 studies (n = 5,614) compared the diagnostic performance of S3 to left ventricular ejection fraction in detecting heart failure. Results were reported with 95% confidence intervals. Compared to left ventricular ejection fraction, S3 alone had lower sensitivity (0.23, 0.15 to 0.33 versus 0.70, 0.53 to 0.83) but higher specificity (0.94, 0.82 to 0.98 versus 0.79, 0.75 to 0.82). The predictive values of both measures were limited. S3 may have value in early pathological assessment using machine learning or deep learning methods (Dao, 2022).

Individual studies (n > 100), reported below, attempt to establish the diagnostic accuracy of acoustic cardiography, to correlate acoustic biomarkers measured by acoustic cardiography as prognostic variables for cardiac outcomes, and to noninvasively measure treatment efficacy.

The Heart Failure and Audicor Technology for Rapid Diagnosis and Initial Treatment trial evaluated the ability of Audicor acoustic cardiography to accurately predict adverse events for heart failure (n = 995) through S3 (third heart sound). Audicor increased diagnostic accuracy of heart failure in patients with "gray zone" B-type natriuretic peptide levels (100 – 499 pg/mL), from 47% to 69%, and improved S3 detection sensitivity in obese patients when compared to auscultation (Maisel, 2011).

A study of systolic heart failure measurement accuracy (n = 433), i.e., ability to diagnose left ventricular systolic dysfunction, compared acoustic cardiography, B-type natriuretic peptide, and echocardiography. Acoustic cardiography was superior to B-type natriuretic peptide ($P < .0001$). Combining both tests was not more effective than the acoustic model alone ($P = .14$) (Kosmicki, 2010).

A prospective study examined the ability of a noninvasive, acoustic coronary artery disease-score to detect coronary artery disease in enrollees referred for elective coronary angiography. Participants were randomized into development (n = 127) and validation cohorts (n = 91). In both cohorts, the acoustic coronary artery disease-score was significantly increased in participants with coronary artery disease compared to those without ($P < .0001$). In the validation group, the sensitivity, specificity, and area under the receiver-operating curve of the acoustic coronary artery disease-score was 71%, 64%, and 77%, respectively (Schmidt, 2022).

A prospective study of patients with acute heart failure (n = 225) randomized subjects into groups guided by symptoms or guided by acoustic cardiography to adjust medications. Subjects were followed for a mean of 238 days. Authors observed significant reductions in electromechanical activation time normalized by cardiac cycle length < 15%, and in reductions of S3 (third heart sound) < 5 ($P = .0095$). Patients managed post-discharge using acoustic cardiography data had superior one-year outcomes, defined as the time to cardiovascular death or heart failure hospitalization within one year after randomization, than patients managed by symptom-driven therapy ($P = .0095$) (Sung, 2020).

A review of heart failure patients (n = 474) reported 169 died after average follow-up of 484 days. Acoustic cardiography showed patients with systolic/diastolic interval ≥ 5 or S3 (third heart sound) score ≥ 4 independently predicted all-cause mortality (52.2% versus 69.2%, $P < .001$) compared to those with a lower systolic/diastolic interval or S3 score. Authors suggest the technique may predict high-risk cases requiring intensive treatment (Wang, 2016).

In a prospective study of participants hospitalized with heart failure with a left ventricular ejection fraction lower than 50% (n = 145), acoustic cardiography measured electromechanical activation time. Major cardiac adverse events (n = 22) were predicted with a sensitivity of 81.8% and a specificity of 65.9% (Zhang, 2020).

A study of patients who underwent successful electric cardioversion (n = 140) were tested with acoustic cardiography (Audicor 200) at baseline, and at four to six weeks, three months, and 12 months after the procedure. Audicor was able to accurately and consistently predict atrial fibrillation risk with S3 (third heart sound) strength ($P = .003$). Only 82 patients were evaluated at 12 months (Erne, 2017).

In 2022, we added four individual studies examining the role of acoustic cardiographic parameters in predicting outcomes following hemodialysis (Chung, 2021) and diagnosing coronary heart disease (Zhang, 2021). We added the 2022 American College of Cardiology and American Heart Association joint guideline on the management of heart failure, which does not mention acoustic cardiography as a noninvasive testing option (Heidenreich, 2022). These results confirm previous findings, and no policy changes are warranted.

In 2023, we updated the references and added a systematic review and meta-analysis (Dao, 2022) and a validation study (Schmidt, 2022) to the policy with no policy changes warranted.

In 2024, we identified no newly relevant, published studies to add to the policy. No policy changes are warranted.

References

On August 2, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “acoustic cardiography,” “acoustic heart sound recording,” and “electronic heart auscultation.” We included the best available evidence according to established

evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

9/2021: initial review date and clinical policy effective date: 10/2021.

9/2022: Policy references updated.

9/2023: Policy references updated.

9/2024: Policy references updated.