

02.02.21 Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting

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Related Policies:

- [02.02.19 Baroreflex Stimulation Devices](#)
- [02.02.17 Cardiac Contractility Modulation Therapy](#)
- [02.02.22 Noninvasive Heart Failure and Arrhythmia Management and Monitoring System](#)

Summary

Description

A variety of outpatient cardiac hemodynamic monitoring devices are intended to improve quality of life and reduce morbidity for individuals with heart failure by decreasing episodes of acute decompensation. Monitors can identify physiologic changes that precede clinical symptoms and thus allow preventive intervention. These devices operate through various mechanisms, including implantable pressure sensors, inert gas rebreathing, estimation of left ventricular end-diastolic pressure by arterial pressure during the Valsalva maneuver and noninvasive measurement of cardiac bioimpedance.

Summary of Evidence

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring with inert gas rebreathing, no studies have been identified on clinical validity or clinical utility. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have heart failure in the outpatient setting who receive noninvasive monitoring by cardiac bioimpedance (thoracic electrical bioimpedance [TEB] or impedance cardiography [ICG]), The evidence on cardiac bioimpedance (thoracic electrical bioimpedance (TEB) or impedance cardiography (ICG)) devices consists of nonrandomized studies that correlate measurements with other measures of cardiac function and studies that use bioimpedance measurement as part of an algorithm for predicting future heart failure events. There is lack of randomized clinical trial (RCT) evidence that evaluated this technology improves health outcomes over standard active management of heart failure patient. Additional randomized clinical trials are needed that evaluate whether prediction of heart failure decompensation through cardiac bioimpedance allows earlier intervention or other management changes are needed to demonstrate that outcomes are improved. The evidence is insufficient to determine the effects on net health outcomes.

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring of arterial pressure during the Valsalva maneuver, a single study was identified. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. The study assessed the use of left ventricular end-diastolic pressure (LVEDP) monitoring and reported an 85% sensitivity and an 80% specificity to detect left ventricular end-diastolic pressure (LVEDP) greater than 15 mm Hg. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Not applicable.

OBJECTIVE

The objective of this evidence review is to determine whether outpatient hemodynamic monitoring using thoracic bioimpedance, inert gas rebreathing, or during the Valsalva maneuver improves the net health outcome in individuals with heart failure.

PRIOR APPROVAL

Not applicable.

POLICY

Note: This policy only addresses the use of these technologies in ambulatory care and outpatient settings.

Note: This Wellmark medical policy is NOT an evidence review for the implantation (33289) or remote monitoring (93264) of a wireless pulmonary artery pressure sensor. Please refer to Wellmark Authorization Table for the applicable EviCore Evidence-based Guideline regarding the implantation of a

wireless pulmonary artery pressure sensor (33289). Because the primary procedure of implantation of a wireless pulmonary artery pressure sensor (33289) is considered investigational per the applicable EviCore evidence-based Guideline, Wellmark also considers its remote monitoring to be investigational for all indications (93264).

In the ambulatory care and outpatient setting, cardiac hemodynamic monitoring for the management of heart failure including but not limited to one of the following is considered **investigational**, because the evidence is insufficient to determine that the technology results in an improvement in the net health outcome:

- Inert gas rebreathing (i.e., Innocor®)
- Measurement of left ventricular end-diastolic pressure during Valsalva maneuver (i.e. Vericor)
- Thoracic cardiac bioimpedance (thoracic electrical bioimpedance [TEB] or impedance cardiography [ICG]).

POLICY GUIDELINES

Coding

See the [Codes table](#) for details.

BACKGROUND

Chronic Heart Failure

Patients with chronic heart failure are at risk of developing acute decompensated heart failure, often requiring hospital admission. Patients with a history of acute decompensation have the additional risk of future episodes of decompensation and death. Reasons for the transition from a stable, chronic state to an acute, decompensated state include disease progression, as well as acute events such as coronary ischemia and dysrhythmias. While precipitating factors are frequently not identified, the most common preventable cause is noncompliance with medication and dietary regimens.

Management

Strategies for reducing decompensation, and thus the need for hospitalization, are aimed at early identification of patients at risk for imminent decompensation. Programs for early identification of heart failure are characterized by frequent contact with patients to review signs and symptoms with a health care provider, education, and medication adjustments as appropriate. These encounters may occur face-to-face in the office or at home, or via cellular or computed technology.

Precise measurement of cardiac hemodynamics is often employed in the intensive care setting to carefully manage fluid status in acutely decompensated heart failure. Transthoracic echocardiography, transesophageal echocardiography, and Doppler ultrasound are noninvasive methods for monitoring cardiac output on an intermittent basis for the more stable patient but are not addressed herein. A variety of biomarkers and radiologic techniques may be used for dyspnea when the diagnosis of acute decompensated heart failure is uncertain.

The criterion standard for hemodynamic monitoring is pulmonary artery (PA) catheters and central venous pressure catheters. However, they are invasive, inaccurate, and inconsistent in predicting fluid responsiveness. Several studies have demonstrated that catheters fail to improve outcomes in critically ill patients and may be associated with harm. To overcome these limitations, multiple techniques and devices have been developed that use complex imaging technology and computer algorithms to estimate fluid responsiveness, volume status, cardiac output, and tissue perfusion. Many are intended for use in outpatient settings but can be used in the emergency department, intensive care unit, and operating

room. Three methods are reviewed here: inert gas rebreathing, and arterial waveform during the Valsalva maneuver. Use of the last 2 is not widespread because of several limitations including use of proprietary technology making it difficult to confirm their validity and lack of large randomized controlled trials to evaluate treatment decisions guided by these hemodynamic monitors.

Regulatory Status

Please note for the devices in each section below are not intended to be a comprehensive list.

Inert Gas Breathing Devices

In 2006, the Innocor® (Innovision), an inert gas rebreathing device, was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing inert gas rebreathing devices for use in computing blood flow.

Noninvasive Left Ventricular End-Diastolic Pressure Measurement Devices

In 2004, the VeriCor® (CVP Diagnostics), a noninvasive left ventricular end-diastolic pressure measurement device, was cleared for marketing by U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for the following indication:

"The VeriCor is indicated for use in estimating non-invasively, left ventricular end-diastolic pressure (LVEDP). This estimate, when used along with clinical signs and symptoms and other patient test results, including weights on a daily basis, can aid the clinician in the selection of further diagnostic tests in the process of reaching a diagnosis and formulating a therapeutic plan when abnormalities of intravascular volume are suspected. The device has been clinically validated in males only. Use of the device in females has not been investigated."

Thoracic Biimpedance Measurement Devices

Multiple thoracic impedance measurement devices that do not require invasive placement have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that the device was substantially equivalent to existing devices for use of peripheral blood flow monitoring. The list below includes noninvasive thoracic impedance devices, this is not meant to be a comprehensive list.

Table 1. Noninvasive Thoracic Impedance Plethysmography Devices

Device	Manufacturer	Year of FDA Clearance
BioZ Thoracic Impedance Plethysmograph	SonoSite	2009
Bodyport Cardiac Scale	Bodyport Inc.	2022
Cheetah NICOM System	Cheetah Medical	2008
Hemosphere Alta™ Advanced Monitoring Platform	Edwards Lifesciences, LLC	2023
PhysioFlow Signal Morphology-based	Vasocom, now NeuMeDx	2008

Device	Manufacturer	Year of FDA Clearance
Impedance Cardiography (SM-ICG)		
ReDS Wearable System	Sensible Medical Innovations	2015
Sensinel Cardiopulmonary Management (CPM) System	Analog Devices	2024
Sorba Steorra® Non-Invasive Impedance Cardiography	Sorba Medical Systems	2001
Zoe Fluid Status Monitor	Noninvasive Medical Technologies	2004

Also, several manufacturers market thoracic impedance measurement devices integrated into implantable cardiac pacemakers, cardioverter defibrillator devices, and cardiac resynchronization therapy devices. Thoracic bioimpedance devices integrated into implantable cardiac devices are not addressed in this evidence review.

RATIONALE

This evidence review was created in January 2016 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through May 2026.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The RCT is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

For indications 1, and 2 we assess the evidence as a medical test. Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition. The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Noninvasive Thoracic Bioimpedance/Impedance Cardiography

Clinical Context and Test Purpose

The purpose of thoracic bioimpedance in individuals who have heart failure (HF) in an outpatient setting is (1) to guide volume management, (2) to identify physiologic changes that precede clinical symptoms and thus allow preventive interventions, and (3) to prevent hospitalizations.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with chronic heart failure who are at risk of developing acute decompensated heart failure (ADHF).

Interventions

The test being considered is thoracic bioimpedance.

Bioimpedance is defined as the electrical resistance of current flow through tissue. For example, when small electrical signals are transmitted through the thorax, the current travels along the blood-filled aorta, which is the most conductive area. Changes in bioimpedance, measured during each beat of the heart, are inversely related to pulsatile changes in volume and velocity of blood in the aorta. Cardiac output is the product of stroke volume by heart rate, thus, can be calculated from bioimpedance. Cardiac output is generally reduced in patients with systolic heart failure. Acute decompensation is characterized by worsening of cardiac output from the individual's baseline status. The technique is alternatively known as impedance cardiography.

Comparators

The comparator of interest is standard clinical care without testing. Decisions on guiding volume management are being made based on signs and symptoms.

Outcomes

The general outcomes of interest are the prevention of decompensation episodes, reductions in hospitalization and mortality, and improvements in quality of life.

Generally, demonstration of outcomes over a 1-year period is meaningful for interventions.

Study Selection Criteria

Methodologically credible studies were selected using the following principles.

- Comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations will be considered.
- Larger sample size studies and longer duration studies are preferred.
- Studies with duplicative or overlapping populations were excluded.

The AMULET RCT (NCT03476590) comparing standard care to outpatient telemedicine based on nurse-led non-invasive assessments was excluded as the impact of impedance cardiography on outcomes

beyond the benefits of frequent nursing surveillance cannot be isolated and it is unclear to what extent impedance cardiography was utilized in the standard care setting.

Review of Evidence

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Several studies were excluded from the evaluation of the clinical validity of thoracic bioimpedance testing because they did not include information needed to assess clinical validity.

Packer et al (2006) reported on the use of impedance cardiography measured by BioZ impedance cardiography monitor to predict decompensation in patients with chronic heart failure. In this study, 212 stable patients with heart failure and a recent episode of decompensation underwent serial evaluation and blinded impedance cardiography testing every 2 weeks for 26 weeks and were followed for the occurrence of death or worsening heart failure requiring hospitalization or emergent care. Results are summarized in Table 11. A composite score of 3 impedance cardiography parameters was a predictor of an event during the next 14 days ($p < .001$).

Table 2. Clinical Validity of 3-Level Risk Score for BioZ Impedance Cardiography Monitor

Author	Initial N	Final N	Excluded Samples	Prevalence of Condition	Clinical Validity: Mean Probability of Outcome (95% CI), %		
					Low Risk	Medium Risk	High Risk
Packer et al (2006)	212	212	None	59 patients had 104 episodes of decompensated HF including 16 deaths, 78 hospitalizations, 10 ED visits	1.0 (0.5 to 1.9)	3.5 (2.4 to 4.8)	8.4 (5.8 to 11.6)

CI: confidence interval; ED: emergency department; HF: heart failure.

Section Summary: Clinically Valid

The clinical validity of using thoracic bioimpedance for patients with chronic heart failure who are at risk of developing ADHF has not been established. Association studies are insufficient evidence to determine whether thoracic bioimpedance can improve outcomes in individuals with chronic heart failure who are at risk of developing ADHF. There are no studies reporting the clinical validity regarding sensitivity, specificity, or predictive value.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if individuals receive correct therapy, more effective therapy, avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for individuals managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

Amir et al (2017) reported on the results of a prospective study in which 59 patients recently hospitalized for heart failure were selected for remote dielectric sensing (ReDS)-guided treatment for 90 days. The number of heart failure hospitalizations during 90-day ReDS-guided therapy was compared with hospitalizations in the preceding 90 days before enrollment and the 90 days following discontinuation of ReDS monitoring. During treatment, patients were equipped with the ReDS wearable vest, which was worn once a day at home to measure lung fluid content. Study characteristics and results are summarized in Tables 3 and 4. The rate of heart failure hospitalizations was lower during the ReDS-guided follow-up compared with pre- and post-treatment periods. Interpretation of results is uncertain due to the lack of concurrent control and randomization, short-term follow-up, large CIs, and lack of clarity about lost-to-follow-up during the post-ReDS period. An RCT comparing ReDS monitoring with the standard of care (SMILE; NCT02448342) was initiated but terminated before its completion.

Table 3. Summary of Key Nonrandomized Study Characteristics

Author	Study Type	Country	Dates	Participants	Treatment	Mean FU (SD), d
Amir et al (2017)	Pre-post prospective cohort	Israel	2012-2015	Patients ≥18 y with stage C heart failure, regardless of LVEF (n=59)	ReDS Wearable System	83.0 (25.4)

FU: follow-up; LVEF: left ventricular ejection fraction; ReDS: remote dielectric sensing; SD: standard deviation.

Table 4. Summary of Key Nonrandomized Study Results

Study	HFH (events/patient/3 mo)	Deaths
Amir et al (2017)	50	50
Pre-90-day period (control)	0.04	0
90-day treatment period	0.30	2
Post-90-day period (control)	0.19	2
Hazard ratio (95% confidence interval); p	0.07 (0.01 to 0.54); .01 ^a 0.11 (0.014 to 0.88); .037 ^b	

HFH: heart failure-related hospitalizations.

^a Treatment versus pretreatment period;

^b Treatment versus posttreatment period.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility. Because the clinical validity of using thoracic bioimpedance has not been proved, a chain of evidence to support its clinical utility cannot be constructed.

Section Summary: Clinical Utility

The clinical utility of using thoracic bioimpedance for individuals with chronic heart failure who are at risk of developing ADHF has not been established. One prospective longitudinal study reported that ReDS-guided management reduced heart failure readmissions in ADHF individuals recently discharged from the

hospital. However, interpretation of results is uncertain due to the lack of concurrent controls and randomization, short-term follow-up, large CIs, and lack of clarity about lost-to-follow-up during the post-ReDS monitoring period. An RCT comparing ReDS monitoring with the standard of care was initiated but terminated before its completion.

Inert Gas Rebreathing

Clinical Context and Test Purpose

The purpose of inert gas breathing in individuals who have heart failure in an outpatient setting is (1) to guide volume management, (2) to identify physiologic changes that precede clinical symptoms and thus allow preventive interventions, and (3) to prevent hospitalizations.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with chronic heart failure who are at risk of developing ADHF.

Interventions

The test being considered is inert gas breathing.

Inert gas rebreathing is based on the observation that the absorption and disappearance of a blood-soluble gas are proportional to cardiac blood flow. The individual is asked to breathe and rebreathe from a bag filled with oxygen mixed with a fixed proportion of 2 inert gases, typically nitrous oxide and sulfur hexafluoride. The nitrous oxide is soluble in blood and is therefore absorbed during the blood's passage through the lungs at a rate proportional to the blood flow. The sulfur hexafluoride is insoluble in blood and therefore stays in the gas phase and is used to determine the lung volume from which the soluble gas is removed. These gases and carbon dioxide are measured continuously and simultaneously at the mouthpiece.

Comparators

The comparator of interest is standard clinical care without testing. Decisions on guiding volume management are being made based on signs and symptoms.

Outcomes

The general outcomes of interest are the prevention of decompensation episodes, reduction in hospitalization and mortality, and improvement in quality of life.

Trials of using inert gas rebreathing for this population were not found. Generally, demonstration of outcomes over a 1-year period is meaningful for interventions.

Study Selection Criteria

Methodologically credible studies were selected using the following principles.

- Comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations will be considered.
- Larger sample size studies and longer duration studies are preferred.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

No studies on the clinical validity were identified that would establish how the use of inert gas rebreathing measurements helps detect the likelihood of decompensation.

Section Summary: Clinically Valid

The clinical validity of using inert gas breathing for individuals with chronic heart failure who are at risk of developing ADHF has not been established.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy or more effective therapy, avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for individuals managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

No studies were identified that determined how the use of inert gas rebreathing measurements is associated with changes in patient management or evaluated the effects of this technology on individuals outcomes.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility. Because the clinical validity of using inert gas breathing has not been proved, a chain of evidence to support clinical utility cannot be constructed.

Section Summary: Clinically Useful

No studies of clinical utility were identified that determined how the use of inert gas breathing measurements in managing heart failure affects patient outcomes. It is unclear how such devices will improve patient outcomes.

Noninvasive Left Ventricular End-Diastolic Pressure Estimation

Clinical Context and Test Purpose

The purpose of left ventricular end-diastolic pressure (LVEDP) estimation in individuals who have heart failure in an outpatient setting is (1) to guide volume management, (2) to identify physiologic changes that precede clinical symptoms and thus allow preventive interventions, and (3) to prevent hospitalizations.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with chronic heart failure who are at risk of developing ADHF.

Interventions

The test being considered is noninvasive LVEDP estimation.

LVEDP is elevated with acute decompensated heart failure. While direct catheter measurement of LVEDP is possible for individuals undergoing cardiac catheterization for diagnostic or therapeutic reasons, its invasive nature precludes outpatient use. Noninvasive measurements of LVEDP have been developed based on the observation that arterial pressure during the strain phase of the Valsalva maneuver may directly reflect the LVEDP. Arterial pressure responses during repeated Valsalva maneuvers can be recorded and analyzed to produce values that correlate to the LVEDP.

Comparators

The comparator of interest is standard clinical care without testing. Decisions guiding volume management are being made based on signs and symptoms.

Outcomes

The general outcomes of interest are the prevention of decompensation episodes, reduction in hospitalization and mortality, and improvement in quality of life.

Trials of using noninvasive LVEDP estimation for this population were not found. Generally, demonstration of outcomes over a 1-year period is meaningful for interventions.

Study Selection Criteria

Methodologically credible studies were selected using the following principles.

- Comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations will be considered.
- Larger sample size studies and longer duration studies are preferred.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Silber et al (2012) reported on finger photoplethysmography during the Valsalva maneuver performed in 33 patients before cardiac catheterization. LVEDP was measured via a catheter placed in the left ventricle and used as the reference standard. For identifying LVEDP greater than 15 mm Hg, finger photoplethysmography during the Valsalva maneuver was 85% sensitive (95% CI, 54% to 97%) and 80% specific (95% CI, 56% to 93%).

Section Summary: Clinically Valid

Only 1 study was identified assessing the use of LVEDP monitoring in this patient population; it reported an 85% sensitivity and an 80% specificity to detect LVEDP greater than 15 mmHg.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for individuals managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

No studies were identified that determined how the use of noninvasive LVEDP estimation is associated with changes in patient management or evaluated the effects on patient outcomes.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Because the clinical validity of using noninvasive LVEDP estimation has only been demonstrated in a small, single study, a chain of evidence to support clinical utility cannot be constructed.

Section Summary: Clinically Useful

No studies of clinical utility were identified that assessed how the use of noninvasive LVEDP estimation in managing heart failure affects patient outcomes. A chain of evidence on the clinical utility of noninvasive LVEDP estimation cannot be constructed because it is unclear how these devices will improve patient outcomes.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Cardiology, the American Heart Association, and the Heart Failure Society of America

In 2017, the American College of Cardiology, the American Heart Association, and the Heart Failure Society of America issued joint guidelines on the management of heart failure that offered no recommendations for the use of ambulatory monitoring devices.

In the 2022 update to the heart failure management guidelines, only 2 recommendations were provided regarding remote hemodynamic monitoring in heart failure. Both related to the usefulness of wireless monitoring of PA pressure by an implanted hemodynamic monitor, which is no longer in the scope of this medical policy and will be not discussed here.

Heart Failure Society of America

In 2018, the Heart Failure Society of America Scientific Statements Committee published a white paper consensus statement on remote monitoring of patients with heart failure.

The committee concluded that: "Based on available evidence, routine use of external RPM devices is not recommended. Implanted devices that monitor pulmonary arterial pressure and/or other parameters may be beneficial in selected patients or when used in structured programs, but the value of these devices in routine care requires further study."

National Institute of Health and Care Excellence (NICE)

No guidance was identified regarding cardiac hemodynamic monitoring for the management of heart failure using thoracic bioimpedance, inert gas rebreathing, or during the Valsalva maneuver.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional (CardioMEMS)
	93701	Bioimpedance-derived physiologic cardiovascular analysis
	93799	Unlisted cardiovascular service or procedure (May be utilized for inert gas rebreathing (Innocor® [Innovision])
HCPCS		
	No Code(s)	

Codes	Number	Description
Type of Service	Cardiology	
Place of Service	Outpatient	

POLICY HISTORY

Date	Reason	Action
June 2026	Annual Review	Policy Renewed
June 2025	Annual Review	Policy Revised
July 2024	Annual Review	Policy Renewed
July 2023	Annual Review	Policy Revised
January 2023	Annual Review	Policy Revised
January 2022	Annual Review	Policy Revised, Content Moved and New Medical Policy Created

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
 Medical Policy Analyst
 PO Box 9232
 Des Moines, IA 50306-9232

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