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Health Plan of Washington

MEDICAL POLICY – 2.02.24

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

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EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Hemodynamic monitoring measures blood pressure inside the heart, veins, and arteries. It's often done in a hospital for individuals with acute heart failure. Implantable hemodynamic monitoring devices have been developed for outpatient use. The device measures the pressure of the pulmonary artery (which transports blood from the heart to the lungs) and the heart rate. The data is transmitted through a computerized system to the individual's doctor. The goal of the device is to try to see the early signs of acute heart failure and prevent hospitalizations. In the studies published so far, there is limited data about safety and no demonstration that the devices save more lives. There are also unanswered questions about whether these devices reduce hospitalization. For these reasons, implantable hemodynamic monitoring devices are considered investigational (unproven).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Cardiac hemodynamic monitoring	**In the ambulatory care and outpatient setting, cardiac hemodynamic monitoring for the management of heart failure using any of the following devices is considered investigational:** • Arterial pressure during the Valsalva maneuver • Implantable direct pressure monitoring of the pulmonary artery (this includes the implantation of the device, e.g., CardioMEMS device) • Inert gas rebreathing • Thoracic bioimpedance

Coding

Code	Description
CPT	
33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed
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
93701	Bioimpedance-derived physiologic cardiovascular analysis
HCPCS	
G0555	Provision of replacement patient electronics system (e.g., system pillow, handheld reader) for home pulmonary artery pressure monitoring (new code effective 1/1/2025)

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

This policy refers only to the use of stand-alone cardiac output measurement devices designed for use in ambulatory care and outpatient settings. The use of cardiac hemodynamic monitors or intrathoracic fluid monitors that are integrated into other implantable cardiac devices, including implantable cardioverter defibrillators, cardiac resynchronization therapy devices, and cardiac pacing devices are not addressed in this policy.

Evidence Review

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, thoracic bioimpedance measurement, inert gas rebreathing, and estimation of left ventricular end-diastolic pressure (LVEDP) by arterial pressure during the Valsalva maneuver.

Background

Chronic Heart Failure

Individuals with chronic heart failure are at risk of developing acute decompensated heart failure, often requiring hospital admission. Individuals 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.[1]

Management

Strategies for reducing decompensation, and thus the need for hospitalization, are aimed at early identification of individuals at risk for imminent decompensation. Programs for early identification of heart failure are characterized by frequent contact with individuals 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.[2]

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 individual 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 individuals 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. Four methods are reviewed here: implantable pressure monitoring devices, thoracic bioimpedance, inert gas rebreathing, and arterial waveform during the Valsalva maneuver. Use of the last three 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 (RCTs) to evaluate treatment decisions guided by these hemodynamic monitors.

Summary of Evidence

For individuals with New York Heart Association (NYHA) class II-IV heart failure in outpatient settings who have had a hospitalization in the past year and/or have elevated natriuretic peptides who receive hemodynamic monitoring with an implantable pulmonary artery pressure sensor device, the evidence includes two meta-analyses, randomized controlled trials (RCTs) and nonrandomized studies. The relevant outcomes are overall survival, symptoms, functional

outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. One implantable pressure monitor, the CardioMEMS device, has US Food and Drug Administration (FDA) approval. The pivotal CHAMPION RCT reported a statistically significant 28% decrease in heart failure-related hospitalizations (HFH) in individuals implanted with CardioMEMS device compared with usual care. However, trial results were potentially biased in favor of the treatment group due to the use of additional nurse communication to enhance protocol compliance with the device. The manufacturer conducted multiple analyses to address potential bias from the nurse interventions. Results were reviewed favorably by the FDA. While these analyses demonstrated the consistency of benefit of the CardioMEMS device, all such analyses have methodologic limitations. Early safety data have been suggestive of a higher rate of procedural complications, particularly related to pulmonary artery injury. While the US CardioMEMS post-approval study and CardioMEMS European Monitoring Study for Heart Failure (MEMS-HF) study reported a significant decrease in HFH with few device- or system-related complications at one year, the impact of nursing interventions remains unclear. The subsequent GUIDE-HF RCT failed to meet its primary efficacy endpoint, the composite of HFH, urgent heart failure visits, and death at 1 year. With the approval of the FDA, the statistical analysis plan was updated to pre-specify sensitivity analyses to assess the impact of COVID-19 on the trial. For the 72% of individuals who completed follow-up prior to the public health emergency declaration in March 2020, a statistically significant 19% reduction in the primary endpoint was reported, driven by a 28% reduction in HFH. However, lifestyle changes during the COVID-19 pandemic such as changes in physical activity, exposure to infections, willingness to seek medical care, and adherence to medications are unmeasured and add imprecision to treatment effect estimates, as do alterations in provider behaviors. Enrollment of NYHA Class II individuals was significantly enriched in the first 500 individuals, potentially impacting the pre-COVID-19 analysis. The MONITOR-HF trial, an open-label RCT conducted in the Netherlands, showed that hemodynamic monitoring significantly improved quality of life on the Kansas City Cardiomyopathy Questionnaire (KCCQ) and reduced HFH but did not impact mortality at one year follow-up. Overall, the beneficial effect of CardioMEMS, if any, appears to be on the hospitalization outcome of the composite. Both urgent heart failure visits and death outcomes had hazard ratios (HRs) favoring the control group with wide confidence intervals (CIs) including the null value in pre-COVID-19, during-COVID-19, and overall analyses of the GUIDE-HF trial. The MONITOR-HF trial found improvement in quality of life on the KCCQ for the CardioMEMS group relative to the control, but no significant differences were observed in secondary quality of life and functional status outcomes in the other included trials. While the HFH reduction of 28% found in the pre-COVID-19 analysis is consistent with findings from the CHAMPION trial, it is unclear whether physician knowledge of treatment assignment biases the decision to hospitalize and administer intravenous diuretics. The two included meta-analyses showed a reduction in HFHs with hemodynamic monitoring in heart failure patients but had discordant

findings regarding the impact on mortality. One meta-analysis found no pooled difference in mortality between hemodynamic monitoring and control groups; however, a patient-level meta-analysis revealed a significant 25% decrease in mortality associated with hemodynamic monitoring in patients with heart failure with reduced ejection fraction. Given that the intervention is invasive and intended to be used for a highly prevalent condition and, in light of the conflicting evidence of benefit on mortality and functional outcomes, the lack of periprocedural safety data, and unclear impact of COVID-19 on remote monitoring in the GUIDE-HF trial, the net benefit of the CardioMEMS device remains uncertain. Concerns may be clarified by the ongoing open access phase of the GUIDE-HF RCT and the German non-industry-sponsored PASSPORT-HF trial. 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 outpatient settings who receive hemodynamic monitoring by thoracic bioimpedance, the evidence includes uncontrolled prospective studies and case series. The relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. There is a lack of RCT evidence evaluating whether the use of these technologies improves health outcomes over standard active management of heart failure individuals. The case series have reported physiologic measurement-related outcomes and/or associations between monitoring information and heart failure exacerbations, but do not provide definitive evidence on device efficacy. 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 outpatient settings who receive hemodynamic monitoring with inert gas rebreathing, no studies have been identified on clinical validity or clinical utility. The 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 outpatient settings who receive hemodynamic monitoring of arterial pressure during the Valsalva maneuver, a single study was identified. The 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 LVEDP greater than 15 mm Hg. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04398654	Pulmonary Artery Sensor System Pressure Monitoring to Improve Heart Failure (HF) Outcomes (PASSPORT-HF)	554	Dec 2026 (recruiting)
NCT04441203	Patient SELF-management With HemodynamIc Monitoring: Virtual Heart Failure Clinic and Outcomes (SELFIe-HF)	150	Jun 2024 (recruiting)
NCT04012944[a]	A Prospective, Multi-Center, Open-Label, Single-Arm Clinical Trial Evaluating the Safety and Efficacy of the Cordella Pulmonary Artery Sensor System in New York Heart Association (NYHA) Class III Heart Failure Patients (SIRONA 2 Trial)	81	Jul 2025 (ongoing)
NCT03020043	CardioMEMS Registry of the Frankfurt Heart Failure Center	500	Dec 2025 (recruiting)
NCT04089059[a]	A Prospective, Multi-Center, Open Label, Single Arm Clinical Trial Evaluating the Safety and Efficacy of the Cordella Pulmonary Artery Sensor System in NYHA Class III Heart Failure Patients (PROACTIVE- HF Trial)	456	Mar 2026 (ongoing)
NCT04419480[a]	Hemodynamic Monitoring to Prevent Adverse Events foLlowing cardiOgenic Shock Trial	40	Dec 2026 (ongoing)
NCT05284955[a]	Screening for Advanced Heart Failure IN Stable outPatientS - The SAINTS Study (SAINTS B) (SAINTS B)	60	Dec 2025 (recruiting)
NCT03020043[a]	Evaluation of Longterm Outcome of New York Heart Association Class III Heart Failure Patients Receiving Telemonitoring Using a Pulmonary Artery Pressure Sensor System (CardioMEMS)	500	Dec 2025 (recruiting)
NCT05934487[a]	PROACTIVE-HF-2 Trial Heart Failure NYHA Class II and III	1650	Sep 2029 (recruiting)

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

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

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the 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 et al

In 2017, the American College of Cardiology (ACC), the American Heart Association (AHA), and Heart Failure Society of America (HFSA) issued joint guidelines on the management of heart failure that offered no recommendations for the use of ambulatory monitoring devices.[41]

In the 2022 update to the heart failure management guidelines, two recommendations were provided regarding remote hemodynamic monitoring in heart failure. These recommendations are summarized below in **Table 2**.

Table 2. 2022 ACC/AHA/HFSA Recommendation for Wearables and Remote Monitoring (including Telemonitoring and Device Monitoring)[42]

Class of Recommendation	Level of Evidence	Recommendation
2b (Weak Evidence)	B-R (Moderate quality randomized evidence)	1. "In selected adult patients with NYHA class III HF and history of HF hospitalization in the past year or elevated natriuretic peptide levels, on maximally tolerated doses of GDMT with optimal device therapy, the usefulness of wireless monitoring of PA pressure by an implanted hemodynamic monitor to reduce the risk of subsequent HF hospitalizations is uncertain."
Value Statement: Uncertain Value (B-NR) (Moderate quality nonrandomized evidence)		2. "In patients with NYHA class III HF with a HF hospitalization within the previous

Class of Recommendation	Level of Evidence	Recommendation
		year, wireless monitoring of the PA pressure by an implanted hemodynamic monitor provides uncertain value."

ACC: American College of Cardiology; AHA: American Heart Association; GDMT: guideline-directed medical therapy; HF: heart failure; HFSA: Heart Failure Society of America; NYHA: New York Heart Association; PA: pulmonary artery. Adapted from Heidenreich et al (2022).[42]

National Institute for Health and Care Excellence

In 2021, the National Institute for Health and Care Excellence (NICE) issued a new interventional procedures guidance regarding the use of percutaneous implantation of pulmonary artery pressure sensors for monitoring the treatment of chronic heart failure.[43] The Institute's recommendation stated that "Evidence on the safety and efficacy of percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure is adequate to support using this procedure provided that standard arrangements are in place for clinical governance, consent, and audit."

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.[44]

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."

Medicare National Coverage

In 2014, the Centers for Medicare & Medicaid Services updated its 2006 decision memorandum on thoracic electrical bioimpedance.[45] Medicare's national coverage determination found thoracic bioimpedance to be reasonable and necessary for the following indications:

1. Differentiation of cardiogenic from pulmonary causes of acute dyspnea;

2. Optimization of atrioventricular interval for patients with atrioventricular sequential cardiac pacemakers;

3. Monitoring of continuous inotropic therapy for patients with terminal heart failure;

4. Evaluation for rejection in patients with a heart transplant as a predetermined alternative to myocardial biopsy; and

5. Optimization of fluid management in patients with congestive heart failure.

While Medicare permits coverage of thoracic bioimpedance in these conditions, it has acknowledged that there is a "…general absence of studies evaluating the impact of using thoracic bioimpedance for managing patients with cardiac disease…." Medicare does not cover the use of thoracic bioimpedance in the management of hypertension due to inadequate evidence.

Medicare has also specified that thoracic bioimpedance is not covered for "the management of all forms of hypertension (with the exception of drug-resistant hypertension…)." Further, Medicare specified that:

> "[Contractors] have discretion to determine whether the use of TEB [thoracic bioimpedance] for the management of drug-resistant hypertension is reasonable and necessary. Drug resistant hypertension is defined as failure to achieve goal blood pressure in patients who are adhering to full doses of an appropriate 3-drug regimen that includes a diuretic."

There is no Medicare national coverage determination on implantable direct pressure monitoring, inert gas rebreathing, and arterial pressure with Valsalva.

Regulatory Status

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 the US 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.

FDA product code: DXN

Thoracic Bioimpedance Devices

Multiple thoracic impedance measurement devices that do not require invasive placement have been cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices used for peripheral blood flow monitoring. **Table 3** presents an inexhaustive list of representative devices.

FDA product code: DSB

Table 3. Noninvasive Thoracic Impedance Plethysmography Devices

Device	Manufacturer	Clearance Date
BioZ Thoracic Impedance Plethysmograph	SonoSite	2009
Zoe Fluid Status Monitor	Noninvasive Medical Technologies	2004
Cheetah Starling SV	Cheetah Medical	2008
PhysioFlow Signal Morphology-based Impedance Cardiography (SM-ICG)	Vasocom, now NeuMeDx	2008
ReDS Wearable System	Sensible Medical Innovations	2015
Bodyport Cardiac Scale	Bodyport Inc.	2022
Hemosphere Alta Advanced Monitoring Platform	Edwards Lifesciences, LLC	2023

Also, several manufacturers market thoracic impedance measurement devices integrated into implantable cardiac pacemakers, cardioverter defibrillator devices, and cardiac resynchronization therapy devices.

Inert Gas Rebreathing 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.

FDA product code: BZG.

Implantable Pulmonary Artery Pressure Sensor Devices

In 2014, the CardioMEMS Heart Failure Monitoring System (CardioMEMS, now Abbott) was approved for marketing by the FDA through the premarket approval process. This device consists of an implantable pulmonary artery (PA) sensor, which is implanted in the distal PA, a transvenous delivery system, and an electronic sensor that processes signals from the implantable PA sensor and transmits PA pressure measurements to a secure database.[3] The device originally underwent FDA review in 2011, at which point the FDA found no reasonable assurance that the monitoring system would be effective, particularly in certain subpopulations, although the FDA agreed this monitoring system was safe for use in the indicated patient population.[4] In 2022, the CardioMEMS HF Monitoring System received expanded approval for the treatment of New York Heart Association (NYHA) Class II-III patients who had been hospitalized at least one time in the prior year and/or had elevated natriuretic peptides.

Several other devices that monitor cardiac output by measuring pressure changes in the PA or right ventricular outflow tract have been investigated in the research setting but have not received FDA approval. They include the Chronicle implantable continuous hemodynamic monitoring device (Medtronic), which includes a sensor implanted in the right ventricular outflow tract, and the ImPressure device (Remon Medical Technologies), which includes a sensor implanted in the PA, and the Cordella PA Pressure Sensor System (Endotronix, Inc.), which includes a sensor implanted in the PA.

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

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History

Date	Comments
08/01/18	New policy, approved July 10, 2018, effective November 2, 2018. Add to Cardiology section. This policy was previously archived, but it is now being reinstated. Literature review through March 2018. Policy statement: cardiac hemodynamic monitoring for the management of heart failure in the outpatient setting using any of the stated devices is considered investigational.
01/01/19	Interim Review, approved December 19, 2018. Clarified that implantable direct pressure monitoring of the pulmonary artery includes the implantation of the device as well. Added CPT code 33289 and 93264.
08/01/19	Annual Review, approved July 25, 2019. Policy updated with literature review through April 2019, references added and removed. Policy statement unchanged.

Date	Comments
07/02/20	Coding update. Removed CPT 93701.
12/01/20	Annual Review, approved November 19, 2020. Policy updated with literature review through March 9, 2020; no references added. Policy statement unchanged. Added CPT 93701.
11/01/21	Annual Review, approved October 5, 2021. Policy updated with literature review through April 5, 2021; references added. Policy statement unchanged. Removed CPT code 93799,
10/01/22	Annual Review, approved September 12, 2022. Policy updated with literature review through May 2, 2022; references added. Policy statement unchanged.
09/01/23	Annual Review, approved August 7, 2023. Policy updated with literature review through May 5, 2023; references added. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
08/01/24	Annual Review, approved July 22, 2024. Policy updated with literature review through May 3, 2024; references added. Policy statement unchanged.
01/01/25	Coding update. Added new HCPCS code G0555.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.