Medical Policy

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

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Populations	Interventions	Comparators	Outcomes
Individuals: • With NYHA class II-IV heart failure in outpatient settings who have had a hospitalization in the past year and/or have elevated natriuretic peptides	Interventions of interest are: • Hemodynamic monitoring with an implantable pulmonary artery pressure sensor device	Comparators of interest are: • Usual care without hemodynamic monitoring	Relevant outcomes include: • Overall survival • Symptoms • Functional outcomes • Quality of life • Morbid events • Hospitalizations • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • With heart failure in outpatient settings	Interventions of interest are: • Hemodynamic monitoring by thoracic bioimpedance	Comparators of interest are: • Usual care without hemodynamic monitoring	Relevant outcomes include: • Overall survival • Symptoms • Functional outcomes • Quality of life • Morbid events • Hospitalizations • Treatment-related morbidity
Individuals: • With heart failure in outpatient settings	Interventions of interest are: • Hemodynamic monitoring with inert gas rebreathing	Comparators of interest are: • Usual care without hemodynamic monitoring	Relevant outcomes include: • Overall survival • Symptoms • Functional outcomes • Quality of life • Morbid events • Hospitalizations • Treatment-related morbidity
Individuals: • With heart failure in outpatient settings	Interventions of interest are: • Hemodynamic monitoring of arterial pressure during the Valsalva maneuver	Comparators of interest are: • Usual care without hemodynamic monitoring	Relevant outcomes include: • Overall survival • Symptoms • Functional outcomes • Quality of life • Morbid events • Hospitalizations • Treatment-related morbidity

DESCRIPTION

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.

OBJECTIVE

The objective of this evidence review is to determine whether outpatient hemodynamic monitoring improves the net health outcome in individuals with heart failure.

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.[1,]

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.[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 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. 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.

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 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."

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 1 presents an inexhaustive list of representative devices (FDA product code: DSB).

Table 1. 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
Sensinel Cardiopulmonary Management (CPM) System	Analog Devices	2024

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 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 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 Heart Failure Monitoring System received expanded approval for the treatment of New York Heart Association (NYHA) Class II-III patients who had been hospitalized at least 1 time in the prior year and/or had elevated natriuretic peptides.

In 2024, the Cordella™ PA Sensor System (Endotronix, Inc.) received FDA approval through the premarket approval process.[5,] This system consists of an implantable PA sensor placed in the right PA, a catheter delivery system, a handheld patient reader with a dock, calibration equipment, and a data analysis platform that transmits PA pressure measurements to a secure database for clinician review. The device was approved for measuring PA pressure in NYHA Class III heart failure patients who are at home on diuretics and guideline-directed medical therapy, with the goal of reducing hospitalizations for heart failure. The FDA is requiring a post-approval study to collect additional evidence of continued safety and effectiveness in the NYHA Class III 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 the 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.

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

POLICY

In the ambulatory care and outpatient setting, cardiac hemodynamic monitoring for the management of heart failure using implantable direct pressure monitoring of the pulmonary artery, thoracic bioimpedance, inert gas rebreathing, and arterial pressure during the Valsalva maneuver is considered **experimental / investigational**.

POLICY GUIDELINES

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 evidence review.

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

RATIONALE

This evidence review was created using searches of the PubMed database. The most recent literature update was performed through April 4, 2025.

For the first indication, because there is direct evidence from a large randomized controlled trial (RCT), we focus on it and assess the evidence it provides on clinical utility. 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 2, 3, and 4, 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.

IMPLANTABLE PULMONARY ARTERY PRESSURE MONITORING

(CARDIOMEMS AND CORDELLA DEVICES)

Clinical Context and Therapy Purpose

The purpose of the CardioMEMS system in individuals who have heart failure is to provide remote monitoring of pulmonary artery pressure to inform therapy modification and prevent or reduce hospitalization. Studies on the safety and/or efficacy of the CardioMEMS system consist of 2 RCTs (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA III Heart Failure Patients [CHAMPION], Hemodynamic GUIDEd Management of Heart Failure [GUIDE-HF]) and several nonrandomized studies featuring pre-post, matched cohort comparative, and postmarket surveillance analyses. Studies on the safety and efficacy of the Cordella system include three open-label studies, which evaluated pulmonary artery pressure-guided management in NYHA class III individuals with heart failure.

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

Populations

The relevant population(s) of interest is individuals with New York Heart Association (NYHA) Class II-IV heart failure who have had a hospitalization in the past year and/or have elevated natriuretic peptides.

Interventions

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 Heart Failure Monitoring System, has approval from the U.S. Food and Drug Administration (FDA) for the ambulatory management of heart failure patients. The CardioMEMS device is implanted using a heart catheter system fed through the femoral vein and generally requires individuals to have an overnight hospital admission for observation after implantation. Specific target pressure ranges provided to investigators to achieve hemodynamic stability included 10 to 25 mm Hg for mean pulmonary artery pressure, 14 to 35 mm Hg for systolic pressure, and 8 to 20 mm Hg for diastolic pressure. An elevation or decrease in pulmonary artery pressure outside of a person's individualized baseline was considered to arise from overload or depletion, respectively.

The Cordella™ Pulmonary Artery Pressure Sensor System is an implantable device designed to monitor pulmonary artery pressures in patients with NYHA Class III heart failure. The Cordella device is implanted using a transcatheter delivery system via the femoral vein. Once implanted,

the Cordella Sensor enables daily, seated measurements of mean, systolic, and diastolic pulmonary artery pressures using a handheld reader placed against the chest. These readings are wirelessly transmitted to clinicians, allowing them to make adjustments to therapy based on individualized hemodynamic targets.

Comparators

The comparator of interest is standard clinical care without hemodynamic testing. Treatment decisions, such as medication adjustments or hospitalization, are made based on changes in clinical signs (eg, body weight, blood pressure, laboratory parameters) and symptoms (eg, dyspnea, fatigue, exercise intolerance) without measurement of pulmonary artery pressure.

Outcomes

The International Consortium for Health Outcomes Measurement has identified 3 domains of outcomes for a standard outcome set for individuals with heart failure.[6,]

- Survival and disease control (ie, mortality)
- Functioning and disease control (ie, symptom control including dyspnea, fatigue and tiredness, disturbed sleep, and peripheral edema, activities of daily living including health-related quality of life, maximum physical exertion, independence and psychosocial health including depression and anxiety, confidence and self-esteem)
- Burden of care to the individual (ie, hospital visits including admissions and appointments, treatment side effects, complications)

The Heart Failure Association of the European Society of Cardiology has published a consensus document on heart failure outcomes in clinical trials.[7,] They likewise categorize important outcomes for clinical trials as mortality outcomes (all-cause and cause-specific), morbidity and clinical composites (including hospitalizations, worsening of heart failure, implantable cardioverter device shocks) and symptoms and patient-reported outcomes. The consensus document recommends that hospitalization for heart failure be defined as a hospitalization requiring at least an overnight stay caused by substantive worsening of symptoms and/or signs requiring augmentation of therapy.

Measurements of maximal oxygen consumption during exercise, the 6-minute hall walk test (6MHW), stair climb test, Short Physical Performance Battery or hand-grip strength are functional measures.

Patient-reported outcome measures may include the Kansas City Cardiomyopathy Questionnaire (KCCQ-12), the Minnesota Living with Heart Failure Questionnaire (MLHFQ), and the EuroQol 5-Dimension, 5-Level (EQ-5D-5L) Questionnaire.

Generally, demonstration of outcomes over a 1-year period is meaningful to assess outcomes for the intervention.

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.

Post-hoc and/or exploratory subgroup analyses of CardioMEMS trials in patients with reduced ejection fraction,[8,9,]preserved ejection fraction,[10,] Medicare-eligible patients,[11,]chronic obstructive pulmonary disease[12,], and various subtypes of pulmonary hypertension[13,14,] are outside of the scope of this review and are therefore not discussed. Studies reporting physiological measures in the absence of clinical outcomes were also excluded.[15,]

REVIEW OF EVIDENCE

Systematic Reviews

Lindenfeld et al (2024) reported the results of a patient-level meta-analysis of 3 RCTs (GUIDE-HF, CHAMPION, and LAPTOP-HF) evaluating CardioMEMs hemodynamic monitoring for the management of patients with heart failure and a left ventricular ejection fraction ≤40%.[16,] The meta-analysis included 1,350 patients with a median follow-up of 12.2 months with a maximum follow-up of 4 years. Patients were randomized to a treatment group receiving hemodynamic-guided management via CardioMEMs (n=667) or a control group receiving standard care (n=683). The pooled analysis demonstrated a significant 36% reduction in heart failure hospitalizations (Hazard Ratio [HR]: 0.64; 95% CI: 0.55 to 0.76; p<.0001) and a significant 25% reduction in mortality (HR: 0.75; 95% CI: 0.57 to 0.99; p=.043) in the treatment group compared to the control group. This mortality benefit was observed after the first year of follow-up. The LAPTOP-HF study is only available as an abstract and is not otherwise reviewed in this medical policy.

Urban et al (2024) conducted a meta-analysis of RCTs assessing the effectiveness of remote hemodynamic monitoring in patients with heart failure.[17,] Five trials (COMPASS-HF, REDUCE-HF, CHAMPION, GUIDE-HF, and MONITOR-HF) enrolling a total of 2,572 patients were included. Patients were randomized to hemodynamic monitoring guided management (n=1279) or standard care (n=1293) with a mean follow-up of 11.25 months. In the pooled analysis, hemodynamic-guided management significantly reduced the risk of heart failure-related hospitalizations (HFH) by 33% (Hazard Ratio [HR] 0.67; 95% CI 0.58 to 0.76; p<.00001) and heart failure-related events by 14% (Relative Risk [RR] 0.86; 95% CI 0.75 to 0.99; p=.03). However, no significant differences were observed for all-cause mortality (Odds Ratio [OR] 0.91; 95% CI 0.72 to 1.16; p=.46) or cardiovascular mortality (OR 0.92; 95% CI 0.68 to 1.25; p=.61). Subgroup analysis suggested that the observed benefits were driven primarily by studies of the CardioMEMS device (n=3 trials), with no significant effect seen for studies evaluating the Chronicle system (n=2 trials). The certainty of evidence was rated as low for all outcomes with the exception of heart failure events which was rated as a moderate risk of bias. The COMPASS-HF and REDUCE-HF studies investigated the Chronicle device, which is not FDA-approved and is not otherwise reviewed in this medical policy.

RANDOMIZED CONTROLLED TRIALS

CHAMPION

Abraham et al (2011, 2016) reported on the results of CHAMPION, a single-blind RCT enrolling patients with NYHA Class III heart failure who have had a hospitalization in the prior year. All enrolled patients were implanted with the CardioMEMS device.[18,19,] Patients were randomized to the CardioMEMS group, in which daily uploaded pulmonary artery pressures were used to guide medical therapy, or to the control group, in which investigators were blinded to daily uploaded pressures and managed patients based on clinical signs and symptoms.. An independent clinical endpoints classification (CEC) committee, blinded to the treatment groups, reviewed abstracted clinical data and determined if hospitalization was related to heart failure. It is unclear what criteria were used for adjudication of heart failure hospitalizations.[20,]

The randomized phase ended when the last patient enrolled completed at least 6 months of study follow-up (average, 18 months) and was followed in an open-access phase during which investigators had access to pulmonary artery pressure for all patients (former control and treatment group). Trial characteristics and results are summarized in Tables 2 through 4. The trial met its primary efficacy endpoint, with a statistically significant 28% relative reduction in the rate of HFH at 6 months. This outcome was accompanied by a significant improvement in MLHFQ scores at 6 and 12 months. No significant reduction in mortality was observed at 6 months or at the conclusion of the randomized phase. However, members of the FDA advisory committee in 2011 were unable to distinguish the effect of the device on HFH from the effect of nurse communications in cases where the investigator did not document a medication change in response to an abnormal pulmonary artery pressure elevation. Therefore, the FDA denied the initial approval of CardioMEMS and requested additional clarification from the manufacturer.[3,] Subsequently, the FDA held a second advisory committee meeting in 2013 to review additional data (including open-access phase) and address previous concerns related to the impact of nurse communication on the CHAMPION trial.[21,22,] Post-hoc analyses to address the impact of nurse interventions on HFH conducted by the sponsor were judged to have methodologic limitations by the FDA.[3,] However, the FDA stated that longitudinal analyses, such as those demonstrating a significant decrease in HFH when former control patients entered the treatment arm of the open-access phase, were the most useful regarding support for device effectiveness. It is important to acknowledge that all such analyses were conducted with the intent to test the robustness of potentially biased RCT results; therefore, results from these analyses should be evaluated to assess consistency and not as an independent source of evidence to support efficacy. Additional trial aspects limit the interpretation of these analyses; notably, subject dropouts were not random, and patient risk profiles could have changed from the randomized phase to the open-access phase. In the open-access phase, 93 (34%) of 270 subjects in the treatment group and 110 (39%) of 280 subjects in the control group remained in the analysis.

While the CHAMPION trial failed to demonstrate a treatment effect in women, the overall reduction in HFH subsequently observed in the CardioMEMS post-approval study (see Tables 7 and 8) was also observed in the subgroup analysis of women, which comprised 37.7% of the study population.[23,24,]

GUIDE-HF

Lindenfeld et al (2021) reported on the results of the Hemodynamic GUIDEd Management of Heart Failure trial (GUIDE-HF), a single-blind RCT in which all patients were implanted with the CardioMEMS device.[25,] As in the CHAMPION trial, patients were randomized to control and

treatment groups in which investigators were blinded or unblinded, respectively, to pulmonary artery pressures uploaded daily by all patients. The GUIDE-HF trial expanded enrollment to patients with NYHA Class II-IV heart failure with a hospitalization in the prior year and/or elevated natriuretic peptides. Patient management was composed of 2 phases: (1) an optimization phase through 3 months post-implantation and (2) a maintenance phase. The optimization phase required clinicians to monitor and manage patients more closely to optimize pulmonary artery pressures to an individualized target range, while the maintenance phase focused on maintaining optimal pulmonary artery pressures. Generally, a 3 to 5 mm Hg persistent pressure change over 2 to 3 days or a change of 5 mm Hg in a single day were recommended as actionable deviations. Blinded trial personnel were instructed to contact subjects with scripted language provided by unblinded study coordinators at least once every 2 weeks during the optimization phase and at least monthly during the maintenance phase. Efforts were made to balance the frequency of site-initiated communications.

Trial characteristics and results are summarized in Tables 2 through 4. The GUIDE-HF trial failed to meet its overall primary efficacy endpoint, finding a statistically insignificant 12% reduction in the composite of HFH (>24 h due to acute decompensation and requiring administration of intravenous diuretics), urgent heart failure visits (ie, unscheduled or unplanned admission to the emergency department, hospital outpatient observation visit, or hospital inpatient visit [<24 h] due to acute decompensation and requiring administration of intravenous diuretics), and all-cause mortality at 12 months post-implantation. An independent CEC committee adjudicated all endpoints contributing to the primary outcome to confirm that they were heart failure-related. No significant improvements in individual components of the primary outcome or secondary efficacy endpoints were observed in GUIDE-HF. Subgroup analyses for the primary endpoint found a reduced treatment effect in patients with NYHA Class IV heart failure and men. The more favorable treatment effect in women observed in GUIDE-HF is inconsistent with results from the CHAMPION trial which found limited benefit. Overall, fewer patients were receiving primary classes of guideline-directed medical therapy at 12 months in both treatment and control groups. A significantly higher reduction in mean pulmonary artery pressure was observed in the treatment group; however, it is unclear whether the proportion of patients meeting target pressure ranges improved and whether absolute reductions were clinically meaningful.

With approval from the FDA in August 2020, the statistical analysis plan was updated to include sensitivity analyses with a 15% interaction significance level to evaluate the possible impact of the COVID-19 pandemic. Results of overall, pre-COVID-19, and during-COVID-19 analyses are summarized in Table 3. All patients were enrolled for at least 3 months and 71.7% of follow up occurred before the US national emergency declaration date of March 13, 2020. The CEC committee determined that there were 7 events related or possibly related to COVID-19; all occurring in the control group. Planned sensitivity analyses based on the timing of the COVID-19 pandemic included evaluation of primary endpoint events observed for subjects completing study participation prior to the pandemic and for subject follow-up occurring prior to the pandemic. The pre-COVID-19 impact analysis based on subject follow-up suggested an effect of COVID-19 on the primary endpoint (p=.11). A significant 19% reduction (p=.049) in the primary endpoint was found, driven by a 28% reduction in HFH (p=.0072). No significant improvements in heart failure visits, mortality, or secondary efficacy outcomes were observed. Additional analysis of patient data obtained during the COVID-19 pandemic as subsequently reported by Zile et al (2022)[26,] failed to find a significant reduction in the composite outcome and its individual

components. Study authors noted that this was driven by an unexpected reduction in the primary event rate in the control group, potentially due to patient-dependent factors.

Study relevance, design, and conduct limitations are summarized in Tables 5 and 6. Lifestyle changes during the 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. During COVID-19, the monthly rate of medication changes fell by 19.2% in the treatment group and 10.7% in the control group. This was accompanied by a deintensification of medication management (ie, decreased ratio of dosage increases to decreases) by 8.8% and 17.4% in the treatment and control groups, respectively. The number of site-initiated (blinded) and overall contacts was similar pre- and during-COVID-19 after exclusion of contacts occurring in the initial 90-day optimization phase. The final 500 trial subjects enrolled had a significantly higher proportion of NYHA Class III-IV heart failure as enrollment of subjects with NYHA Class II heart failure was limited to 300 patients. Reductions in mean pulmonary artery pressure were not significantly different between groups during COVID-19 and it is unclear what proportion of medication changes were concordant with deviations in hemodynamic data over the course of the trial.

MONITOR-HF

Brugts et al (2023) reported the results of MONITOR-HF, an open-label RCT conducted in 25 centers in the Netherlands.[27,] Eligible patients had NYHA class III chronic heart failure, a previous heart failure hospitalization, and had been treated with optimal or maximally tolerated treatment according to the European Society of Cardiology guidelines. Patients were randomly assigned (1:1) to either hemodynamic monitoring using CardioMEMS or standard of care. All patients were scheduled for follow-up at 3 months, 6 months, and every 6 months thereafter, up to 48 months. In the control group, patients were managed with guideline-directed medical therapy and diuretics based on signs, symptoms, laboratory measurements, and echocardiography without hemodynamic information. The primary endpoint was the mean difference in the Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary score at 12 months. Trial characteristics and results are summarized in Tables 2 through 4. The MONITOR-HF study achieved its primary efficacy endpoint, demonstrating a statistically significant change in the mean KCCQ overall summary score at 12 months, favoring the CardioMEMs group with a mean difference of 7.05 points (95% CI: 2.77 to 11.33; p=.013) compared to the control group. Secondary outcomes included a responder analysis that revealed the CardioMEMS group had a significantly higher proportion of patients achieving a ≥ 5-point improvement in KCCQ score at 12 months compared to the standard of care group (47.7% vs. 38.1%, p = 0.046). Participants in the CardioMEMS group also experienced a lower rate of total heart failure hospitalizations or urgent visits requiring IV diuresis, with 117 events per patient-year compared to 212 in the standard of care group (HR 0.56; 95% CI 0.38 to 0.84l; p=.0053). Additionally, the CardioMEMS group showed a significant reduction in median NT-proBNP levels at 12 months (-669 pg/mL, p = 0.013) and a significant improvement in mean 6-minute walk test distance (+29.3 m, p = 0.033), while the control group did not demonstrate significant changes in these parameters. Freedom from sensor failure in the CardioMEMS group was 98.8%. The trial included a sensitivity analysis to assess the potential impact of the COVID-19 pandemic on the results. The analysis revealed no significant interaction between the treatment effects and the COVID-19 pandemic. Study relevance, design, and conduct limitations are summarized in Tables 5 and 6. Limitations of the MONITOR-HF study included the lack of blinding, the absence of sham control, and the treatment arm having a two-month lead-in optimization phase which was not present in the control group.

Table 2. Summary of Key Randomized Controlled Trial Characteristics

Author; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	*Comparator*
Abraham et al (2011, 2016);[18,19,] CHAMPION	U.S.	64	2007-2010	Main Eligibility Criteria: At least 1 previous HFH in the past 12 mo and NYHA class III HF for at least 3 mo Patient Baseline Characteristics: • Sex: 72.5% male, 27.5% female • Mean Age: ~61 y • Race: 72.9% White, NR Black • NYHA Class: 100% III • Mean PAP: ~29-30 mm Hg • HFpEF: 21.6%	Disease management by daily measurement of pulmonary artery pressures (via CardioMEMS) plus standard of care (n=270)	Disease management by standard of care alone (n=280)
Lindenfeld et al (2021);[25,] Zile et al (2022);[26,] GUIDE-HF	U.S.	139	2018-2021	Main Eligibility Criteria: NYHA Class II-IV HF and at least 1 previous HFH in the past 12 mo or elevated natriuretic peptides within prior 30 days Patient Baseline Characteristics: • Sex: 62.5% male, 37.5% female • Mean Age: ~70-71 y • Race: 80.7% White, 17.9% Black • NYHA Class: 29.6% II, 65% III, 5.4% IV • Mean PAP: ~28-29 mm Hg	Disease management by daily measurement of pulmonary artery pressures (via CardioMEMS) plus standard of care (n=497)	Disease management by standard of care alone (n=503)
Brugts et al (2023); [27,]	The Netherlands	25	2019-2022	Main Eligibility Criteria: NYHA Class III HF with a	Disease management by daily	Disease management by standard

Author; Trial	Countries	Sites	Dates	Participants	Interventions	
				previous hospital admission for decompensated HF or urgent visit with necessity of IV diuretics in the past 12 mo while on optimal or maximally tolerated medical management according to ESC guidelines. Patients were required to be evaluated for implantable cardioverted defibrillators or cardiac resynchronization therapy devices as indicated. Patient Baseline Characteristics (CardioMEMs; Standard care): • Female: 21.6%; 27.3% • Mean Age: 69; 70 • NYHA Class III: 100%; 100% • Mean PAP: 33.3 mm Hg	measurement of pulmonary artery pressures (via CardioMEMS) plus standard of care (n=176)	of care alone (n=172)

CHAMPION: CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA III Heart Failure Patients trial; ESC: European Society of Cardiology; GUIDE-HF: Hemodynamic GUIDEd Management of Heart Failure trial; HF: heart failure; HFH: heart failure hospitalization; NR: not reported; NYHA: New York Heart Association; PAP: pulmonary artery pressure

Table 3. Summary of Key Randomized Controlled Trial Results: Main Safety and Efficacy Outcomes

Trial	N	HFH, Urgent HF Events, and Death, N (events/patient-time)	HFH, N (events/patient-time)	Urgent HF Visits, N (events/patient-time)	Death, N (%) or N (events/patient-time)	Device- or System-Related Complications, N (%)	Pressure-Sensor Failures, N (%)
Abraham et al (2011, 2016); CHAMPION [18,19],							
At 6 months							
CardioMEMS	270	NA	84 (0.32)	NA	15 (5.6%)	3 (1)	0 (0)
Control	280	NA	120 (0.44)	NA	20 (7.1%)	3 (1)	0 (0)
HR (95% CI); p-value		NA	0.72 (0.60 to 0.85);[a] .002	NA	NR	NA	NA
At 12 months							
CardioMEMS	270	NA	182 (0.46)	NA	50 (19%)	3 (1)	0 (0)
Control	280	NA	279 (0.68)	NA	64 (23%)	3 (1)	0 (0)
HR (95% CI); p-value		NA	0.67 (0.55 to 0.80); <.0001	NA	0.80 (0.55 to 1.15); 0.23	NA	NA
Lindenfeld et al (2021); Zile et al (2022); GUIDE-HF[25,26],							
At 12 Months							
Overall Analysis							

Trial	N	HFH, Urgent HF Events, and Death, N (events/patient-time)	HFH, N (events/patient-time)	Urgent HF Visits, N (events/patient-time)	Death, N (%) or N (events/patient-time)	Device- or System-Related Complications, N (%)	Pressure-Sensor Failures, N (%)
CardioMEMS	497	253 (0.563)	185 (0.410)	28 (0.065)	40 (0.094)	3 (0.6)	NA
Control	503	289 (0.640)	225 (0.497)	27 (0.063)	37 (0.086)	5 (1)	NA
HR (95% CI); p-value		0.88 (0.74 to 1.05);[b] .16	0.83 (0.68 to 1.01); .064	1.04 (0.61 to 1.77); .89	1.09 (0.70 to 1.70); 0.71	NA	NA
Pre-COVID-19 Impact Analysis							
CardioMEMS	497	177 (0.553)	124 (0.380)	23 (0.074)	30 (0.110)	NR	NA
Control	503	224 (0.682)	176 (0.525)	23 (0.073)	25 (0.088)	NR	NA
HR (95% CI); p-value		0.81 (0.66 to 1.00); .049	0.72 (0.57 to 0.92); .0072	1.02 (0.57 to 1.82); 0.95	1.24 (0.73 to 2.11); 0.42	NR	NA
During-COVID-19 Impact Analysis							
CardioMEMS	310	76 (0.597)	61 (0.490)	5 (0.048)	10 (0.067)	NR	NA
Control	307	65 (0.536)	49 (0.414)	4 (0.041)	12 (0.085)	NR	NA
HR (95% CI); p-value		1.11 (0.80 to 1.55); .53	1.18 (0.81 to 1.73); .38	1.19 (0.82 to 1.70); .80	0.79 (0.35 to 1.83); .59	NR	NA
Brugts et al (2023); [27,]							
At 12 months						**Freedom of device-related or system-related complications and sensor failure**	

Trial	N	HFH, Urgent HF Events, and Death, N (events/patient-time)	HFH, N (events/patient-time)	Urgent HF Visits, N (events/patient-time)	Death, N (%) or N (events/patient-time)	Device- or System-Related Complications, N (%)	Pressure-Sensor Failures, N (%)
CardioMEMS	176	159 (0.518)	117 (0.381)	11 (0.036)	42 (0.137)	97.7%	2 (1.2%)
Control	172	257 (0.822)	212 (0.678)	17 (0.054)	45 (0.144)	98.8%	NA
HR (95% CI); p-value		0.63 (0.44 to 0.90);.011	0.56 (0.38 to 4.08);.0053	0.65 (0.23 to 1.88);.44	0.96 (0.63 to 1.46);.846	NR	NR

CHAMPION: CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA III Heart Failure Patients trial; CI: confidence interval; GUIDE-HF: Hemodynamic GUIDEd Management of Heart Failure trial; HF: heart failure; HFH: heart failure hospitalization; HR: hazard ratio; NA: not applicable; NR: not reported;
[a] Primary efficacy outcome in CHAMPION trial.
[b] Primary efficacy outcome in GUIDE-HF trial.

Table 4. Summary of Key Randomized Controlled Trial Results: Secondary Outcomes

Trial	N	MLHFQ[a]	KCCQ-12[b]	EQ-5D-5L VAS[c]	6MHW Test Distance	Mean PAP Change from Baseline	Medication Changes
Abraham et al (2011, 2016); CHAMPION[18,19,]							
At 6 Months		Mean (SD)				Mean AUC Change, mm Hg x days (SD)	Mean (SD)
CardioMEMS	270	45 (26)	NA	NA	NA	-156 (NR)	9.1 (7.4)
Control	280	51 (25)	NA	NA	NA	33 (NR)	3.8 (4.5)
p-value		p=.02	NA	NA	NA	p=.008	p<.0001
At 12 Months		Mean (SD)					
CardioMEMS	270	47.0 (NR)	NA	NA	NA	NR	NR
Control	280	56.5 (NR)	NA	NA	NA	NR	NR
p-value		p=.0267	NA	NA	NA	NR	NR
Lindenfeld et al (2021); Zile et al (2022); GUIDE-HF[25,26,]							

Trial	N	MLHFQ[a]	KCCQ-12[b]	EQ-5D-5L VAS[c]	6MHW Test Distance	Mean PAP Change from Baseline	Medication Changes
At 12 Months							
Overall Analysis			Mean Change from Baseline (SD)	Mean Change from Baseline (SD)	Mean Change from Baseline, m (SD)	Mean AUC Change, mm Hg x days (SD)	Mean Changes/Month Per Patient (SD)
CardioMEMS	497	NA	5.20 (21.35) (n=421)	0.94 (20.17) (n=421)	-12.83 (100.08) (n=288)	-792.7 (1767.0)	1.031 (NR)
Control	503	NA	4.12 (22.50) (n=408)	2.90 (20.71) (N=409)	-6.46 (106.57) (n=291)	-582.9 (1698.1)	0.608 (NR)
p-value		NA	p=.48	p=.17	p=.46	p=.040	NR
Pre-COVID-19 Impact Analysis							
CardioMEMS	497	NA	4.19 (18.29) (n=140)	-1.28 (20.18) (n=140)	-19.46 (87.63) (n=120)	-518.0 (1327.0)	0.835 (NR)
Control	503	NA	5.05 (22.10) (n=137)	3.89 (17.73) (n=138)	-9.78 (112.70) (n=127)	-324.2 (1328.5)	0.475 (NR)
p-value		NA	p=.72	p=.024	p=.45	p=.014	p<.001
Brugts et al (2023); [27,]						Mean AUC Change, mm Hg x days (SD)	Mean Changes/Month Per Patient (SD)
At 12 months							
CardioMEMS	176	NA	63.3 (25.7)	≥5 point change: 10.6 ≥10 point change: 12.4 ≥15 point change: 15.2	-29.3	-16.23.8 (2003.4)	1.65 (1.09)
Control	172	NA	56.1 (24.5)	NR	-9.8	NR	1.14 (0.82)

Trial	N	MLHFQ[a]	KCCQ-12[b]	EQ-5D-5L VAS[c]	6MHW Test Distance	Mean PAP Change from Baseline	Medication Changes
HR (95% CI); p-value		NA	p=.012	NR	p=.033 and p=.52 vs baseline, for CardioMEMs and Control	p=.013 vs. baseline	NR

6MHW: 6 minute Hall Walk; AUC: area under the curve; CHAMPION: CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA III Heart Failure Patients trial; EQ-5D-5L VAS: EuroQOL 5-dimension 5-level Visual Analog Scale questionnaire; GUIDE-HF: Hemodynamic GUIDEd Management of Heart Failure trial; kCCQ-12: Kansas MLHFQ: Minnesota Living with Heart Failure Questionnaire; NA: not applicable; NR: not reported; SD: standard deviation.
[a] Higher scores (range, 0-105) indicate more significant impairment in health-related quality of life.
[b] Higher scores (range, 0-100) indicate better health status.
[c] Higher scores (range, 0-100) indicate better health status.
[d] Increased distances indicate improved functional capacity.

Tables 5 and 6 display notable limitations identified in each study.

Table 5. Study Relevance Limitations

Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Abraham et al (2011, 2016); CHAMPION[18,19,]		3. Delivery not similar intensity as comparator. Treatment group received additional nurse communication for enhanced protocol compliance.		5. Criteria for adjudication of heart failure hospitalizations unclear.	
Lindenfeld et al (2021); Zile et al (2022); GUIDE-HF[25,26,]		3. Unclear whether patient contacts were balanced during study optimization phase.			
Brugts et al (2023); [27,]		3. Delivery not similar intensity as treatment. Control group lacked a sham procedure and the treatment group received 2 months of active treatment optimization.			

CHAMPION: CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA III Heart Failure Patients trial; GUIDE-HF: Hemodynamic GUIDEd Management of Heart Failure trial.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No

CONSORT reporting of harms; 4. Not established and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 6. Study Design and Conduct Limitations

Trial	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Abraham (2011, 2016);CHAMPION[18,19,]		1. Physicians not blinded to treatment assignment but outcome adjudication (heart failure-relatedness) was independent and blinded.				
Lindenfeld et al (2021); Zile et al (2022); GUIDE-HF[25,26,]	4. COVID-19 impact analyses limited due to potential selection bias. Pre-COVID-19 analysis was enriched with patients with NYHA Class II HF.	1. Physicians not blinded to treatment assignment but outcome adjudication was independent and blinded.		1. High loss to follow-up or missing data for secondary outcomes.		5. The impact of COVID-19 on treatment effect estimates is uncertain. COVID-19-related sources of bias and imprecision may include patient lifestyle changes and altered provider behaviors.
Brugts et al (2023); [27,]		1. Physicians not blinded to treatment assignment but outcome adjudication (heart failure-relatedness) was independent and blinded.		1. Missing data for secondary outcomes in control group.		

CHAMPION: CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA III Heart Failure Patients trial; GUIDE-HF: Hemodynamic GUIDEd Management of Heart Failure trial; HF: heart failure; NYHA: New York Heart Association.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Nonrandomized Studies

As previously described in the selection criteria, studies will be included here to assess long-term outcomes and adverse effects if they capture longer periods of follow-up and/or larger populations than the RCTs. Nonrandomized studies have featured pre-post, retrospective matched cohort, and post-market surveillance analyses. Key nonrandomized study characteristics and results are summarized in Tables 7 and 8. Nonrandomized study relevance, design, and conduct limitations are summarized in Tables 9 and 10.

Kishino et al (2022) analyzed the Nationwide Readmissions Database (NRD) between 2014 and 2019 for patients with CardioMEMS implantation.[28,] CardioMEMS patients (n=1839) and their readmissions were compared to a matched cohort of patients with heart failure without CardioMEMS implantation (n=1924). Readmission rates at 30 days (17.35 vs. 21.5%; p=.002), 90 days (29.6% vs. 36.5%; p=.002), and 180 days (39.6% vs. 46.6%; p=.009) were lower in the CardioMEMS group. Based on multivariable regression analysis, only use of the CardioMEMS device was associated with a significantly lower risk of readmission at 30 days (hazard ratio [HR], 0.75; 95% confidence interval [CI], 0.63 to 0.89; p=.001), 90 days (HR, 0.73; 95% CI, 0.63 to 0.86; p<.001) and 180 days (HR, 0.80; 95% CI, 0.71 to 0.91; p=.001). However, in-hospital mortality at 30 days was significantly higher in the CardioMEMS group both before (6.9% vs. 2.8%; p<.001) and after propensity score matching (7% vs. 3.6%; p=.002). Use of the CardioMEMS device was also associated with higher rates of acute kidney injury (43.8% vs. 34.7%; p<.001), acute kidney injury requiring hemodialysis (3.5% vs. 1.8%; p=.019), and transfusions (9.8% vs. 3.4%; p<.001).

Cowie et al (2021) published 1-year outcomes from the prospective, international, multicenter, open-label CardioMEMS HF System for Post-Market Study (COAST).[29,] The study was designed to evaluate the safety, feasibility, and effectiveness of hemodynamic-guided heart failure management in patients with NYHA Class III heart failure in the UK, Europe, and Australia. The current report focuses on initial results from COAST-UK, which evaluated the first 100 patients who completed all follow-up in the UK before the COVID-19 pandemic emergency declaration date. The primary efficacy outcome was the change in the annualized HFH rate during the 12 months prior to implantation compared with 12 months after implantation. All clinical events were adjudicated by investigators responsible for the treatment. There were 165 HFH events (1.52

events/patient-year) before implant and 27 HFH events (0.27 events/patient-year) after implant, resulting in a significant 82% risk reduction (HR, 0.178; 95% confidence interval CI, 0.12 to 0.28; p<.0001). No significant improvements in EQ-5D-5L scores were observed at 6- or 12-month time points. Over 12 months, functional class improvements were noted for 41 patients reclassified as NYHA Class II and 3 patients reclassified as Class I. The primary safety endpoints of freedom from device- and system-related complications and freedom from pressure sensor failures at 2 years occurred in 100% and 99% of patients, respectively, exceeding pre-specified performance goals of 80% and 90%, respectively.

Shavelle et al (2020) reported 1-year outcomes from the open-label, observational, single-arm, post-approval study of CardioMEMS in 1200 patients (37.7% female) across 104 centers in the U.S. with NYHA Class III heart failure and a HFH event in the prior year.[23,] The primary efficacy outcome was the difference between rates of adjudicated HFH 1 year after compared to 1 year prior to device implantation. The 12-month visit was completed in 875 patients (72.9%). Prior to 1 year, 76 patients (6.3%) withdrew from the study and 186 patients (15.5%) died. The HFH rate was significantly lower at 1 year post-implantation (0.54 vs. 1.25 events/patient-year; HR, 0.43; 95% CI, 0.39 to 0.47; p<.0001). The rate decrease remained significant regardless of the number of pre-enrollment HFH events, with a trend towards a more significant benefit in a small subgroup of patients (n=21) with ≥5 pre-enrollment HFH events. The rate of all-cause hospitalization (ACH) was also significantly lower (1.67 vs. 2.28 events/patient-year; HR, 0.73; 95% CI, 0.68 to 0.78; p<.0001). During the study, 94.1% of patients had a medication change, with an average of 1.6 medication changes per month. Medication changes related to an increase or decrease in pulmonary artery pressure were implemented in 81.8% and 55.8% of patients, respectively. At 1 year, freedom from device- or system-related complications was 99.6% (5 events) and freedom from pressure sensor failure was 99.9% (1 event). The nature of these events and the frequency of procedure-related adverse events were not reported. Heywood et al published 2-year outcomes from the U.S. post-approval study in 2023.[30,] Two-year follow-up was completed by 710 patients (59.2%). Both HFH and ACH rates further decreased at 2 years to 0.37 events/patient-year (HR, 0.69; 95% CI, 0.58 to 0.82; p<.0001) and 1.42 events/patient-year (HR, 0.85; 95% CI, 0.77 to 0.94; p=.0014), respectively. During 2 year follow-up, 59.4% of all participants experienced freedom from HFH. Of 487 patients who were hospitalized, 53.6% were only hospitalized once. The rate of medication changes declined from 1.3 per subject in the first 90 days compared to 1.3 at years 1 and 2. Compared to baseline, the change in mean pulmonary artery pressure was -2.4 mm Hg at 1 year and -2.6 mm Hg at 2 years. Therefore, despite the decreasing frequency of interventions over time, the reduction of mean pulmonary artery pressures was largely sustained. Freedom from device- or system-related complications was 99.6% at 2 years, exceeding the 80% predefined performance goal for the primary safety endpoint. Freedom from sensor failure was 99.9%, exceeding the 90% predefined performance goal. The mortality rate through 2 years was 29%.

Angermann et al (2020) published results from the CardioMEMS European Monitoring Study for Heart Failure (MEMS-HF).[31,] This was an industry-sponsored, prospective, observational, non-randomized study designed to assess the safety and feasibility of the CardioMEMS heart failure system over a 12-month follow up in 31 centers across Germany, the Netherlands, and Ireland. A total of 239 patients (22% female) with NYHA class III heart failure and ≥1 HFH in the prior year were enrolled for remote pulmonary artery pressure-guided heart failure management. Co-primary outcome measures, 1-year rates of freedom from device- or system-related complications and sensor failure, were 98.3% (95% CI, 95.8 to 100) and 99.6% (95% CI, 97.6

to 100), respectively. Twenty-one serious adverse events (8.9%) were reported during 236 implant attempts, of which 4 were categorized as device- or system-related and 21 as procedure-related. Three procedure-related cardiac deaths were reported. The overall 12-month mortality rate was 13.8%, with no device- or system-related deaths. The secondary outcome measures included HFH rate at 12 months compared to the prior year before implantation and health-related quality of life. The HFH rate decreased 62% (0.60 vs. 1.55 events/patient year; HR, 0.38; 95% CI, 0.31 to 0.48; p<.0001). These reductions were consistent across subgroups defined by sex, age, heart failure etiology, device use, ejection fraction, baseline pulmonary artery pressure, and various comorbidities. Patient-reported health-related quality of life outcomes were assessed with the Kansas City Cardiomyopathy Questionnaire (KCCQ), 9-Item Patient Health Questionnaire (PHQ-9), and the EQ-5D-5L. All measures significantly improved at 6 months and were sustained through 12 months. Cumulative medication changes and the average rate of monthly per-patient medication changes were highest in months 0 to 3 postimplant.

Abraham et al (2019) published a retrospective matched cohort study of Medicare beneficiaries who received the CardioMEMS device between 2014 and 2016.[32,] Patients were matched to 1087 controls by demographics, history and timing of HFH, and number of ACH. Propensity scoring based on arrhythmia, hypertension, diabetes, pulmonary disease, and renal disease was used for additional matching. Follow-up was censored at death, ventricular assist device implant, or heart transplant. At 12 months postimplantation, 616 and 784 HFH events occurred in the treatment and control cohorts, respectively. Study characteristics and results are summarized in Tables 7 and 8. The rate of HFH was lower in the treatment cohort at 12 months (HR, 0.76; 95% CI, 0.65 to 0.89; p<.001). Percentage of days lost to HFH (HR, 0.73; 95% CI, 0.64 to 0.84; p<.001) and ACH or death (HR, 0.77; 95% CI, 0.68 to 0.88; p<.001) were both significantly lower in the treatment group. The percentage of days lost owing to HFH or death was reduced in the treatment cohort (relative risk [RR], 0.73; 95% CI, 0.63 to 0.83).

Desai et al (2017) published a retrospective cohort study of Medicare administrative claims data for individuals who received the CardioMEMS device following the FDA approval.[33,] Of 1935 Medicare enrollees who underwent implantation of the device, 1114 were continuously enrolled and had evaluable data for at least 6 months before, and following, implantation. A subset of 480 enrollees had complete data for 12 months before and after implantation. The cumulative incidence of HFH events was significantly lower in the postimplantation period than in the preimplantation period at both 6- and 12-month follow-ups.

Guichard et al (2024) reported the results of PROACTIVE-HF, a prospective, multicenter, open-label single-arm trial conducted at 75 sites across the United States and Europe of the Cordella System.[34,] Eligible patients had NYHA class III chronic heart failure, a recent HFH, or elevated natriuretic peptides, and were on maximally tolerated guideline-directed therapy for a minimum of 3 months. After an initial RCT design, the trial transitioned to a single-arm study at the device manufacturer's request. This change, made with FDA input, was prompted by the publication of the GUIDE-HF trial which showed benefit for usage of the CardioMEMs device in a similar patient population.[35,] Patients were implanted with the Cordella pulmonary artery sensor and managed to a target seated mean pulmonary artery pressure (mPAP) of 5-20 mm Hg through diuretic titration and guideline-directed medical therapy. The primary endpoint was the 6-month rate of HFH or all-cause mortality compared to a prespecified performance goal of 0.43 events per patient, which was derived from the control groups of the CHAMPION-HF, MEMS-HF and GUIDE-HF trials. The trial met its primary effectiveness endpoint, with an observed event rate of 0.15 (95% CI:

0.12 to 0.20; p<.0001) at 6 months; FDA SSED data reported an increase in the event rate to.33 at 12 months follow-up. All-cause mortality at 6 months occurred in 10 patients (0.2 events per individual). Secondary endpoints included improvements in quality of life (KCCQ score +5.0 points from baseline [BL], p<.0001), 6-minute walk distance (6MWT, +23.7 meters from BL, p=.001), and NYHA functional class (32% improved from BL; p<.0001), along with significant reductions in NT-proBNP in the subgroup of patients with elevated BL levels. Freedom from device-related complications was 99.2%, and freedom from pressure sensor failure was 99.8% at 6 months follow-up. Medication adjustments were frequent during the 6-month follow-up period, with a total of 2,956 changes recorded, 69% involving diuretics and 27% involving guideline-directed medical therapy. Study limitations included a single-arm design without a concurrent randomized control, a short follow-up duration of 6 months, and an increased risk of bias for patient-reported outcomes in a non-blinded study.

Sharif et al (2022) reported results from the SIRONA 2 trial, a prospective, multi-center, single-arm study evaluating the safety and accuracy of the Cordella System in NYHA class III heart failure patients.[36,] A total of 75 patients were enrolled across 7 European sites and 70 underwent successful implant and comprised the modified intent-to-treat population. The primary safety endpoint, freedom from adverse events at 30 days, was achieved in 98.6% of patients, with only 1 device/system-related complication (Left ventricular lead dislodgement) and no pressure sensor failures. The FDA Summary of Safety and Effectiveness Data presented data at 12 months post-implant and showed adverse events occurring in 9 (12.0%) patients with no further device/system-related complications or pressure sensor failures.[35,] The primary efficacy endpoint, assessed in 58 (77%) patients at 90 days, demonstrated strong agreement between sensor and reference catheter measurements (mean difference [MD]: 1.4 mmHg; p=.003). At 6 months, 11 patients (15.7%) experienced a HFH, with a composite event rate (HFH and all-cause mortality) of 0.20 events per patient which increased to.33 events per patient at 12 months follow-up. NYHA class improved in 65.7% of individuals, although changes in KCCQ and 6MWT were not statistically significant compared to baseline.

Mullens et al (2020) published results from the feasibility study of the Cordella System (SIRONA).[37,] This multicenter, open-label study enrolled 15 individuals with NYHA class III heart failure across Belgium, Ireland, and the UK. Patients were eligible if they had been treated for 3 or more months with guideline-directed medical therapy and experienced 1 or more HFH in the prior year. The study evaluated the safety and accuracy of the Cordella sensor and its integration with daily remote hemodynamic monitoring. The primary safety endpoint, freedom from device-related adverse events, was achieved with no device-related complications and no pressure sensor failures reported over a 3 month period. Four procedure-related adverse events were observed, all of which resolved without sequelae. The primary efficacy endpoint (mean difference in PAP vs. Swan–Ganz catheter at 90 days) was met in all patients but 1 who was excluded for safety, with a mean difference of 2.7 mmHg. NYHA class improved in 53% of participants, but no statistically significant changes in KCCQ were observed.

Postmarketing Safety

Lin et al (2022) analyzed the FDA Manufacturer and User Facility Device Experience (MAUDE) database for adverse events filed for the CardioMEMS device from May 2014 to November 2020.[38,] A conservative approach was used, with reports with multiple events counted once for the most severe event. A total of 2861 reports were filed in the reporting period, of which 2858 (99.9%) were categorized as mandatory reports by the manufacturer or user facility. Per 6-

month period between May 2014 and May 2017, the mean number of reports was 41, increasing to 356 in the second half of 2017. The majority of reports were for inaccurate measurements requiring replacement of the external CardioMEMS unit (n=1109; 38.8%), repeat noninvasive testing (n=314; 11.0%), repeat right heart catheterization (n=677; 23.7%), or surgery (n=23; 0.8%). Nonfatal complications included hemoptysis (n=70; 2.4%), heart failure exacerbation (n=43; 1.5%), and significant bleeding at the site of catheterization (n=24; 0.8%). Patient death or transition to end-of-life care was the terminal event in 167 (5.8%) reports. The authors suggest that the safety of CarioMEMS be considered in the context of its lack of a mortality benefit in multiple RCTs, particularly in light of approved expanded use in individuals with NYHA class II heart failure.

Vaduganathan (2017) analyzed mandatory and voluntary reports of device-related malfunctions reported to the FDA to identify CardioMEMS system-related adverse events within the first 3 years of the FDA approval.[39,] From among the more than 5500 CardioMEMS implants in the first 3 years, there were 155 adverse event reports covering 177 distinct adverse events for a rate of 2.8%. There were 28 reports of pulmonary artery injury/hemoptysis (0.5%) that included 14 intensive care unit stays, 7 intubations, and 6 deaths. Sensor failure, malfunction, or migration occurred in 46 cases, of which 35 required recalibrations. Compared with a reported 2.8% event rate, the serious adverse event rate in the CHAMPION trial was 2.6% with 575 implant attempts, including 1 case of pulmonary artery injury and 2 deaths.

Table 7. Summary of Key Nonrandomized Study Characteristics

Author	Study Type	Country/Institution	Dates	Participants	Treatment	Follow-Up
Comparative Studies						
Kishino et al (2022)[28,]	Retrospective matched cohort	U.S./AHRQ	2014-2019	Individuals with ICD codes consistent with use of procedure	CardioMEMS implant	6 mo
Abraham et al (2019)[32,]	Retrospective matched cohort	U.S./Medicare/Abbott	2014-2016	Individuals with CPT codes consistent with the use of procedure and at least 1 HFH within the previous 12 months	CardioMEMS implant	12 mo
Pre-post Studies						

Author	Study Type	Country/Institution	Dates	Participants	Treatment	Follow-Up
Cowie et al (2021)[29,]	Post-approval multicenter study	U.K/Abbott	2017-2019	Individuals with NYHA class III HF and at least 1 HFH within the previous 12 months	CardioMEMS implant	12 and 24 mo
Shavelle et al (2020);[23,]Heywood et al (2023)[30,]	Post-approval multicenter study	U.S./Abbott	2014-2017	Individuals with a diagnosis of NYHA class III HF and at least 1 HFH within the previous 12 months	CardioMEMS implant	12 mo and 24 mo
Angermann et al (2020)[31,]	Prospective multicenter study	Germany, the Netherlands, Ireland/Abbott	2016-2018	Individuals with a diagnosis of NYHA class III HF and at least 1 HFH within the previous 12 months	CardioMEMS implant; communications with trained non-physician staff	12 mo
Desai et al (2017)[33,]	Retrospective cohort	U.S./Medicare	2014-2015	Individuals with inpatient CPT codes consistent with the use of the procedure	CardioMEMS implant	6 mo: preimplant and postimplant data (n=1114) 12 mo: preimplant and postimplant data (n=480)
Guichard et al (2024)[34,]	Prospective single-arm trial	U.S. and Europe (75 sites) / Endotronix	2020-2023	Individuals with NYHA class III HF and recent HFH or elevated NT-proBNP	Cordella Implant	12 mo (from FDA Summary of Safety and Effectiveness Data, published data are

Author	Study Type	Country/Institution	Dates	Participants	Treatment	Follow-Up
						from 6 mo only)
Sharif et al (2022)[36,]	Prospective single-arm trial	Europe (7 sites) / Endotronix	2019-2021	Individuals with NYHA class III HF and recent HFH or elevated NT-proBNP	Cordella Implant	12 mo (from FDA Summary of Safety and Effectiveness Data, published data are from 6 mo only)
Mullens et al (2020)[37,]	Prospective single-arm trial	Belgium, Ireland, UK / Endotronix	2017-2019	Individuals with NYHA class III HF and recent HFH	Cordella Implant	3 mo
Postmarketing Safety Studies						
Lin et al (2022)[38,]	Postmarketing MAUDE database analysis	U.S./FDA and Abbott	2014-2020	Mandatory reports of CardioMEMS-related adverse events	CardioMEMS implant	NA
Vaduganathan et al (2017)[39,]	Postmarketing surveillance study	U.S./FDA and Abbott	2014-2017	Individuals reporting Cardio-MEMS-related adverse event	CardioMEMS implant	NA

AHRQ: Agency for Healthcare Research and Quality; FDA: U.S. Food and Drug Administration; HF: heart failure; HFH: heart failure-related hospitalization; MAUDE:Manufacturer and User Facility Device Experience; NA: not applicable; NYHA: New York Heart Association,

Table 8. Summary of Key Nonrandomized Study Results

Study	HFH at 6 Months	HFH at 12 Months	Safety
Comparative Studies			
Kishino et al (2022)[28,]	728	NR	In-hospital mortality at 30 days (7% vs. 3.6%; p=.002); acute kidney injury (43.8% vs. 34.7%; p<.001); acute kidney injury requiring hemodialysis (3.5% vs. 1.8%; p=.019); transfusions (9.8% vs. 3.4%; p<.001).
HR (95% CI); p-value	0.80 (0.71 to 0.91);.001	NR	
Abraham et al (2019)[32,]	NR	1087	NR
HR (95% CI); p-value	NR	0.76 (0.65 to 0.89); <.001	NR
Pre-post Studies			
Cowie et al (2021)[29,]	NR	80	100
HR (95% CI); p-value	NR	0.178 (0.12 to 0.28); <.0001	Freedom from DSRC: 100% Freedom from pressure sensor failure: 99%
Shavelle et al (2020)[23,]	NR	628 (12 mo)	NR
Heywood et al (2023)[30,]	NR	307 (24 mo)	Freedom from DSRC at 2 yr: 99.6% Freedom from pressure sensor failure at 2 yr: 99.9%
HR (95% CI); p-value	NR	0.43 (0.39 to 0.47); <.0001 (12 mo) 0.30 (0.25 to 0.35); <.0001 (24 mo)	Freedom from DSRC: 99.6% Freedom from pressure sensor failure: 99.9%
Angermann et al (2020)[31,]	198	234[a]; 180[b]	236
HR (95% CI); p-value	NR	0.38 (0.31 to 0.48); <.0001[a] 0.34 (0.26 to 0.44); <.0001[b]	DSRC: 1.7% Pressure sensor failure: 0.4% SAE: 21/236 (8.9%) Delivery system-related events: 4 Implant procedure-related events: 21 Pulmonary artery perforation: 1 (0.4%) Procedure-related cardiac deaths: 3 (1.3%)

Study	HFH at 6 Months	HFH at 12 Months	Safety
Desai et al (2017)[33,]	1114	480	NR
Preimplant, n	1020	696	NR
Postimplant, n	381	300	NR
HR (95% CI); p-value	0.55 (0.49 to 0.61); <0.001	0.66 (0.57 to 0.76); <.001	NR
Guichard et al (2024)[34,]	60 HFH or all-cause mortality events; 0.13 events/individual	.34 events/individual	Device/system-related complications: 4 (0.8%); Pressure sensor failures: 1 (0.2%)
HR (95% CI); p-value	0.15 (.12 to.20); <.0001	NR	
Sharif et al (2022)[36,]	11 events (15.7%); 0.16 events/individual	.33 events/individual	LV Lead Dislodgement: 1 (1.3%) LV Lead Revision: 1 (1.3%) Pressure sensor failure: 0% Skin irritation: 1 (1.3%) Haemoptysis: 1 (1.3%) Vessel Trauma: 1 (1.3%) Hematoma: 1 (1.3%)
Mullens et al (2020)[37,]	1 event at 3 months; 6 mo data NR	NR	Device/system-related complications: 0% Pressure sensor failures: 0% Sensor dislodgement 1 (%) Complete heart block 1 (%) Haemoptysis: 2 (%)
Postmarketing Safety Studies			
Lin et al (2022)[38,]			2858 (99.9%) mandatory CardioMEMS reports
AE cohort identified from MAUDE database	NR	NR	Inaccurate measurements requiring replacement of the external CardioMEMS unit (n=1109; 38.8%); repeat noninvasive testing (n=314; 11.0%); repeat right heart catheterization (n=677; 23.7%); surgery (n=23; 0.8%); hemoptysis (n=70; 2.4%); heart failure exacerbation (n=43; 1.5%); significant bleeding at the site of catheterization (n=24; 0.8%); death or transition to end-of-life care as terminal event (167; 5.8%).

Study	HFH at 6 Months	HFH at 12 Months	Safety
Vaduganathan et al (2017)[39,]			Estimated 5500 received CardioMEMS
AE cohort identified from MAUDE database	NR	NR	155 (2.8%) AEs; 28 pulmonary artery injury or hemoptysis (0.5%), and 2 (0.4%) deaths

AE: adverse event; CI: confidence interval; DSRC: device- or system-related complications, HFH: heart failure hospitalization; HR: hazard ratio; MAUDE:Manufacturer and User Facility Device Experience; NR: not reported; SAE: serious adverse event.
[a] The primary efficacy analysis consisted of all 234 patients implanted with the CardioMEMS device.
[b] Results at 12-month follow-up as completed by 180 patients.

Table 9. Nonrandomized Study Relevance Limitations

Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Comparative Studies					
Kishino et al (2022)[28,]	3. NYHA Class data not reported. Database data may lack complete medical history information.		2. While propensity scoring was applied for several patient factors, residual confounding by unmeasured covariates remains possible. Database data may lack complete medical history data.		
Abraham et al (2019)[32,]	3. NYHA Class data not reported. Medicare claims data may lack complete medical history information.	1. Details regarding the frequency of nursing and/or provider communications were not described.	2. While propensity scoring was applied for several patient factors, residual confounding by unmeasured covariates remains		

Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
			possible. Medicare claims data may lack complete medical history data.		
Pre-post Studies					
Cowie et al (2021)[29,]		1. Details regarding the frequency of nursing and/or provider communications were not described.			
Shavelle et al (2020);[23,]Heywood et al (2023)[30,]		1. Details regarding the use of nursing and/or provider communications were not described.			
Angermann et al (2020)[31,]		3. Frequency of nursing communications varied based on patient NYHA Class.			
Desai et al (2017)[33,]	3. NYHA Class data not reported. Medicare claims data may lack complete medical history information.				
Guichard et al (2024)[34,]					1-2. Published follow-up duration of 6 months; select outcomes have 12 months data from FDA Summary of Safety and Effectiveness Data

Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Sharif et al (2022)[36,]					1-2. Published follow-up duration of 6 months; select outcomes have 12 months data from FDA Summary of Safety and Effectiveness Data
Mullens et al (2020)[37,]					1-2. Follow-up duration of 3 months only
Postmarketing Safety Studies					
Lin et al (2022)[38,]					
Vaduganathan et al (2017)[39,]					

NYHA: New York Heart Association.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not established and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 10. Nonrandomized Study Design and Conduct Limitations

Trial	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]		Statistical[f]
Comparative Studies						
Kishino et al (2022)[28,]	1-2. Participants were not randomly allocated and allocation was not concealed. 4. While propensity scoring was applied for several patient factors, residual confounding by unmeasured covariates remains possible. Medicare claims data may lack complete medical history data.	1. Physicians were not blinded to treatment assignment. Events were not formally adjudicated and were limited by retrospective claims data.				
Abraham et al (2019)[32,]	1-2. Participants were not randomly allocated and allocation was not concealed. 4. While propensity scoring was applied for several patient factors,	1. Physicians were not blinded to treatment assignment. Events were not formally adjudicated and were limited by retrospective claims data.				

Trial	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]		Statistical[f]
	residual confounding by unmeasured covariates remains possible. Medicare claims data may lack complete medical history data.					
Pre-post Studies						
Cowie et al (2021)[29,]	1-2 Participants were not randomly allocated and allocation was not concealed. 4. Assessing HFH as a study entry requirement and endpoint may reflect a bias of prior hospitalizatio n in favor of any intervention	1. Physicians were not blinded to treatment assignment. Events were adjudicated by treating physicians.	2. Only results for patients with follow-up completed before COVID-19 have been reported.			
Shavelle et al (2020);[23,]Heywoo d et al (2023)[30,]	1-2. Participants were not randomly allocated and allocation was not concealed. 4. Assessing HFH as a study entry requirement and endpoint	1. Physicians were blinded to treatment assignment. Events were adjudicated by an independent committee. Unclear whether				

Trial	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]		Statistical[f]
	may reflect a bias of prior hospitalization in favor of any intervention.	adjudication criteria were similar to criteria used in RCTs.				
Angermann et al (2020)[31],	1-2. Participants were not randomly allocated and allocation was not concealed. 4. Assessing HFH as a study entry requirement and endpoint may reflect a bias of prior hospitalization in favor of any intervention.	1. Physicians were blinded to treatment assignment. Outcome adjudication was unclear.				
Desai et al (2017)[33],	1-2. Participants were not randomly allocated and allocation was not concealed. 4. Assessing HFH as a study entry requirement and endpoint may reflect a bias of prior hospitalization in favor of any intervention. Medicare claims data may lack	1. Physicians were not blinded to treatment assignment. Events were not formally adjudicated and were limited by retrospective claims data.				

Trial	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]		Statistical[f]
	complete medical history.					
Guichard et al (2024)[34,]	1-2. Participants were not randomly allocated and allocation was not concealed. 4. Assessing HFH as a study entry requirement and endpoint may reflect a bias of prior hospitalization in favor of any intervention.	1. Physicians were not blinded to treatment assignment. Events were adjudicated by an independent endpoint committee.				
Sharif et al (2022)[36,]	1-2. Participants were not randomly allocated and allocation was not concealed. 4. Assessing HFH as a study entry requirement and endpoint may reflect a bias of prior hospitalization in favor of any intervention.	1. Physicians were not blinded to treatment assignment. Events were adjudicated by an independent endpoint committee.		1. High loss to follow-up or missing data		
Mullens et al (2020)[37,]	1-2. Participants were not randomly allocated and allocation	1. Physicians were not blinded to treatment assignment.			1. Power calculations not performed	

Trial	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]		Statistical[f]
	was not concealed. 4. Assessing HFH as a study entry requirement and endpoint may reflect a bias of prior hospitalization in favor of any intervention.	Events were adjudicated by treating physicians.				
Postmarketing Safety Studies						
Lin et al (2022)[38,]	1-2. Participants were not randomly allocated and allocation was not concealed.	1. Physicians were not blinded to treatment assignment. No formal outcome adjudication was used due to limitations with self-reports.		1. Voluntary reporting of adverse events limits the interpretation of results as all events are not captured.		
Vaduganathan et al (2017)[39,]	1-2. Participants were not randomly allocated and allocation was not concealed.	1. Physicians were not blinded to treatment assignment. No formal outcome adjudication was used due to limitations with self-reports.		1. Voluntary reporting of adverse events limits the interpretation of results as all events are not captured.		

HFH: heart failure hospitalization; RCT: randomized controlled trial.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear;

4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other

Section Summary: Implantable Pulmonary Artery Pressure Monitoring (CardioMEMS and Cordella Devices)

The pivotal CHAMPION RCT reported a statistically significant 28% decrease in HFH in patients implanted with CardioMEMS device compared with usual care at 6 months. 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 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. The MONITOR-HF trial, an open-label RCT conducted in the Netherlands, showed that hemodynamic monitoring significantly improved quality of life and reduced HFH but did not impact mortality. Nonrandomized studies have also consistently reported significant reductions in HFH, but are limited by the use of historical controls, within-group comparisons, and retrospective claims data. The impact of COVID-19 on the GUIDE-HF trial met the pre-specified 15% interaction significance level. 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. Provider behaviors may have also been altered, partly evidenced by decreased medication changes and deintensification of medical management during COVID-19. Enrollment of NYHA Class II patients was significantly enriched in the first 500 patients enrolled, potentially impacting the pre-COVID-19 analysis.

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 HRs favoring the control group with wide 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 Kansas City Cardiomyopathy Questionnaire for the CardioMEMS group relative to control, but no significant differences were observed in secondary quality of life and functional status outcomes in the other included trials. While an 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 for individuals with NYHA class III heart failure. 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 most participants; however, quality-of-life and functional outcomes did not show significant improvement. Two meta-analyses were included, which found a significant reduction in HFHs but conflicting findings on mortality, with one finding no difference between hemodynamic monitoring and control with another patient-level meta-analysis which demonstrated a significant 25% reduction in mortality with hemodynamic monitoring in patients with heart failure with reduced ejection fraction. Given the discordant findings regarding mortality benefits in the meta-analyses as well as mixed findings of the benefits to functional outcomes, lack of procedural safety data, and unclear impact of COVID-19 on remote monitoring in the GUIDE-HF trial, the net benefit of the CardioMEMS and Coredella devices remains uncertain. Concerns may be clarified by the ongoing open access phase of the GUIDE-HF RCT and PROACTIVE-HF trial, and the German non-industry-sponsored PASSPORT-HF trial.

NONINVASIVE THORACIC BIOIMPEDANCE/IMPEDANCE CARDIOGRAPHY

Clinical Context and Test Purpose

The purpose of thoracic bioimpedance 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 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 individuals 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.

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 impedence cardiography on outcomes beyond the benefits of frequent nursing surveillance cannot be isolated and it is unclear to what extent impedence cardiography was utilized in the standard care setting.[40,]

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.[41,42,43,]

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.[44,] 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 11. 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)[44,]	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 patients 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 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 patients 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.[45,] 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 12 and 13. 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 12. Summary of Key Nonrandomized Study Characteristics

Author	Study Type	Country	Dates	Participants	Treatment	Mean FU (SD), d
Amir et al (2017)[45,]	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 13. Summary of Key Nonrandomized Study Results

Study	HFH (events/patient/3 mo)	Deaths
Amir et al (2017)[45,]	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 patients 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 patients 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 ndividual 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 patients 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 patients 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 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 inert gas breathing has not been proved, a chain of evidence to support clinical utility cannot be constructed.

Section Summary: Clinically Valid
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 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.[46,] 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 mm Hg.

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 patients 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 et al
In 2017, the American College of Cardiology (ACC), the American Heart Association (AHA), and the 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.[47,]

In the 2022 update to the heart failure management guidelines, 2 recommendations were provided regarding remote hemodynamic monitoring in heart failure. These recommendations are summarized below in Table 14.

Table 14. 2022 ACC/AHA/HFSA Recommendation for Wearables and Remote Monitoring (including Telemonitoring and Device Monitoring)[48,]

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 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).[48,]

European Society of Cardiology

The 2025 consensus statement from the Heart Failure Association of the European Society of Cardiology (ESC) endorses remote pulmonary artery pressure-guided management as a tool to manage heart failure and prevent hospitalizations.[49,] The panel highlights that pulmonary artery pressure-guided therapy allows early detection of hemodynamic congestion, enabling timely adjustments in therapy such as diuretics, vasodilators, or other guideline-directed medical therapy. The panel issued the following advice with a high strength of evidence based on RCT data: 'CardioMEMS is useful in patients with symptomatic heart failure at moderate to high risk of new worsening heart failure events as shown by a hospitalization for heart failure in the previous year.' The society defines the ideal candidate as an individual with symptomatic heart failure, regardless of left ventricular ejection fraction, who is classified as NYHA class II or III, has experienced at least one heart failure-related hospitalization or urgent care visit in the past year, or has elevated natriuretic peptide levels, and does not have end-stage heart failure or significant primary lung disease.

National Institute for Health and Care Excellence

In 2021, the 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.[50,] 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 (2018) published a white paper consensus statement on remote monitoring of patients with heart failure.[51,]

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."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 15.

Table 15. 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	Dec 2025 (recruiting)
NCT03020043	CardioMEMS Registry of the Frankfurt Heart Failure Center	500	Dec 2025 (recruiting)
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)
NCT04452149[a]	Algorithm Using LINQ Sensors for Evaluation And Treatment of Heart Failure (ALLEVIATE- HF)	826	May 2025 (ongoing)
NCT06306573[a]	CardioMEMS™ HF System Real-World Evidence Post-Approval Study	2500	Dec 2028 (recruiting)
NCT06779552[a]	CardioMEMS HF System Coverage with Evidence Development Study	1000	Mar 2032 (recruiting)
NCT03375710[a]	A Prospective, Multi-Center, Open-Label, Single-Arm Clinical Trial Evaluating the Safety and Efficacy of the Cordella™ Heart Failure System in (New York Heart Association) NYHA Class III Heart Failure Patients	15	Feb 2029 (ongoing)
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 2027 (ongoing)

NCT No.	Trial Name	Planned Enrollment	Completion Date
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)	738	April 2028 (ongoing)
NCT05934487[a]	A Prospective, Multi-Center, Open Label, Randomized Control Clinical Trial Evaluating the Safety and Efficacy of the Cordella™ Pulmonary Artery Sensor System in New York Heart Association (NYHA) Class II-III Heart Failure Patients	1750	August 2033 (recruiting)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
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

REVISIONS	
09-10-2010	Title revised: From: "Thoracic Bioimpedance as a Measurement of Cardiac Hemodynamics in the Ambulatory Care - Outpatient Setting" To: "Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting"
	In Policy section: Added arterial pressure/Valsalva and implantable direct pressure monitoring of the pulmonary artery as mechanisms for cardiac hemodynamic monitoring for the management of heart failure in the outpatient setting.
	In Coding section: ▪ Added CPT Code: 93799 ▪ Updated wording for CPT Code: 93701
	Description section updated.
	Rationale section added.
	References section updated.
03-07-2011	In Coding section: ▪ Removed CPT codes: 0104T, 0105T
09-20-2011	Description section updated.
	Rationale section added.
	References section updated.

REVISIONS	
09-18-2012	Description section updated.
	Rationale section added.
	References section updated.
10-31-2013	Description section updated
	Rationale section updated
	References updated
04-28-2015	Updated Description section.
	Updated Rationale section.
	Updated References section.
10-13-2015	Updated Description section.
	Updated Rationale section.
	In Coding section: ▪ Revised bulleted information.
	Updated References section.
09-03-2016	Updated Description section.
	In Policy section: ▪ Removed "/" and added "during" and "maneuver" to read "In the ambulatory care and outpatient setting, cardiac hemodynamic monitoring for the management of heart failure utilizing thoracic bioimpedance, inert gas rebreathing, arterial pressure during Valsalva maneuver, and implantable direct pressure monitoring of the pulmonary artery is considered experimental / investigational."
	Updated Rationale section.
	In Coding section: ▪ Added HCPCS code: C9741. ▪ Revised bulleted information.
	Updated References section.
07-11-2017	Updated Description section.
	Updated Rationale section.
	Updated References Section.
09-12-2018	Updated Description section.
	Updated Rationale section.
	Updated References section.
01-01-2019	In Coding section: ▪ Added new CPT codes: 33289, 93264. ▪ Removed deleted HCPCS code: C9741.
06-19-2019	Updated Description section.
	Updated Rationale section.
	In Coding section: ▪ Added HCPCS code: C2624.
	Updated References section
07-02-2021	Updated Description section
	In Policy Section: ▪ Added Item A, Item B, and Item C ▪ Added "except for the CardioMEMS™ HF System," in Item D.
	Updated Rationale section
	In Coding Section ▪ Removed C2624 ▪ Added ICD-10 diagnosis codes: I50.1, I50.20, I50.21, I50.22, I50.23, I50.30, I50.31, I50.32, I50.33, I50.40, I50.41, I50.42, I50.43, I50.810, I50.811, I50.812, I50.813, I50.814, I50.82, I50.83, I50.84, I50.89, I50.9

<table>
<tr><th colspan="2">REVISIONS</th></tr>
<tr><td></td><td>Updated References Section</td></tr>
<tr><td>Posted
3-14-2023
Effective
04-13-2023</td><td>Updated Description Section</td></tr>
<tr><td></td><td>Updated Policy Section
▪ Removed:
A. The CardioMEMS™ HF System may be considered medically necessary for individuals meeting ALL of the following criteria:
1. Diagnosis of NYHA Class III HF (historical assessment documented at screening visit); AND
2. Diagnosis of HF ≥ 3 months, with either preserved or reduced LVEF; AND
3. Receiving a beta blocker for 3 months with a stable dose for one month prior to the screening visit; AND
4. Receiving an ACE-I or ARB for one month unless there is a documented intolerance or contraindication present with a stable dose for one month prior to the screening visit (Beta blockers and ACE-I/ARB doses should be stable for one month prior to the screening visit); AND
5. At least 1 HF hospitalization within 12 months of the Screening Visit; AND
6. Documentation of a pulmonary artery branch diameter sized between 7mm and 15mm (implanted vessel); AND
7. Body mass index (BMI) of less than or equal to 35; or if BMI is greater than 35, a measurement of chest circumference at axillary level is required. If the chest circumference is greater than 165 cm, the sensor should not be implanted due to poor signal strength.
B. The CardioMEMS™ HF System not meeting the above criteria is experimental / investigational.
C. For individuals with the following contraindications the CardioMEMS™ HF System is considered experimental / investigational:
1. history of recurrent (> 1) pulmonary embolism or deep vein thrombosis
2. unable to tolerate a right heart catheterization
3. Likely to undergo heart transplantation within 6 months of Screening Visit
4. Presence of any one of the following:
a. major cardiovascular event (e.g., myocardial infarction, stroke) within 2 months of the Screening Visit
b. implantation of a Cardiac Resynchronization Device (CRT) ≤ 3 months prior to the screening visit
c. Glomerular Filtration Rate (GFR) <25 ml/min who are non-responsive to diuretic therapy or who are on chronic renal dialysis
d. congenital heart disease or mechanical right heart valve(s)
e. known coagulation disorders
f. hypersensitivity or allergy to aspirin, and/or clopidogrel
g. Active infection
D. In the ambulatory care and outpatient setting, cardiac hemodynamic monitoring for the management of heart failure utilizing thoracic bioimpedance, inert gas rebreathing, arterial pressure during Valsalva maneuver, and implantable direct pressure monitoring of the pulmonary artery except for the CardioMEMS™ HF System, is considered experimental / investigational.
▪ Added:
"In the ambulatory care and outpatient setting, cardiac hemodynamic monitoring for the management of heart failure using implantable direct pressure monitoring of the pulmonary artery, thoracic bioimpedance, inert gas rebreathing, and arterial pressure during the Valsalva maneuver is considered experimental / investigational."</td></tr>
<tr><td></td><td>Updated Policy Guidelines
▪ Added Policy Guidelines
"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</td></tr>
</table>

REVISIONS	
	resynchronization therapy devices, and cardiac pacing devices, are not addressed in this evidence review."
	Updated Rationale Section
	Updated Coding Section ▪ Removed Coding Bullets o There is a specific CPT code for bioimpedance: 93701 o Inert gas rebreathing measurement and left ventricular end diastolic pressure should be reported using the unlisted code: 93799. ▪ Removed CPT code 93799 ▪ Removed ICD-10 codes
	Updated References Section
07-25-2023	Updated Descriptions Section
	Updated Rationale Section
	Updated References Section
07-23-2024	Updated Descriptions Section
	Updated Rationale Section
	Updated References Section
07-22-2025	Updated Descriptions Section
	Updated Rationale Section
	Updated References Section

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