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

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Related Policies (if applicable)
SUR707.003: Implantable Cardioverter Defibrillators
MED202.054: Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Cardiac hemodynamic monitoring for the management of heart failure (HF) utilizing thoracic electrical bioimpedance (TEB)/impedance cardiography (ICG) **may be considered medically necessary** in the ambulatory and outpatient setting when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB/ICG hemodynamic data are necessary for appropriate management of the patient, for **ANY** of the following indications:

- Differentiation of cardiogenic from pulmonary causes of acute dyspnea; or
- Optimization of atrioventricular interval for patients with atrioventricular sequential cardiac pacemakers; or
- Monitoring of continuous inotropic therapy for patients with terminal congestive HF, including patients waiting at home for a heart transplant; or
- Evaluation for rejection in patients with a heart transplant as a predetermined alternative to a myocardial biopsy; or

- Optimization of fluid management in patients with congestive HF.

Other cardiac hemodynamic monitoring in the ambulatory care and outpatient setting for the management of HF **is considered experimental, investigational and/or unproven**, including but not limited to, the following technologies:

- Inert gas rebreathing;
- Arterial pressure/Valsalva;
- Implantable direct pressure monitoring of the pulmonary artery; and/or
- Left atrial pressure monitoring.

Policy Guidelines

This policy only addresses use of stand-alone cardiac output measurement devices that are designed to be used in ambulatory care and outpatient settings. For information on the use of cardiac hemodynamic monitors or intra-thoracic fluid monitors that are integrated into other implantable cardiac devices, including implantable cardioverter defibrillators, cardiac resynchronization therapy devices, and cardiac pacing devices, refer to Medical Policies Implantable Cardioverter Defibrillators-SUR707.003 and Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure – MED202.054.

Description

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

Chronic Heart Failure

Patients with chronic HF are at risk of developing acute decompensated HF, 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)

<u>Management</u>

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 HF 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 HF. Transthoracic echocardiography (TTE), transesophageal echocardiography (TEE), and Doppler ultrasound (U/S) 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 HF 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 LVEDP Measurement Devices

In 2004, the VeriCor® (CVP Diagnostics), a non-invasive LVEDP measurement device, was cleared for marketing by the 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 (Bothell, WA)	2009
Zoe® Fluid Status Monitor	Noninvasive Medical Technologies LLC (Las Vegas, NV)	2004
Cheetah NICOM® System	Cheetah Medical Inc. (Tel Aviv, Israel)	2008
Physioflow® Signal Morphology-based Impedance Cardiography (SM-ICG™)	Vasocom Inc., now Neumedx Inc. (Bristol, PA)	2008
ReDS™ Wearable System	Sensible Medical Innovations (Trenton, NJ and Netanya, Israel)	2015
Bodyport Cardiac Scale	Bodyport Inc.	2022

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 (PA) Pressure Sensor Devices

In 2014, the CardioMEMS Champion Heart Failure Monitoring System (CardioMEMS, now Abbott) was approved for marketing by the FDA through the premarket approval process. This device consists of an implantable pulmonary artery sensor, which is implanted in the distal pulmonary artery, a transvenous delivery system, and an electronic sensor that processes signals from the implantable pulmonary artery sensor and transmits pulmonary artery pressure measurements to a secure database. (3) The device originally underwent FDA review in 2011, at which point the FDA found no reasonable assurance that the monitoring system would be effective, particularly in certain subpopulations, although the FDA agreed this monitoring system was safe for use in the indicated patient population. (4) In 2022, the CardioMEMS HF Monitoring System received expanded approval for the treatment of New York Heart Association (NYHA) Class II-III patients who had been hospitalized at least 1 time in the prior year and/or had elevated natriuretic peptides.

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

Left Atrial Pressure Devices

The HeartPOD System (Savacor Inc., Los Angeles, CA) is used for patients with ischemic or non-ischemic cardiomyopathy with systolic or diastolic dysfunction for at least 6 months or HF classified by NYHA class III. The HeartPOD system is a standalone device for use in patients not requiring implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D) therapy, or who already received ICD or CRT-D therapy. The system monitors LAP with a permanently implantable sensory sensor used in ambulatory patients with HF. The HeartPOD System is not available for commercial use in the United States. (47)

NOTE 1: This medical policy only addresses the use of these technologies in ambulatory care and outpatient settings.

Rationale

This policy was created in 2005 and is based on published scientific peer-reviewed literature and updated regularly with searches of the PubMed database. The most recent search was performed through May 5, 2023.

Medical policies assess the clinical evidence to determine whether the use of a 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 to 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 a technology, 2 domains are examined: the relevance and the 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.

Medical policies 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. Medical policies 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 Device)

Clinical Context and Therapy Purpose

The purpose of the CardioMEMS system in individuals who have heart failure is to provide remote monitoring for early symptoms of heart failure in order to modify therapy 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.

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

Populations

The relevant population(s) of interest is individuals with New York Heart Association (NYHA) Class III 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 Champion 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 patients to have an overnight hospital admission for observation after implantation. Specific target pressure ranges provided to investigators to achieve hemodynamic stability included 10-25 mmHg for mean pulmonary artery pressure, 14-35 mmHg for systolic pressure, and 8-20 mmHg for diastolic

pressure. An elevation or decrease in pulmonary artery pressure outside of a patient's individualized baseline was considered to arise from overload or depletion, respectively.

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 (e.g., body weight, blood pressure, laboratory parameters) and symptoms (e.g., 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 patients with heart failure. (5)

- Survival and disease control (i.e., mortality).
- Functioning and disease control (i.e., 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 patient (i.e., 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. (6) 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 walk test (6MHW), stair climb test, Short Physical Performance Battery or hand-grip strength are functional measures.

Patient-reported outcome measures 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.

<u>Study Selection Criteria</u>
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 the CHAMPION trial in patients with reduced ejection fraction, (7, 8) preserved ejection fraction, (9) Medicare-eligible patients, (10) and chronic obstructive pulmonary disease (11), and various subtypes of pulmonary hypertension (12) are outside of the scope of this policy and are therefore not discussed. Studies reporting physiological measures in the absence of clinical outcomes were also excluded. (13)

Randomized Controlled Trials

CHAMPION

Abraham et al. (2011, 2016) have reported on the results of the CHAMPION (CardioMEMS™ Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Patients Trial Study was a prospective, single-blind RCT in which all enrolled patients were implanted with the CardioMEMS™ device. (14, 15) 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 daily uploaded pressures were not made available to investigators and patients continued to receive standard of care management, which included drug adjustments in response to patients' clinical signs and symptoms. An independent clinical end points committee, blinded to the treatment groups, reviewed abstracted clinical data and determined if hospitalization was related to HF hospitalization. It is unclear what criteria were used for adjudication of heart failure hospitalizations. (16)

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 end point, with a statistically significant 28% relative reduction in the rate of HF related hospitalizations at 6 months. This outcome was accompanied by a significant improvement in Minnesota Living with Heart Failure Questionnaire 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. (17, 18) 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.

Importantly, the CHAMPION trial failed to demonstrate a treatment effect in women. According to FDA documents, the apparent lack of reduction in HFH in women resulted from a greater number of deaths among women in the control group early in the trial, and this early mortality resulted in a competing risk for future HFH. While both the FDA and sponsor conducted multiple analyses to understand device effectiveness in women, the FDA statisticians concluded that such analyses did clearly delineate the limited treatment effect in women. (17) However, 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. (19, 20)

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. (21) 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 3-5 mmHg persistent pressure change over 2-3 days or a change of 5 mmHg 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 (i.e., 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) (22) 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 (i.e., 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.

Table 2. Summary of Key RCT Characteristics

Author; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
Abraham et al. (2011, 2016) (14, 15); CHAMPION	United States	64	2007-2009	Main Eligibility Criteria: At least 1 previous HFH in the past 12 months and NYHA class III HF for at least 3 months Patient Baseline Characteristics: • Sex: 72.5% male and 27.5% female • Mean Age: ~61 y • Race: 72.9% White, NR Black • NYHA Class: 100% III • Mean PAP: ~29-30 mmHg • 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); (21) Zile et al. (2022); (22) GUIDE-HF	United States	139	2018-2021	Main Eligibility Criteria: NYHA Class II-IV HF and at least 1 previous HFH in the past 12 months or elevated natriuretic peptides within prior 30 days Patient Baseline Characteristics: • Sex: 62.5% male, 37.5% female • Mean Age: ~70-71 y	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)

				• Race: 80.7% White, 17.9% Black • NYHA Class: 29.6% II, 65% III, 5.4% IV • Mean PAP: ~		

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; HFH: heart failure hospitalization; NR: not reported; NYHA: New York Heart Association; PAP: pulmonary artery pressure; RCT: randomized controlled trial.

Table 3. Summary of Key RCT 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 (14, 15)							
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	NA	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 (21, 22)							

At 12 Months							
Overall Analysis							
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] .016	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	.079 (0.35 to 1.83); .59	NR	NA

CHAMPION: CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA III Heart Failure Patients trial; COVID: coronavirus disease; 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; RCT: randomized controlled trial.

[a] Primary efficacy outcome in CHAMPION trial.

[b] Primary efficacy outcome in GUIDE-HF trial.

Table 4. Summary of Key RCT 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 (14, 15)							
At 6 Months		*Mean (SD)*				*Mean AUC*	*Mean (SD)*

						Change, mmHg x days (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
Lindenfeld et al. (2021); Zile et al. (2022); GUIDE-HF (21, 22)							
At 12 months							
Overall Analysis			*Mean Change from Baseline (SD)*	*Mean Change from Baseline (SD)*	*Mean Change from Baseline, m(SD)*	*Mean AUC Change, mmHg 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 (20.17) 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

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; COVID: coronavirus disease; 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; RCT: randomized controlled trial; 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

Study; Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Abraham et al. (2011, 2016); CHAMPION (14, 15)		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 (21, 22)		3. Unclear whether patient contacts were balanced during study optimization phase.			

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 evidence gaps stated in this table are those notable in the current literature 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 establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinically significant difference not supported;
[e]: Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.
RCT: randomized controlled trial.

Table 6. Study Design and Conduct Limitations

Study; Trial	Allocation[a]	Binding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Abraham et al. (2011, 2016); CHAMPION (14, 15)		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 (21, 22)	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.

CHAMPION: CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA III Heart Failure Patients trial; COVID: coronavirus disease; 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 literature 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]: Follow-Up 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. (23) 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). (24) 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 (hazard ratio [HR], 0.178; 95% confidence interval [CI], 0.12 to 028; 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 heart failure-related hospitalization in the prior year. (19) The primary efficacy outcome was the difference between rates of adjudicated heart failure-related hospitalization 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 heart failure-related hospitalization rate was significantly lower at 1-year post-implantation (0.54 versus 1.25 events/patient-year; hazard ratio [HR], 0.43; 95% confidence interval [CI], 0.39 to 0.47; *P*<0.0001). The rate decreases remained significant regardless of the number of pre-enrollment heart failure-related hospitalizations, with a trend towards a more significant benefit in a small subgroup of patients (n=21) with ≥ 5 pre-enrollment heart failure-related hospitalizations. The rate of all-cause hospitalization (ACH) was also significantly lower (1.67 versus 2.28 events/patient-year; HR, 0.73; 95% CI, 0.68 to 0.78; *P*<0.0001). 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. (25) 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). (26) This was an industry-sponsored, prospective, observational, non-randomized study designed to assess the safety and feasibility of the CardioMEMS HF system over 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 heart failure-related hospitalization 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 100.0) 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 heart failure-related hospitalization rate at 12 months compared to the prior year before implantation and health-related quality of life. Heart failure-related hospitalizations decreased 62% (0.60 versus 1.55 events/patient year; HR, 0.38; 95% CI, 0.31 to 0.48; P<0.0001). 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. (27) Patients were matched to 1087 controls by demographics, history and timing of heart failure-related hospitalizations, 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 heart failure-related hospitalizations occurred in the treatment and control cohorts, respectively. Study characteristics and results are summarized in Tables 7 and 8. The rate of heart failure-related hospitalizations was lower in the treatment cohort at 12 months (HR, 0.76; 95% CI, 0.65 to 0.89; *P*<0.001). Percentage of days lost to heart failure-related hospitalizations (HR, 0.73; 95% CI, 0.64 to 0.84; *P*<0.001) and ACH or death (HR, 0.77; 95% CI, 0.68 to 0.88; *P*<0.001) were both significantly lower in the treatment group. The percentage of days lost owing to heart failure-related hospitalization 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. (28) 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 HF-related hospitalizations was significantly lower in the post-implantation period than in the preimplantation period at both 6- and 12-month follow-ups.

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. (29) 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 et al. (2017) analyzed mandatory and voluntary reports of device-related malfunctions reported to the FDA to identify CardioMEMS™ HF System-related adverse events within the first 3 years of the FDA approval. (30) 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) (23)	Retro-spective matched cohort	U.S./AHRQ	2014-2019	Individuals with ICD codes consistent with use of procedure	CardioMEMS implant	6 months
Abraham et al. (2019) (27)	Retrospecti ve matched cohort	U.S./ Medicare/ Abbott	2014-2016	Individuals with CPT codes consistent with use of procedure and at least 1 HFH within the previous 12 months	CardioMEMS implant	12 months
Pre-post Studies						
Cowie et al. (2021) (24)	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 months
Shavelle et al. (2020 (19) Heywood et al.	Post-approval multicenter study	U.S./ Abbott	2014-2017	Individuals with a diagnosis of NYHA class III heart failure and at least 1 HFH within the	CardioMEMS implant	12 months and 24 months

(2023) (25)				previous 12 months.		
Angerman n et al. (2020) (26)	Prospective multicenter study	Germany, the Netherlands, Ireland/ Abbott	2016-2018	Individuals with a diagnosis of NYHA class III heart failure and at least 1 HFH within the previous 12 months.		12 months
Desai et al. (2017) (28)	Retrospective cohort	United States/ Medicare	2014-2015	Individuals with inpatient CPT codes consistent with use of procedure	CardioMEMS implant	2 cohorts: 6-month pre-implant and post-implant data (n=1114) 12-month pre-implant and post-implant data (n=480)
Postmarketing Safety Studies						
Lin et al. (2022) (29)	Post-marketing MAUDE Database analysis	U.S./FDA and Abbott	2014-2020	Mandatory reports of CardioMEMS-Related adverse events	CardioMEMS implant	NA
Vadugana than et al. (2017) (30)	Post-marketing surveillance study	United States/ FDA and Abbott	2014-2017	Individuals reporting Cardio-MEMS™-related adverse event	CardioMEMS implant	Not applicable

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

Table 8. Summary of Key Nonrandomized Study Results

Study	HFH at 6 Months	HFH at 12 Months	Safety
Comparative Studies			
Kishino et al. (2022) (23)	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	NR
Abraham et al. (2019) (27)	NR	1087	NR
HR (95% CI); p-value	NR	0.76 (0.65 to 0.89); <0.001	NR
Pre-Post Studies			
Cowie et al. (2021) (24)	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) (19)	NR	628 (12 months)	NR
HR (95% CI); p-value	NR	0.43 (0.39 to 0.47); <.0001	Freedom from DSRC: 99.6% Freedom from pressure sensor failure: 99.9%
Angermann et al. (2020) (26)	198	234[a], 180[b]	236
HR (95% CI); p-value	NR	0.38 (0.31 to 0.48); <0.0001[a] 0.34 (0.26 to 0.44); <0.0001[b]	Freedom from DSRC: 1.7% Freedom from 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%)
Desai et al. (2017) (28)	1114	480	NR
Pre-implant, n	1020	636	NR
Post-implant, 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); <0.001	NR
Postmarketing Safety Studies			
Lin et al. (2022) (29)			2859 (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%).
Vaduganathan et al. (2017) (30)			Estimated 5500 received CardioMEMS™
Adverse event cohort identified from MAUDE database	NR	NR	155 (2.8%) adverse events; 28 pulmonary artery injury or hemoptysis (0.5%), and 2 (0.4%) deaths

CI: confidence interval; HFH: heart failure hospitalization; HR: hazard ratio; NR: not reported; MAUDE: Manufacturer and User Facility Device Experience (from U.S. Food and Drug Administration); AE: adverse event; DSRC: device- or system-related complications; 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 Studites					
Kishino et al. (2022) (23)	3. NYHA Class data not reported. Medicare claims data may lack complete medical history information.		2. 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.		
Abraham et al. (2019) (27)	3. NYHA Class data not reported.	1. Details regarding the frequency of nursing and/or	2. While propensity scoring was applied for several patient factors, residual		

	Medicare claims data may lack complete medical history information.	provider communications were not described.	confounding by unmeasured covariates remains possible. Medicare claims data may lack complete medical history data.		
Pre-post Studies					
Cowie et al. (2021) (24)		1. Details regarding the frequency of nursing and/or provider communications were not described.			
Shavelle et al. (2020) (19) Heywood et al. (2023) (25)		1. Details regarding the frequency of nursing and/or provider communications were not described.			
Angermann et al. (2020) (26)		3. Frequency of nursing communications varied based on patient NYHA Class.			
Desai et al. (2017) (28)	3. NYHA Class data not reported. Medcare claims data may lack complete medical history information.				
Postmarketing Safety Studies					

Lin et al. (2022) (29)					
Vaduganathan et al. (2017) (30)					

NYHA: New York Heart Association.

The study limitations stated in this table are those notable in the current literature 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]	Power[e]	Statistical[f]
Comparative Studies						
Kishino et al. (2022) (23)	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	1. Physicians were not blinded to treatment assignment. Events were not formally adjudicated and were limited by retrospective claims data.				

	possible. Medicare claims data may lack complete medical history data.					
Abraham et al. (2019) (27)	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 retrospectiv e claims data.				
Pre-post Studies						
Cowie et al. (2021) (24)	1-2 Participants were not randomly allocated and allocation was not concealed. 4.	1. Physicians were not blinded to treatment assignment. Events were adjudicated	2. Only results for patients with follow-up complete d before			

	Assessing HFH as a study entry requirement and endpoint may reflect a bias of prior hospitalization in favor of any intervention.	by treating physicians.	COVID-19 have been reported.			
Shavelle et al. (2020) (19) Heywood et al. (2023) (25)	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. Events were adjudicated by an independent committee. Unclear whether adjudication criteria were similar to criteria used in RCTs.				
Angermann et al. (2020) (26)	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. Outcome adjudication was unclear.				

	may reflect a bias of prior hospitalization in favor of any intervention.					
Desai et al. (2017) (28)	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 complete medical history.	1. Physicians were not blinded to treatment assignment. Events were not formally adjudicated and were limited by retrospective claims data.				
Postmarketing Safety Studies						
Lin et al. (2022) (29)	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		1. Voluntary reporting of adverse events limits the interpretation of results as all events are not captured.		

		with self-reports.				
Vaduganathan et al. (2017) (30)	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.		

COVID: coronavirus disease; 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

ECRI Clinical Evidence Assessment

ECRI clinical evidence assessment (2022) was based on the identification of 7 studies (n=9970 patients) from January 1, 2016 to October 18, 2022, (41) 6 being previously discussed earlier including Lindenfeld et al. (21), Kishino et al. (23), Abraham et al. (27), Cowie et al. (24), Shavelle et al. (19), and Desai et al., (28). In the Thakker et al. study (2022), not previously discussed above, 718 patients with heart failure were studied to compare conventional and CardioMEMS-guided heart failure management in independent patient groups with a New York Heart Association (NYHA) Class III or IV score. The follow-up periods ranged from 90 days to 12 months. Patients who underwent remote PA [pulmonary artery] monitoring were less likely to be hospitalized compared with patients who did not (Odds Ratio: 0.52; 95% Confidence Interval 0.39, 0.69). The "analysis confirmed that in patients undergoing remote PA pressure monitoring

there was a 52% chance of patients having reduced rates of hospitalizations. Our findings are consistent with prior studies supporting the use of remote PA pressure monitoring in reducing hospitalizations."

Evidence from a systematic review (SR) and six additional studies shows that CardioMEMS monitoring is safe and reduces hospitalizations in patients with moderate HF. However, recent reports of electric and fire hazard related to CardioMEMS interrogation devices raise safety concerns. Until these are addressed, physicians and patients should exercise caution. Available data are also too limited in quality and quantity to determine how CardioMEMS affects mortality, physical function, and quality of life; whether CardioMEMS benefits patients with mild HF; and how CardioMEMS compares with other HF monitoring systems. ECRI concluded the evidence is somewhat favorable and future clinical trials (16 studies with the largest [n=3500] concluding in 2023) may partially address evidence gaps.

UpToDate

A 2022 UpToDate article from Colucci stated "we do not routinely use device-based therapies". (46) For highly selected patients with (heart failure with preserved ejection fraction) HFpEF who have refractory New York Heart Association (NYHA) class II to III HF symptoms and multiple hospitalizations despite traditional chronic disease management, a remote, wireless, pulmonary artery (PA) pressure monitoring device is an option.

Section Summary: Implantable Pulmonary Artery Pressure Measurement Methods (Cardio MEMS Device

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. 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. No significant differences were observed in secondary quality of life and functional status outcomes. While a 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. In light of the absence of a demonstrated benefit on mortality and 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 device remains uncertain. Concerns may be clarified by the ongoing GUIDE-HF RCT that proposes to enroll 2600 subjects for its open access phase and the recruiting German non-industry-sponsored PASSPORT-HF trial.

Noninvasive Thoracic (Electrical) Bioimpedance (TEB)/Impedance Cardiography (ICG)

Clinical Context and Test Purpose

The purpose of TEB in individuals who have HF in an outpatient setting is:

1. To guide volume management,
2. To identify physiologic changes that precede clinical symptoms and thus allow preventive interventions, and
3. To prevent hospitalizations.

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

Populations

The relevant population of interest is individuals with chronic HF 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 and, thus, can be calculated from bioimpedance. Cardiac output is generally reduced in patients with systolic heart failure. Acute decompensation is characterized by worsening of cardiac output from the patient's baseline status. The technique is alternatively known as impedance cardiography.

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 QOL.

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. (31)

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 the TEB testing because they did not include information needed to assess clinical validity. (32-34)

Packer et al. (2006) reported on use of ICG measured by BioZ ICG monitor to predict decompensation in patients with chronic HF. (35) In this study, 212 stable patients with HF and a recent episode of decompensation underwent serial evaluation and blinded ICG testing every 2 weeks for 26 weeks and were followed for the occurrence of death or worsening HF requiring hospitalization or emergent care. Results are summarized in Table 11. A composite score of 3 ICG parameters was a predictor of an event during the next 14 days ($p<0.001$).

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) (35)	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; N: number.

Subsection Summary: Clinically Valid

The clinical validity of using TEB for patients with chronic HF who are at risk of developing acute decompensated heart failure (ADHF) has not been established. Association studies are insufficient evidence to determine whether TEB can improve outcomes patients with chronic HF 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, or more effective therapy, or 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 results of a prospective study in which 59 patients recently hospitalized for HF was selected for ReDS-guided treatment for 90 days. (36) The number of HF hospitalizations during 90-day ReDS-guided therapy were 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 HF 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 confidence intervals (CIs), and lack of clarity about lost-to-follow-up during the post-ReDS period. An RCT comparing ReDS monitoring with 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), days

Amir et al. (2017) (36)	Pre-post prospective cohort	Israel	2012-2015	Patients ≥18 years with stage C - HF, regardless of LVEF (n=59)	ReDS Wearable System	83.0 (25.4)

FU: follow-up; HF: heart failure; LVEF: left ventricular ejection fraction; n: number; SD: standard deviation.

Table 13. Summary of Key Nonrandomized Study Results

Study	HF-Related Hospitalizations (events/patient/3 months)	Deaths
Amir et al. (2017) (36)	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
HR (95% CI); p	• 0.07 (0.01 to 0.54); 0.01[a] • 0.11 (0.014 to 0.88); 0.037[b]	

CI: confidence interval; HR: hazard ratio; HF: heart failure.
[a] Treatment versus pre-treatment period.
[b] Treatment versus post-treatment 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 TEB has not been proved, a chain of evidence to support its clinical utility cannot be constructed.

Subsection Summary: Clinical Utility
The clinical utility of using TEB for patients with chronic HF who are at risk of developing ADHF has not been established. One prospective longitudinal study reported that ReDS-guided management reduced HF 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 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 HF in an outpatient setting is:
1. To guide volume management,
2. To identify physiologic changes that precede clinical symptoms and thus allow preventive interventions, and
3. To prevent hospitalizations.

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

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 patient 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.

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.

Subsection Summary: Clinically Valid
The clinical validity of using inert gas breathing for patients with chronic HF 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, or 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.

Subsection Summary: Clinically Useful
No studies of clinical utility were identified that determined how the use of inert gas breathing measurements in managing HF affects patient outcomes. It is unclear how such devices will improve patient outcomes.

Noninvasive Left Ventricular End Diastolic Pressure (LVEDP) Estimation Methods
Clinical Context and Test Purpose
The purpose of noninvasive LVEDP in individuals who have HF in an outpatient setting is:
1. To guide volume management,
2. To identify physiologic changes that precede clinical symptoms and thus allow preventive interventions, and
3. To prevent hospitalizations.

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

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 patients undergoing cardiac catheterization for diagnostic or therapeutic reasons, its invasive nature precludes outpatient use. Noninvasive measurements of LVEDP have been developed based on the observation that arterial pressure during the strain phase of the Valsalva maneuver may directly reflect the LVEDP. Arterial pressure responses during repeated Valsalva maneuvers can be recorded and analyzed to produce values that correlate to the LVEDP.

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.

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. (37) 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%).

Subsection 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, or more effective therapy, or 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.

Subsection Summary: Clinically Useful

No studies of clinical utility were identified that assessed how the use of noninvasive LVEDP estimation in managing HF 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.

Left Atrial Pressure Devices

The first reported study of an implantable left atrial hemodynamic monitor was conducted by Ritzema et al. (2007) in eight male patients with established heart failure and at least 1 heart failure hospitalization or unplanned outpatient visit for parenteral therapy during the previous 12 months. The 8 subjects from this single center were enrolled in a prospective, multi-center, nonrandomized, open-label feasibility clinical trial called the Hemodynamically Guided Home Self-Therapy in Severe Heart Failure Patients (HOMEOSTASIS I). The LAP hemodynamic monitor device (HeartPOD) was implanted in all patients without device related complications or systemic emboli. The device consisted of an implantable sensor lead coupled with a subcutaneous antenna coil, a patient advisory module (PAM), and the clinician's personal computer software. The sensor system was implanted into the atrial septum oriented to the left atrium. Twelve-weeks post-implantation 87 % of device LAP measurements were within +/- 5 mm Hg of simultaneous pulmonary capillary wedge pressure readings over a wide range of

pressures (1.6 to 71 mm Hg). Net drift corrected by calibration was -0.2 +/- 1.9 mm Hg. The authors concluded that although ambulatory monitoring of direct LAP was well tolerated, feasible, and accurate at a short-term follow-up, further follow-up and investigation were warranted to evaluate the clinical utility of LAP monitoring in patients with heart failure. (38)

Practice Guidelines and Position Statements

American College of Cardiology Foundation and American Heart Association (ACCF/AHA)

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. (39)

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) (40)

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). (40)

European Society of Cardiology (ESC)

The ESC guidelines on the diagnosis and treatment of acute and chronic HF stated the following: “Monitoring of pulmonary artery pressures using a wireless implantable hemodynamic monitoring system may be considered in symptomatic patients with HF [heart failure] in order to improve clinical outcomes” (class IIb, level B recommendation). (42)

National Institute for Health and Clinical Excellence (NICE)

In 2021, the National Institute for Health and Care Excellence (NICE) issued a new interventional procedures guidance regarding the use of percutaneous implantation of pulmonary artery pressure sensors for monitoring the treatment of chronic heart failure. 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." (48)

In 2018, the NICE updated their guidelines on chronic heart failure management and did not include outpatient hemodynamic monitoring as a recommendation. (43).

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. (44)

The committee concluded that: "Based on available evidence, routine use of external remote patient monitoring [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."

Centers for Medicare and Medicaid Services (CMS)

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

1. Differentiation of cardiogenic from pulmonary causes of acute dyspnea;
2. Optimization of atrioventricular interval for patients with atrioventricular sequential cardiac pacemakers;
3. Monitoring of continuous inotropic therapy for patients with terminal HF;
4. Evaluation for rejection in patients with a heart transplant as a predetermined alternative to myocardial biopsy; and
5. Optimization of fluid management in patients with congestive HF.

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

CMS has also specified that TEB is not covered for "the management of all forms of hypertension (with the exception of drug-resistant hypertension…)." Further, CMS specified that: "[Contractors] have discretion to determine whether the use of TEB [thoracic bioimpedance] for the management of drug-resistant hypertension is reasonable and necessary. Drug resistant hypertension is defined as failure to achieve goal blood pressure in

patients who are adhering to full doses of an appropriate 3-drug regimen that includes a diuretic."

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

Summary of Evidence

For individuals with New York Heart Association (NYHA) class II-IV heart failure in outpatient settings who have had a hospitalization in the past year and/or have elevated natriuretic peptides who receive hemodynamic monitoring with an implantable pulmonary artery pressure sensor device, the evidence includes randomized controlled trials (RCTs) and nonrandomized studies. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. One implantable pressure monitor, the CardioMEMS device, has U.S. Food and drug Administration (FDA) approval. The pivotal CHAMPION RCT reported a statistically significant 28% decrease in heart failure hospitalization (HFH) in patients implanted with the CardioMEMS device compared with usual care. However, trial results were potentially biased in favor of the treatment group due to the use of additional nurse communication to enhance protocol compliance with the device. The manufacturer conducted multiple analyses to address potential bias from the nurse interventions. Results were reviewed favorably by the FDA. While these analyses demonstrated the consistency of benefit of the CardioMEMS device, all such analyses have methodologic limitations. Early safety data have been suggestive of a higher rate of procedural complications, particularly related to pulmonary artery injury. While the U.S. CardioMEMS post-approval study and CardioMEMS European Monitoring Study for Heart Failure (MEMS-HF) study reported a significant decrease in HFH with few device- or system-related complications at 1 year, the impact of nursing interventions remains unclear. The subsequent GUIDE-HF RCT failed to meet its primary efficacy endpoint, the composite of HFH, urgent heart failure visits, and death at 1 year. With the approval of the FDA, the statistical analysis plan was updated to pre-specify sensitivity analyses to assess the impact of COVID-19 on the trial. For the 72% of patients who completed follow-up prior to the public health emergency declaration in March 2020, a statistically significant 19% reduction in the primary endpoint was reported, driven by a 28% reduction in HFH. However, lifestyle changes during the COVID-19 pandemic such as changes in physical activity, exposure to infections, willingness to seek medical care, and adherence to medications are unmeasured and add imprecision to treatment effect estimates, as do alterations in provider behaviors. Enrollment of NYHA Class II patients was significantly enriched in the first 500 patients, potentially impacting the pre-COVID-19 analysis. Overall, the beneficial effect of CardioMEMS, if any, appears to be on the hospitalization outcome of the composite. Both urgent heart failure visits and death outcomes had hazard ratios favoring the control group with wide confidence intervals including the null value in pre-COVID-19, during-COVID-19, and overall analyses of the GUIDE-HF trial. No significant differences were observed in secondary quality of life and functional status outcomes. While the HFH reduction of 28% found in the pre-COVID-19 analysis is consistent with findings from the CHAMPION trial, it is unclear whether physician knowledge of treatment assignment biases the decision to hospitalize and administer intravenous diuretics. Given that the intervention is invasive and

intended to be used for a highly prevalent condition and, in light of the absence of a demonstrated benefit on mortality and functional outcomes, the lack of periprocedural safety data, and unclear impact of COVID-19 on remote monitoring in the GUIDE-HF trial, the net benefit of the CardioMEMS device remains uncertain. Concerns may be clarified by the ongoing open access phase of the GUIDE-HF RCT and the German non-industry-sponsored PASSPORT-HF trial. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring by thoracic bioimpedance, the evidence includes uncontrolled prospective studies and case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. There is a lack of randomized controlled trial evidence evaluating whether the use of these technologies improves health outcomes over standard active management of heart failure patients. The case series have reported physiologic measurement-related outcomes and/or associations between monitoring information and heart failure exacerbations, but do not provide definitive evidence on device efficacy. While the evidence for thoracic bioimpedance (TEB) for treatment of heart failure (HF) may be insufficient, the Centers for Medicare and Medicaid Services' (CMS) national coverage determination found TEB to be reasonable and effective for specific indications. However, outside of those indications, CMS has determined that utilization of TEB would be non-covered.

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

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

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 15.

Table 15. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date

Ongoing			
NCT04223271[a]	Heart Failure Event Advance Detection Trial (HEADstart)	165	Apr 2021 (recruiting)
NCT02954341[a]	CardioMEMS HF SystemOUS Post Market Study	300	Dec 2023 (recruiting)
NCT03387813[a]	Hemodynamic-GUIDEd Management of Heart Failure (GUIDE-HF)	2358	Aug 2023 (ongoing)
NCT04398654	Pulmonary Artery Sensor System Pressure Monitoring to Improve Heart Failure (HF) Outcomes	554	Dec 2026 (recruiting)
NCT0441203	Patient SELF-management With HemodynamIc Monitoring: Virtual Heart Failure Clinic and Outcomes (SELFIe-HF)	150	Jun 2024 (not yet recruiting)
NCT04012944[a]	A Prospective, Multi-Center, Open-Label, Single-Arm Clinical Trial Evaluating the Safety and Efficacy of the Cordella™ Pulmonary Artery Sensor System in New York Heart Association (NYHA) Class III Heart Failure Patients (SIRONA 2 Trial)	81	Jul 2025 (ongoing)
NCT03020043	CardioMEMS Registry of the Frankfurt Heart Failure Center	500	Dec 2025 (recruiting)
NCT04089059[a]	A Prospective, Multi-Center, Open Label, Single Arm Clinical Trial Evaluating the Safety and Efficacy of the Cordella™ Pulmonary Artery Sensor System in NYHA Class III Heart Failure Patients (PROACTIVE-HF Trial)	456	Mar 2026 (ongoing)

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	33289, 93264, 93701, 93799
HCPCS Codes	C2624, G0555, G2066

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
08/15/2024	Reviewed. No changes.
10/15/2023	Document updated with literature review. Coverage unchanged. References 8, 12, 23, 25, 29 and 31 added; others updated.
01/01/2023	Document updated with literature review. Coverage unchanged. References 5, 14, 18-21, 23, 34 and 42.
07/15/2021	Reviewed. No changes.
10/15/2020	Document updated with literature review. Coverage unchanged. References 5, 6, 9, 10, 27, 29, 31-35 added; others removed.
01/15/2020	Reviewed. No changes.
10/01/2018	Document updated with literature review. Coverage unchanged. References 9, 17-19, 21-27, and 29 were added; numerous were removed.
08/15/2017	Reviewed. No changes.
10/01/2016	Document updated with literature review. Coverage unchanged.
01/01/2016	Document updated with literature review. Coverage unchanged.
10/01/2014	Document updated with literature review. Coverage unchanged. Description, Rationale, and References significantly revised and reorganized. CPT/HCPCS codes updated.
04/15/2013	Document updated with literature review. Coverage unchanged.
04/01/2012	Document updated with the following changes to the Coverage: The use of left atrial pressure monitoring, as a form of cardiac hemodynamic monitoring in the management of heart failure, is considered experimental, investigational and unproven. Additional revisions to Description, References, and Rationale. CPT/HCPCS codes updated.
09/01/2011	Document updated with literature review. The following topics were added: Thoracic electrical bioimpedance may be considered medically necessary when criteria are met. Inert gas rebreathing is considered experimental, investigational and unproven. These topics were previously addressed on Medical Policy MED202.018, Plethysmography; however, criteria have changed. The title was changed from Non-Invasive Measurement of Left Ventricular End Diastolic Pressure (LVEDP) in the Outpatient Setting, and the document was completely revised.
09/01/2010	Document updated with literature review. Coverage unchanged. This document is no longer scheduled for routine literature review and update.
07/01/2008	Revised/updated entire document
05/15/2005	New medical document originating from a position statement