Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

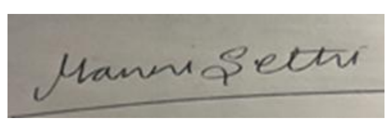
Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date: 10/1/2025
Policy Number: CCP.1495	Effective Date: 10/1/2021 Revision Date: 9/1/2025
Policy Name: Acoustic cardiography/heart sound recording	

Type of Submission: Type of Policy:

Type of Submission	Type of Policy
☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

***All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print):	Signature of Authorized Individual:
Manni Sethi, MD, MBA, CHCQM	

Acoustic cardiography/heart sound recording

Clinical Policy ID: CCP.1495

Recent review date: 9/2025

Next review date: 1/2027

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

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).

A scientific statement by the Heart Failure Society of America lists Audicor among a number of device-based therapies under investigation that may address an unmet need in the future (Estep, 2024).

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 the third heart sound 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.

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 (n = 91) cohorts. 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 < 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 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 updated the references, added two individual studies examining the role of acoustic cardiographic parameters in predicting outcomes following hemodialysis (Chung, 2021) and diagnosing coronary heart disease (Zhang, 2021), and added an 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.

In 2025, we updated the references and added a new scientific statement by the Heart Failure Society of America (Estep, 2024). No policy changes are warranted.

References

On July 16, 2025, 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.

Anbe DT, Armstrong PW, Bates ER, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction. https://www.ahajournals.org/doi/pdf/10.1161/circ.110.9.e82. Last updated 2018.

Chung TL, Liu YH, Huang JC, et al. Changes in acoustic cardiographic parameters before and after hemodialysis are associated with overall and cardiovascular mortality in hemodialysis patients. *Sci Rep.* 2021;11(1):1559. Doi: 10.1038/s41598-021-81286-5.

Dao L, Huang M, Lin X, et al. A systemic review and meta-analysis comparing the ability of diagnostic of the third heart sound and left ventricular ejection fraction in heart failure. *Front Cardiovasc Med*. 2022;9:918051. Doi: 10.3389/fcvm.2022.918051.

Erne P, Resink TJ, Mueller A, et al. Use of acoustic cardiography immediately following electrical cardioversion to predict relapse of atrial fibrillation. *J Atr Fibrillation*. 2017;10(1):1527. Doi: 10.4022/jafib.1527.

Estep JD, Salah HM, Kapadia SR, et al. HFSA scientific statement: Update on device based therapies in heart failure. *J Card Fail*. 2024;30(11):1472-1488. Doi: 10.1016/j.cardfail.2024.07.007.

Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;145(18):e895-e1032. Doi: 10.1161/CIR.0000000000001063.

Montinari MR, Minelli S. The first 200 years of cardiac auscultation and future perspectives. *J Multidiscip Healthc*. 2019;12:183-189. Doi: 10.2147/JMDH.S193904.

Schmidt SE, Madsen LH, Hansen J, et al. Coronary artery disease detected by low frequency heart sounds. *Cardiovasc Eng Technol*. 2022;13(6):864-871. Doi: 10.1007/s13239-022-00622-6.

Sung S-H, Huang C-J, Cheng H-M, Huang W-M, Yu W-C, Chen C-H. Effect of acoustic cardiography-guided management on 1-year outcomes in patients with acute heart failure. *J Card Fail*. 2020;26(2):142-150. Doi: 10.1016/j.cardfail.2019.09.012.

U.S. Food and Drug Administration. Letter to Inovise Medical Inc. 510(k) summary and premarket approval. https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103516.pdf. Published February 4, 2011.

U.S. Food and Drug Administration. Letter to Inovise Medical Inc. 510(k) summary and premarket approval. https://www.accessdata.fda.gov/cdrh_docs/pdf13/K131883.pdf. Published April 11, 2014.

U.S. Food and Drug Administration. Letter to Zargis Medical Corporation. 510(k) premarket approval.https://www.accessdata.fda.gov/cdrh_docs/pdf4/K042128.pdf. Published September 8, 2004.

Wang S, Liu M, Fang F, et al. Prognostic value of acoustic cardiography in patients with chronic heart failure. *Int J Cardiol*. 2016;219:121-126. Doi: 10.1016/j.ijcard.2016.06.004.

Wen Y-N, Lee A P-W, Fang F, Jin C-N, Yu C-M. Beyond auscultation: Acoustic cardiography in clinical practice. *Int J Cardiol*. 2014;172(3):548-560. Doi: 10.1016/j.ijcard.2013.12.298.

Zhang J, Liu W-X, Lyu S-Z, et al. Predictive value of electromechanical activation time for in-hospital major cardiac adverse events in heart failure patients. *Cardiovasc Ther*. 2020;2020:4532596. Doi: 10.1155/2020/4532596.

Zhang FW, Zhang YX, Si LY, et al. Value of acoustic cardiography in the clinical diagnosis of coronary heart disease. *Clin Cardiol.* 2021;44(10):1386-1392. Doi: 10.1002/clc.23694.

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.

9/2025: Policy references updated.