EFFECTIVE DATE: 11|01|2025
|POLICY LAST REVIEWED: 07|15|2026

OVERVIEW

A variety of outpatient cardiac hemodynamic monitoring devices are intended to improve quality of life and reduce morbidity for patients 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 by arterial pressure during the Valsalva maneuver.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Thoracic Electrical Bioimpedance (TEB)

Cardiac hemodynamic monitoring for the management of heart failure using thoracic electrical bioimpedance is covered.

Implantable Direct Pressure Monitoring, Inert Gas Rebreathing and Arterial Pressure during Valsalva Maneuver

Cardiac hemodynamic monitoring for the management of heart failure using implantable direct pressure monitoring of the pulmonary artery, inert gas rebreathing, and arterial pressure during the Valsalva maneuver is covered.

Note: Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all Medicare Advantage Plans policies. Therefore, Medicare Advantage Plans policies may differ from Commercial products. In some instances, benefits for Medicare Advantage Plans may be greater than what is allowed by the CMS.

Commercial Products

Thoracic Electrical Bioimpedance (TEB)

Cardiac hemodynamic monitoring for the management of heart failure using thoracic electrical bioimpedance (TEB) is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

Implantable Direct Pressure Monitoring, Inert Gas Rebreathing and Arterial Pressure during Valsalva Maneuver

Cardiac hemodynamic monitoring for the management of heart failure using implantable direct pressure monitoring of the pulmonary artery, inert gas rebreathing, and arterial pressure during the Valsalva maneuver is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage for diagnostic services and for applicable not medically necessary/not covered benefits/coverage.

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 healthcare provider and with education or adjustment of medications 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 (TEE), 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 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. 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 3 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.

<u>Pulmonary Artery Pressure Measurement to Estimate Left Ventricular End-Diastolic Pressure</u>

Left ventricular end-diastolic pressure (LVEDP) can be approximated by direct pressure measurement of an implantable sensor in the pulmonary artery wall or right ventricular outflow tract. The sensor is implanted via right heart catheterization and transmits pressure readings wirelessly to external monitors. One device, the CardioMEMS Champion Heart Failure Monitoring System, has approval from the U.S. Food and Drug Administration (FDA) for the ambulatory management of heart failure patient. The CardioMEMS device is implanted using a heart catheter system fed through the femoral vein and generally requires patients have an overnight hospital admission for observation after implantation.

<u>Thoracic Bioimpedance</u>

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 and, 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 patient's baseline status. The technique is alternatively known as impedance cardiography.

Inert Gas Rebreathing

Inert gas rebreathing is based on the observation that the absorption and disappearance of a blood-soluble gas is proportional to cardiac blood flow. The patient is asked to breathe and rebreathe from a rebreathing bag filled with oxygen mixed with a fixed proportion of two 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 that is 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.

Arterial Pressure during Valsalva to Estimate LVEDP

Left ventricular end diastolic pressure (LVEDP) is elevated with acute decompensated heart failure. While direct catheter measurement of LVEDP is possible for patients 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.

Noninvasive Left Ventricular End-Diastolic Pressue Measurement Devices (LVEDP)

In 2004, the VeriCor® (CVP Diagnostics), a noninvasive LVEDP measurement device, was cleared for marketing by FDA through the 510(k) process. 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 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.

Inert Gas Rebreathing Devices

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

Implantable Pulmonary Artery Pressure Sensor Devices

In 2014, the CardioMEMS™ Champion Heart Failure Monitoring System (CardioMEMS, now Abbott) was cleared for marketing by 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. The device originally underwent FDA review in 2011, at which point FDA found no reasonable assurance that the monitoring system would be effective, particularly in certain subpopulations, although FDA agreed this monitoring system was safe for use in the indicated patient population.

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.

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 2 meta-analyses, randomized controlled trials (RCTs), and nonrandomized studies. 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 U.S. Food and drug Administration (FDA) approval. The pivotal CHAMPION RCT reported a statistically significant 28% decrease in heart failure hospitalization (HFH) in patients implanted with the 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 U.S. 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 1 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 patients 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 patients was significantly enriched in the first 500 patients, 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 1-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 favoring the control group with wide confidence intervals 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. Evidence for the Cordella System is limited to 3 prospective, single-arm studies. The pivotal PROACTIVE-HF trial was a prospective, multicenter, single-arm study evaluating the Cordella System in NYHA Class III heart failure patients with recent HFH or elevated natriuretic peptides. The trial, which was modified from its original randomized design with FDA input, met its primary endpoint by reporting a 6-month event rate (heart failure hospitalization or all-cause mortality) of 0.15 events per patient, significantly lower than the prespecified benchmark of 0.43, which was derived from a composite of non-contemporaneous control arms from prior CardioMEMS trials. Secondary endpoints showed improvements in KCCQ score, 6-minute walk distance, and NYHA class. Device safety was high, with 99.2% freedom from complications and 99.8% freedom from sensor failure at 6 months. The SIRONA 1 and 2 feasibility studies similarly demonstrated a low rate of adverse events with the Cordella device and an improvement in NYHA class for the majority of participants; however, quality-of-life and functional outcomes did not show significant improvement. The 2 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 and Cordella devices remains uncertain. Concerns may be clarified by the ongoing open access phase of the GUIDE-HF RCT and the PROACTIVE-HF trial, as well as 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. 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 patients. 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. 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 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 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 LVEDP greater than 15 mm Hg. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Medicare Advantage Plans

The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to cover Implantable Pulmonary Artery Pressure Sensors (IPAPS) for heart failure (HF) management under Coverage with Evidence Development (CED) and if furnished according to an FDA market-authorized indication and all of the required conditions are met according to National Coverage Determination (NCD) 20.36 Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management.

According to the Centers for Medicare & Medicaid Services (CMS), effective for services performed on and after January 23, 2004, TEB is covered for the following uses:

1. Differentiation of cardiogenic from pulmonary causes of acute dyspnea when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.
2. Optimization of atrioventricular (A/V) interval for patients with A/V sequential cardiac pacemakers when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.

3. Monitoring of continuous inotropic therapy for patients with terminal congestive heart failure, when those patients have chosen to die with comfort at home, or for patients waiting at home for a heart transplant.
4. Evaluation for rejection in patients with a heart transplant as a predetermined alternative to a myocardial biopsy. Medical necessity must be documented should a biopsy be performed after TEB.
5. Optimization of fluid management in patients with congestive heart failure when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.

CODING

Medicare Advantage Plans

The following CPT/HCPCS code(s) for cardiac hemodynamic monitoring using thoracic electrical bioimpedance and implantation and monitoring of a wireless pulmonary artery pressure sensor are covered for Medicare Advantage Plans and prior authorization is not required:

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
G0555 Provision of replacement patient electronics system (e.g., system pillow, handheld reader) for home pulmonary artery pressure monitoring

Commercial Products

The following CPT/HCPCS code(s) for cardiac hemodynamic monitoring using thoracic electrical bioimpedance and implantation and monitoring of a wireless pulmonary artery pressure sensor are considered not medically necessary for Commercial Products:

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
G0555 Provision of replacement patient electronics system (e.g., system pillow, handheld reader) for home pulmonary artery pressure monitoring

There is no specific code(s) for inert gas rebreathing measurement or left ventricular end diastolic pressure and should be reported using the unlisted code(s):

93799 Unlisted cardiovascular service or procedure

RELATED POLICIES

Unlisted Procedures

PUBLISHED

Provider Update, September 2026
Provider Update, October 2025
Provider Update, October 2024
Provider Update, August 2023
Provider Update, December 2022

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD): Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (20.36).
2. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD): Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB) (20.16).
3. Centers for Medicare & Medicaid Services (CMS). National coverage decision for cardiac output monitoring by thoracic electrical bioimpedance (TEB) (20.16). 2006; http://www.cms.gov/medicare-coverage- database/details/ncd- details.aspx?NCDId=267&ncdver=3&NCAId=82. Accessed June 25, 2026.
4. Centers for Medicare & Medicaid Services. (June 20, 2025). *Pub 100-04 Medicare Claims Processing - CMS Manual System* (Transmittal 13282). https://www.cms.gov/files/document/r13282cp.pdf
5. Opasich C, Rapezzi C, Lucci D, et al. Precipitating factors and decision-making processes of short-term worsening heart failure despite "optimal" treatment (from the IN-CHF Registry). Am J Cardiol. Aug 15 2001; 88(4): 382-7. PMID 11545758
6. McAlister FA, Stewart S, Ferrua S, et al. Multidisciplinary strategies for the management of heart failure patients at high risk for admission: a systematic review of randomized trials. J Am Coll Cardiol. Aug 18 2004; 44(4): 810-9. PMID 15312864
7. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): CardioMEMS HF System. 2014; https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100045b.pdf. Accessed May 5, 2025.
8. Loh JP, Barbash IM, Waksman R. Overview of the 2011 Food and Drug Administration Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting on the CardioMEMS Champion Heart Failure Monitoring System. J Am Coll Cardiol. Apr 16 2013; 61(15): 1571-6. PMID 23352783
9. Food and Drug Administration. Instructions for use: Cordella Pulmonary Artery Sensor System. 2024; https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230040C.pdf. Accessed May 7, 2025.
10. Burns DJP, Arora J, Okunade O, et al. International Consortium for Health Outcomes Measurement (ICHOM): Standardized Patient-Centered Outcomes Measurement Set for Heart Failure Patients. JACC Heart Fail. Mar 2020; 8(3): 212-222. PMID 31838032
11. Zannad F, Garcia AA, Anker SD, et al. Clinical outcome endpoints in heart failure trials: a European Society of Cardiology Heart Failure Association consensus document. Eur J Heart Fail. Oct 2013; 15(10): 1082-94. PMID 23787718
12. Givertz MM, Stevenson LW, Costanzo MR, et al. Pulmonary Artery Pressure-Guided Management of Patients With Heart Failure and Reduced Ejection Fraction. J Am Coll Cardiol. Oct 10 2017; 70(15): 1875-1886. PMID 28982501
13. Curtain JP, Lee MMY, McMurray JJ, et al. Efficacy of implantable haemodynamic monitoring in heart failure across ranges of ejection fraction: a systematic review and meta-analysis. Heart. May 15 2023; 109(11): 823-831. PMID 36522146
14. Adamson PB, Abraham WT, Bourge RC, et al. Wireless pulmonary artery pressure monitoring guides management to reduce decompensation in heart failure with preserved ejection fraction. Circ Heart Fail. Nov 2014; 7(6): 935-44. PMID 25286913
15. Adamson PB, Abraham WT, Stevenson LW, et al. Pulmonary Artery Pressure-Guided Heart Failure Management Reduces 30-Day Readmissions. Circ Heart Fail. Jun 2016; 9(6). PMID 27220593
16. Krahnke JS, Abraham WT, Adamson PB, et al. Heart failure and respiratory hospitalizations are reduced in patients with heart failure and chronic obstructive pulmonary disease with the use of an implantable pulmonary artery pressure monitoring device. J Card Fail. Mar 2015; 21(3): 240-9. PMID 25541376
17. Assmus B, Angermann CE, Alkhlout B, et al. Effects of remote haemodynamic-guided heart failure management in patients with different subtypes of pulmonary hypertension: insights from the MEMS-HF study. Eur J Heart Fail. Dec 2022; 24(12): 2320-2330. PMID 36054647
18. Clephas PRD, Zwartkruis VW, Malgie J, et al. Pulmonary artery pressure monitoring in chronic heart failure: effects across clinically relevant subgroups in the MONITOR-HF trial. Eur Heart J. Aug 21 2024; 45(32): 2954-2964. PMID 38733175
19. Heywood JT, Jermyn R, Shavelle D, et al. Impact of Practice-Based Management of Pulmonary Artery Pressures in 2000 Patients Implanted With the CardioMEMS Sensor. Circulation. Apr 18 2017; 135(16): 1509-1517. PMID 28219895

20. Lindenfeld J, Costanzo MR, Zile MR, et al. Implantable Hemodynamic Monitors Improve Survival in Patients With Heart Failure and Reduced Ejection Fraction. J Am Coll Cardiol. Feb 13 2024; 83(6): 682-694. PMID 38325994
21. Urban S, Szymański O, Grzesiak M, et al. Effectiveness of remote pulmonary artery pressure estimating in heart failure: systematic review and meta-analysis. Sci Rep. Jun 05 2024; 14(1): 12929. PMID 38839890
22. Kapelios CJ, Liori S, Bonios M, et al. Effect of pulmonary artery pressure-guided management on outcomes of patients with heart failure outside clinical trials: A systematic review and meta-analysis of real-world evidence with the CardioMEMS Heart Failure System. Eur J Heart Fail. Oct 2025; 27(10): 1857-1865. PMID 40360446
23. Abraham WT, Adamson PB, Bourge RC, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. Lancet. Feb 19 2011; 377(9766): 658-66. PMID 21315441
24. Abraham WT, Stevenson LW, Bourge RC, et al. Sustained efficacy of pulmonary artery pressure to guide adjustment of chronic heart failure therapy: complete follow-up results from the CHAMPION randomised trial. Lancet. Jan 30 2016; 387(10017): 453-61. PMID 26560249
25. Adamson PB, Abraham WT, Aaron M, et al. CHAMPION trial rationale and design: the long-term safety and clinical efficacy of a wireless pulmonary artery pressure monitoring system. J Card Fail. Jan 2011; 17(1): 3-10. PMID 21187258
26. CardioMEMS ChampionTM HF Monitoring System: FDA Review of P100045/A004FDA Presentation - CardioMEMS: Oct. 9, 2013. 2013; https://wayback.archive-it.org/7993/20170111163259/http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM370955.pdf. Accessed May 5, 2025.
27. CardioMEMSChampionTM Heart Failure Monitoring System: Presentation - CardioMEMS: Oct. 9, 2013. 2013; https://wayback.archive-it.org/7993/20170111163201/http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM370951.pdf. Accessed May 4, 2025.
28. Shavelle DM, Desai AS, Abraham WT, et al. Lower Rates of Heart Failure and All-Cause Hospitalizations During Pulmonary Artery Pressure-Guided Therapy for Ambulatory Heart Failure: One-Year Outcomes From the CardioMEMS Post-Approval Study. Circ Heart Fail. Aug 2020; 13(8): e006863. PMID 32757642
29. DeFilippis EM, Henderson J, Axsom KM, et al. Remote Hemodynamic Monitoring Equally Reduces Heart Failure Hospitalizations in Women and Men in Clinical Practice: A Sex-Specific Analysis of the CardioMEMS Post-Approval Study. Circ Heart Fail. Jun 2021; 14(6): e007892. PMID 34129363
30. Lindenfeld J, Zile MR, Desai AS, et al. Haemodynamic-guided management of heart failure (GUIDE-HF): a randomised controlled trial. Lancet. Sep 11 2021; 398(10304): 991-1001. PMID 34461042
31. Zile MR, Desai AS, Costanzo MR, et al. The GUIDE-HF trial of pulmonary artery pressure monitoring in heart failure: impact of the COVID-19 pandemic. Eur Heart J. Jul 14 2022; 43(27): 2603-2618. PMID 35266003
32. Brugts JJ, Radhoe SP, Clephas PRD, et al. Remote haemodynamic monitoring of pulmonary artery pressures in patients with chronic heart failure (MONITOR-HF): a randomised clinical trial. Lancet. Jun 24 2023; 401(10394): 2113-2123. PMID 37220768
33. Zile MR, Abraham WT, Stevenson LW, et al. Relationship Between Remote, Ambulatory Pulmonary Artery Pressures, and All-Cause Mortality in Patients With Chronic Heart Failure. Circ Heart Fail. Jun 2025; 18(6): e012754. PMID 40223608
34. Kishino Y, Kuno T, Malik AH, et al. Effect of pulmonary artery pressure-guided therapy on heart failure readmission in a nationally representative cohort. ESC Heart Fail. Aug 2022; 9(4): 2511-2517. PMID 35560987
35. Cowie MR, Flett A, Cowburn P, et al. Real-world evidence in a national health service: results of the UK CardioMEMS HF System Post-Market Study. ESC Heart Fail. Feb 2022; 9(1): 48-56. PMID 34882989

36. Heywood JT, Zalawadiya S, Bourge RC, et al. Sustained Reduction in Pulmonary Artery Pressures and Hospitalizations During 2 Years of Ambulatory Monitoring. J Card Fail. Jan 2023; 29(1): 56-66. PMID 36332900
37. Angermann CE, Assmus B, Anker SD, et al. Pulmonary artery pressure-guided therapy in ambulatory patients with symptomatic heart failure: the CardioMEMS European Monitoring Study for Heart Failure (MEMS-HF). Eur J Heart Fail. Oct 2020; 22(10): 1891-1901. PMID 32592227
38. Abraham J, Bharmi R, Jonsson O, et al. Association of Ambulatory Hemodynamic Monitoring of Heart Failure With Clinical Outcomes in a Concurrent Matched Cohort Analysis. JAMA Cardiol. Jun 01 2019; 4(6): 556-563. PMID 31090869
39. Desai AS, Bhimaraj A, Bharmi R, et al. Ambulatory Hemodynamic Monitoring Reduces Heart Failure Hospitalizations in "Real-World" Clinical Practice. J Am Coll Cardiol. May 16 2017; 69(19): 2357-2365. PMID 28330751
40. Guichard JL, Bonno EL, Nassif ME, et al. Seated Pulmonary Artery Pressure Monitoring in Patients With Heart Failure: Results of the PROACTIVE-HF Trial. JACC Heart Fail. Nov 2024; 12(11): 1879-1893. PMID 39152983
41. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Cordella Pulmonary Artery Sensor System. 2024; https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230040B.pdf. Accessed May 6, 2025.
42. Sharif F, Rosenkranz S, Bartunek J, et al. Safety and efficacy of a wireless pulmonary artery pressure sensor: primary endpoint results of the SIRONA 2 clinical trial. ESC Heart Fail. Oct 2022; 9(5): 2862-2872. PMID 35686479
43. Mullens W, Sharif F, Dupont M, et al. Digital health care solution for proactive heart failure management with the Cordella Heart Failure System: results of the SIRONA first-in-human study. Eur J Heart Fail. Oct 2020; 22(10): 1912-1919. PMID 32476191
44. Lin AL, Hu G, Dhruva SS, et al. Quantification of Device-Related Event Reports Associated With the CardioMEMS Heart Failure System. Circ Cardiovasc Qual Outcomes. Oct 2022; 15(10): e009116. PMID 36252112
45. Vaduganathan M, DeFilippis EM, Fonarow GC, et al. Postmarketing Adverse Events Related to the CardioMEMS HF System. JAMA Cardiol. Nov 01 2017; 2(11): 1277-1279. PMID 28975249
46. Krzesiński P, Jankowska EA, Siebert J, et al. Effects of an outpatient intervention comprising nurse-led non-invasive assessments, telemedicine support and remote cardiologists' decisions in patients with heart failure (AMULET study): a randomised controlled trial. Eur J Heart Fail. Mar 2022; 24(3): 565-577. PMID 34617373
47. Kamath SA, Drazner MH, Tasissa G, et al. Correlation of impedance cardiography with invasive hemodynamic measurements in patients with advanced heart failure: the BioImpedance CardioGraphy (BIG) substudy of the Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE) Trial. Am Heart J. Aug 2009; 158(2): 217-23. PMID 19619697
48. Anand IS, Greenberg BH, Fogoros RN, et al. Design of the Multi-Sensor Monitoring in Congestive Heart Failure (MUSIC) study: prospective trial to assess the utility of continuous wireless physiologic monitoring in heart failure. J Card Fail. Jan 2011; 17(1): 11-6. PMID 21187259
49. Anand IS, Tang WH, Greenberg BH, et al. Design and performance of a multisensor heart failure monitoring algorithm: results from the multisensor monitoring in congestive heart failure (MUSIC) study. J Card Fail. Apr 2012; 18(4): 289-95. PMID 22464769
50. Packer M, Abraham WT, Mehra MR, et al. Utility of impedance cardiography for the identification of short-term risk of clinical decompensation in stable patients with chronic heart failure. J Am Coll Cardiol. Jun 06 2006; 47(11): 2245-52. PMID 16750691
51. Amir O, Ben-Gal T, Weinstein JM, et al. Evaluation of remote dielectric sensing (ReDS) technology-guided therapy for decreasing heart failure re-hospitalizations. Int J Cardiol. Aug 01 2017; 240: 279-284. PMID 28341372
52. Silber HA, Trost JC, Johnston PV, et al. Finger photoplethysmography during the Valsalva maneuver reflects left ventricular filling pressure. Am J Physiol Heart Circ Physiol. May 15 2012; 302(10): H2043-7. PMID 22389389
53. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of

Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. J Am Coll Cardiol. Aug 08 2017; 70(6): 776-803. PMID 28461007
54. 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. May 03 2022; 145(18): e895-e1032. PMID 35363499
55. Bayes-Genis A, Pagnesi M, Codina P, et al. Remote pulmonary artery pressure-guided management of patients with heart failure: A clinical consensus statement of the Heart Failure Association (HFA) of the ESC. Eur J Heart Fail. Sep 2025; 27(9): 1644-1657. PMID 40288763
56. National Institute for Health and Care Excellence (NICE). Interventional procedures guidance: Percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure [IPG711]. November 2021; https://www.nice.org.uk/guidance/ipg711. Accessed May 5, 2025.
57. Dickinson MG, Allen LA, Albert NA, et al. Remote Monitoring of Patients With Heart Failure: A White Paper From the Heart Failure Society of America Scientific Statements Committee. J Card Fail. Oct 2018; 24(10): 682-694. PMID 30308242

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.