Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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(See policy history boxes for previous effective dates)

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

Description/Background

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

Chronic Heart Failure

Patients with chronic heart failure are at risk of developing acute decompensated heart failure, often requiring hospital admission. Patients with a history of acute decompensation have the additional risk of future episodes of decompensation, and death. Reasons for the transition from a stable, chronic state to an acute, decompensated state include disease progression, as well as acute events such as coronary ischemia and dysrhythmias. While precipitating factors are frequently not identified, the most common preventable cause is noncompliance with medication and dietary regimens.(1)

Management

Strategies for reducing decompensation, and thus the need for hospitalization, are aimed at early identification of patients at risk for imminent decompensation. Programs for early identification of heart failure are characterized by frequent contact with patients to review signs and symptoms with a healthcare provider and with education or adjustment of medications as appropriate. These encounters may occur face-to-face in the office or at home, or via cellular or computed technology.(2)

Precise measurement of cardiac hemodynamics is often employed in the intensive care setting to carefully manage fluid status in acutely decompensated heart failure. Transthoracic echocardiography, transesophageal echocardiography, and Doppler ultrasound are noninvasive

methods for monitoring cardiac output on an intermittent basis for the more stable patient but are not addressed herein. A variety of biomarkers and radiologic techniques may be used for dyspnea when the diagnosis of acute decompensated heart failure is uncertain.

The criterion standard for hemodynamic monitoring is pulmonary artery (PA) catheters and central venous pressure catheters. However, they are invasive 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 limitations including use of proprietary technology making it difficult to confirm their validity and lack of large randomized controlled trials to evaluate treatment decisions guided by these hemodynamic monitors.

Regulatory Status

Noninvasive Left Ventricular End-Diastolic Pressure Measurement Devices

In 2004, the VeriCor® (CVP Diagnostics, Boston, MA), a noninvasive LVEDP measurement device, was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices for the following indication:

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

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 for use for peripheral blood flow monitoring. Table 1 presents an inexhaustive list of representative devices (FDA product code: DSB).

Table 1. Noninvasive Thoracic Impedance Plethysmography Devices

Device	Manufacturer	Clearance Date
BioZ® Thoracic Impedance Plethysmograph	SonoSite	2009
Zoe® Fluid Status Monitor	Noninvasive Medical Technologies	2004
Cheetah Starling SV	Cheetah Medical	2008

PhysioFlow® Signal Morphology-based Impedance Cardiography (SM-ICG™)	Vasocom, now NeuMeDx	2008
ReDS™ Wearable System	Sensible Medical Innovations	2015
Bodyport Cardiac Scale	Bodyport Inc.	2022

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 FDA through the 510(k) process. FDA determined that this device was substantially equivalent to existing inert gas rebreathing devices for use in computing blood flow. FDA product code: BZG.

Implantable Pulmonary Artery Pressure Devices
In 2014, the CardioMEMS™ Heart Failure Monitoring System (CardioMEMS, now Abbott) was approved for marketing by FDA through the premarket approval process. This device consists of an implantable PA sensor, which is implanted in the distal PA, a transvenous delivery system, and an electronic sensor that processes signals from the implantable PA sensor and transmits PA pressure measurements to a secure database.(3) The device originally underwent FDA review in 2011, at which point the Circulatory System Device Panel decided that there was not reasonable assurance that the discussed monitoring system is effective, particularly in certain subpopulations, although most panel members agreed that that the discussed monitoring system is safe for use in the indicated patient population.(4) In 2022, the CardioMEMS™ Heart Failure Monitoring System received expanded approval for the treatment of New York Heart Association (NYHA) Class II-III patients who had been hospitalized at least 1 time in the prior year and/or had elevated natriuretic peptides.

The Cordella™ PA Pressure Sensor System (CorPASS; Endotronix, Inc.), which includes a sensor implanted in the PA was granted FDA premarket approval (2024) as a restricted device. This device is indicated to measure, record and transmit pulmonary artery pressure (PAP) data from NYHA Class III heart failure patients who are at home on diuretics and guideline-directed medical therapy (GDMT) as well as have been stable for 30 days on GDMT. The device output is meant to aid clinicians in the assessment and management of heart failure, with the goal of reducing heart failure hospitalizations. Continued approval of the PMA (expires in 2 years; granted June 20, 2024) is contingent upon the submission of periodic reports.

The FDA has determined that restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. See the full PMA for the post-approval study requirements.

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

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

Medical Policy Statement

In the ambulatory care and outpatient setting, cardiac hemodynamic monitoring using thoracic bioimpedance, inert gas rebreathing, arterial pressure/Valsalva, and implantable direct pressure monitoring of the pulmonary artery, for the management of heart failure is considered experimental/ investigational. These methods have not been scientifically demonstrated to improve patient clinical outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

33289	93264	93701	93799	C2624	0607T
0608T					

Rationale

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 of pulmonary artery pressure to inform 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 post market surveillance analyses.

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

Populations

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

Interventions
Left ventricular end-diastolic pressure (LVEDP) can be approximated by direct pressure measurement of an implantable sensor in the pulmonary artery wall or right ventricular outflow tract. The sensor is implanted via right heart catheterization and transmits pressure readings wirelessly to external monitors. One device, the CardioMEMS Heart Failure Monitoring System, has approval from the U.S. Food and Drug Administration (FDA) for the ambulatory management of heart failure patients. The CardioMEMS device is implanted using a heart catheter system fed through the femoral vein and generally requires individuals to have an overnight hospital admission for observation after implantation. Specific target pressure ranges provided to investigators to achieve hemodynamic stability included 10-25 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 persons 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 three 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 outcome 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 hall walk test (6MHW), stair climb test, Short Physical Performance Battery or hand-grip strength are functional measures.

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

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

Study Selection Criteria
Methodologically credible studies were selected using the following principles.

- Comparative controlled prospective trials were sought, with preference for randomized controlled trials.
- In the absence of such trials, comparative observational studies were sought, with preference for prospective studies.
- To assess longer 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 CardioMEMS trials in individuals with reduced ejection fraction,(7,8) preserved ejection fraction,(9) Medicare-eligible patients,(10) chronic obstructive pulmonary disease,(11) and various subtypes of pulmonary hypertension (12) are outside of the scope of this review and are therefore not discussed. Studies reporting physiological measures in the absence of clinical outcomes were also excluded.(13)

Review of Evidence

Randomized Controlled Trials

Systematic Reviews
Iaconelli et al (2023) conducted a systematic review and meta-analysis of RCTs evaluating the use of implantable hemodynamic monitoring devices to guide the management of heart failure.(14) Four trials(COMPASS-HF, REDUCE-HF, CHAMPION, and GUIDE-HF) were determined to be eligible for inclusion with follow-up durations ranging from 6 to 18 months. These trials compared management guided by data from implantable hemodynamic monitoring devices (n=1103; including both the CardioMEMs and Chronicle devices)to standard care (n=1121) in a total of 2,224 heart failure patients. In the pooled analysis, hemodynamic-guided management reduced the risk of total heart failure hospitalizations by 25% (Hazard ratio [HR] 0.75;95% CI 0.58 to 0.96; p =.03) but did not significantly reduce all-cause mortality (Risk ratio 0.92; 95% CI 0.68 to1.26; p =.48). Changes in treatment guided by hemodynamic monitoring resulted in small reductions in mean pulmonary artery pressure less than 1 mmHg as a daily average. The COMPASS-HF and REDUCE-HF studies investigated the Chronicle device, which is not FDA-approved and is not otherwise reviewed in this medical policy.

Lindenfeld et al (2024) reported the results of a patient-level meta-analysis of 3 RCTs (GUIDE-HF,CHAMPION, and LAPTOP-HF) evaluating CardioMEMs hemodynamic monitoring for the management of patients with heart failure and a left ventricular ejection fraction ≤40%.(15) The meta-analysis included 1,350 patients with a median follow-up of 12.2 months with a maximum follow-up of 4 years. Patients were randomized to a treatment group receiving hemodynamic-guided management via CardioMEMs (n=667) or a control group receiving standard care (n=683). The pooled analysis demonstrated a significant 36% reduction in heart failure hospitalizations (HR: 0.64; 95% CI: 0.55 to 0.76; p<.0001) and a significant 25% reduction in mortality (HR: 0.75; 95% CI: 0.57 to 0.99; p=.043) in the treatment group compared to the control group. This mortality benefit was observed after the first year of follow-

up. The LAPTOP-HF study is only available as an abstract and is not otherwise reviewed in this medical policy.

Randomized Controlled Trials

CHAMPION

Abraham et al (2011, 2016) reported on the results of CHAMPION, a single-blind RCT enrolling patients with NYHA Class III heart failure who have had a hospitalization in the prior year. All enrolled patients were implanted with the CardioMEMS device.(16,17) Patients were randomized to the CardioMEMS group, in which daily uploaded pulmonary artery pressures were used to guide medical therapy, or to the control group, in which investigators were blinded to daily uploaded pressures and managed patients based on clinical signs and symptoms. An independent clinical end point classification (CEC) committee, blinded to the treatment groups, reviewed abstracted clinical data and determined if hospitalization was related to heart failure. It is unclear what criteria were used for adjudication of heart failure hospitalizations.(18)

The randomized phase ended when the last patient enrolled completed at least 6 months of study follow-up (average, 18 months) and was followed in an open-access phase during which investigators had access to pulmonary artery pressure for all patients (former control and treatment group). Trial characteristics and results are summarized in Tables 2 through 4. The trial met its primary efficacy endpoint, with a statistically significant 28% relative reduction in the rate of heart failure-related hospitalizations (HFH) at 6 months. This outcome was accompanied by a significant improvement in Minnesota Living with Heart Failure Questionnaire scores at 6 and 12months. 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.(19,20) Post-hoc analyses to address the impact of nurse interventions on HFH conducted by the sponsor were judged to have methodologic limitations by the FDA.(3) However, the FDA stated that longitudinal analyses, such as those demonstrating a significant decrease in HFH when former control patients entered the treatment arm of the open-access phase, were the most useful regarding support for device effectiveness. It is important to acknowledge that all such analyses were conducted with the intent to test the robustness of potentially biased RCT results; therefore, results from these analyses should be evaluated to assess consistency and not as an independent source of evidence to support efficacy. Additional trial aspects limit the interpretation of these analyses; notably, subject dropouts were not random, and patient risk profiles could have changed from the randomized phase to the open-access phase. In the open-access phase, 93 (34%) of 270 subjects in the treatment group and 110 (39%) of 280 subjects in the control group remained in the analysis.

While the CHAMPION trial failed to demonstrate a treatment effect in women, the overall reduction in HFH subsequently observed in the CardioMEMS post-approval study (see Tables 7 and 8) was also observed in the subgroup analysis of women, which comprised 37.7% of the study population.(21,22)

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.(23) 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),(24) failed to find a significant reduction in the composite outcome and its individual components. Study authors noted that this was driven by an expected 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.

MONITOR-HF

Brugts et al (2023) reported the results of MONITOR-HF, an open-label RCT conducted in 25 centers in the Netherlands.(25) Eligible patients had NYHA class III chronic heart failure, a previous heart failure hospitalization, and had been treated with optimal or maximally tolerated treatment according to the European Society of Cardiology guidelines. Patients were randomly assigned (1:1) to either hemodynamic monitoring using CardioMEMS or standard of care. All patients were scheduled for follow-up at 3 months, 6 months, and every 6 months thereafter, up to 48 months. In the control group, patients were managed with guideline-directed medical therapy and diuretics based on signs, symptoms, laboratory measurements, and echocardiography without hemodynamic information. The primary endpoint was the mean difference in the Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary score at 12 months. Trial characteristics and results are summarized in Tables 2 through 4. The MONITOR-HF study achieved its primary efficacy endpoint, demonstrating a statistically significant change in the mean KCCQ overall summary score at 12 months, favoring the CardioMEMs group with a mean difference of 7.05 points (95% CI: 2.77 to 11.33; p=.013) compared to the control group. Secondary outcomes included a responder analysis that revealed the CardioMEMS group had a significantly higher proportion of patients achieving a ≥ 5-point improvement in KCCQ score at 12 months compared to the standard of care group (47.7% vs. 38.1%, p = 0.046). Participants in the CardioMEMS group also experienced a lower rate of total heart failure hospitalizations or urgent visits requiring IV diuresis, with117 events per patient-year compared to 212 in the standard of care group (HR 0.56; 95% CI 0.38 to 0.84l;p=.0053). Additionally, the CardioMEMS group showed a significant reduction in median NT-proBNP levels at12 months (-669 pg/mL, p = 0.013) and a significant improvement in mean 6-minute walk test distance (+29.3m, p = 0.033), while the control group did not demonstrate significant changes in these parameters. Freedom from sensor failure in the CardioMEMS group was 98.8%. The trial included a sensitivity analysis to assess the potential impact of the COVID-19 pandemic on the results. The analysis revealed no significant interaction between the treatment effects and the COVID-19 pandemic. Study relevance, design, and conduct

limitations are summarized in Tables 5 and 6. Limitations of the MONITOR-HF study included the lack of blinding, the absence of sham control, and the treatment arm having a two-month lead-in optimization phase which was not present in the control group.

Table 2. Summary of Key Randomized Controlled Trial Characteristics

Author; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Abraham et al (2011, 2016) CHAMPION	U.S.	64	2007-2010	Main Eligibility Criteria: At least 1 previous HFH in the past 12 mo and NYHA class III HF for at least 3 mo Pt Baseline Characteristics: • Sex: 72.5% male,27.5% female • Mean Age: ~61 y • Race: 72.9% White, NRBlack • NYHA Class: 100% III • Mean PAP: ~29-30mmHg • 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); Zile et al (2022); GUIDE-HF	U.S.	139	2018-2021	Main Eligibility Criteria: NYHA Class II-IV HF and at least 1 previous HFH in the past 12 mo or elevated natriuretic peptides within prior 30 days Pt Baseline Characteristics: • Sex: 62.5% male,37.5% female • Mean Age: ~70-71 y • Race: 80.7% White,17.9% Black • NYHA Class: 29.6% II,65% III, 5.4% IV • Mean PAP: ~28-29 mmHg	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)

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; NYHA: New York Heart Association; PAP: pulmonary artery pressure

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

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

			(0.55 to 0.80); <.0001		(0.55 to 1.15); 0.23		
Lindenfeld et al (2021); Zile et al (2022); GUIDE-HF[19,20,]							
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] .16	0.83 (0.68 to 1.01); .064	1.04 (0.61 to 1.77); .89	1.09 (0.70 to 1.70); 0.71	NA	NA
Pre-COVID-19 Impact Analysis							
CardioMEMS	497	177 (0.553)	124 (0.380)	23 (0.074)	30 (0.110)	NR	NA
Control	503	224 (0.682)	176 (0.525)	23 (0.073)	25 (0.088)	NR	NA
HR (95% CI); p-value		0.81 (0.66 to 1.00); .049	0.72 (0.57 to 0.92); .0072	1.02 (0.57 to 1.82); 0.95	1.24 (0.73 to 2.11); 0.42	NR	NA
During-COVID-19 Impact Analysis							
CardioMEMS	310	76 (0.597)	61 (0.490)	5 (0.048)	10 (0.067)	NR	NA
Control	307	65 (0.536)	49 (0.414)	4 (0.041)	12 (0.085)	NR	NA
HR (95% CI); p-value		1.11 (0.80 to 1.55); .53	1.18 (0.81 to 1.73); .38	1.19 (0.82 to 1.70); .80	0.79 (0.35 to 1.83); .59	NR	NA

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

[a] Primary efficacy outcome in CHAMPION trial.

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

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

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

			Baseline (SD)	Baseline (SD)	Baseline, m (SD)		
CardioMEMS	497	NA	5.20 (21.35) (n=421)	0.94 (20.17) (n=421)	-12.83 (100.08) (n=288)	-792.7 (1767.0)	1.031 (NR)
Control	503	NA	4.12 (22.50) (n=408)	2.90 (20.71) (N=409)	-6.46 (106.57) (n=291)	-582.9 (1698.1)	0.608 (NR)
p-value		NA	p=.48	p=.17	p=.46	p=.040	NR
Pre-COVID-19 Impact Analysis							
CardioMEMS	497	NA	4.19 (18.29) (n=140)	-1.28 (20.18) (n=140)	-19.46 (87.63) (n=120)	-518.0 (1327.0)	0.835 (NR)
Control	503	NA	5.05 (22.10) (n=137)	3.89 (17.73) (n=138)	-9.78 (112.70) (n=127)	-324.2 (1328.5)	0.475 (NR)
p-value		NA	p=.72	p=.024	p=.45	p=.014	p<.001

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

Table 5. Study Relevance Limitations

Study; Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-up[e]
Abraham et al (2011, 2016) CHAMPION		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		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 study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not established and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 6. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Abraham (2011, 2016) CHAMPION		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	4. COVID-19 impact analyses limited due to potential selection bias. Pre-COVID-19 analysis was enriched with patients with NYHA[b] 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; GUIDE-HF: Hemodynamic GUIDEd Management of Heart Failure trial; HF: heart failure; NYHA: New York Heart Association

The study limitation stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5.Other.

Nonrandomized Studies

As previously described in the selection criteria, studies will be included here to assess longer 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.(26) 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).(27) 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 0.28; p<.0001). No significant improvements in EQ-5D-5L scores were observed at 6- or 12-month time points. Over 12months, 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.(21) The primary efficacy outcome was the difference between rates of adjudicated HFH 1 year after compared to 1 year prior to device implantation. The 12-month visit was completed in 875 patients (72.9%). Prior to 1 year, 76 patients (6.3%) withdrew from the study and 186 patients (15.5%) died. The HFH rate was significantly lower at 1 year post-implantation (0.54 versus 1.25 events/patient-year; HR, 0.43; 95% CI, 0.39 to 0.47; p<.0001). The rate decrease remained significant regardless of the number of pre-enrollment HFH events, with a trend towards a more significant benefit in a small subgroup of patients (n=21) with ≥ 5 pre-enrollment HFH events. The rate of all-cause hospitalization (ACH) was also significantly lower (1.67 versus 2.28 events/patient-year; HR, 0.73; 95% CI, 0.68 to0.78; p<.0001). During the study, 94.1% of patients had a medication change, with an average of 1.6 medication changes per month. Medication changes related to an increase or decrease in pulmonary artery pressure were implemented in 81.8% and 55.8% of patients, respectively. At 1 year, freedom from device- or system-related complications was 99.6% (5 events) and freedom from pressure sensor failure was 99.9% (1 event). The nature of these events and the frequency of procedure-related adverse events were not reported. Heywood et al published 2-year outcomes from the U.S. post-approval study in 2023.(28) The 2-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 the 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).(29) This was an industry-sponsored, prospective, observational, non-randomized study designed to assess the safety and feasibility of the CardioMEMS heart failure system over a 12-month follow-up in 31 centers across Germany, the Netherlands, and Ireland. A total of 239 patients (22% female) with NYHA class III heart failure and ≥ 1 HFH in the prior year were enrolled for remote pulmonary artery pressure-guided heart failure management. Co-primary outcome measures, 1-year rates of freedom from device- or system-related complications and sensor failure, were 98.3% (95% CI, 95.8 to 100.0) 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 HFH rate at 12 months compared to the prior year before implantation and health-related quality of life. The HFH rate decreased 62% (0.60 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.(30) Patients were matched to 1087 controls by demographics, history and timing of HFH, and number of ACH. Propensity scoring based on arrhythmia, hypertension, diabetes, pulmonary disease, and renal disease was used for additional matching. Follow-up was censored at death, ventricular assist device implant, or heart transplant. At 12 months post implantation, 616and 784 HFH events occurred in the treatment and control cohorts, respectively. Study characteristics and results are summarized in Tables 7 and 8. The rate of HFH was lower in the treatment cohort at 12 months (HR, 0.76; 95% CI, 0.65 to 0.89; p<.001). Percentage of days lost to HFH (HR, 0.73; 95% CI, 0.64 to 0.84; p<.001) and ACH or death (HR, 0.77; 95% CI, 0.68 to 0.88; p<.001) were both significantly lower in the treatment group. The percentage of days lost owing to HFH or death was reduced in the treatment cohort(relative risk [RR], 0.73; 95% CI, 0.63 to 0.83).

Desai et al (2017) published a retrospective cohort study of Medicare administrative claims data for individuals who received the CardioMEMS device following FDA approval.(31) 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 heart failure–related hospitalizations were significantly lower in the post implantation period than in the pre-implantation period at both 6- and 12-month follow-ups.

Post-marketing 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.(32) 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 CardioMEMS be considered in the context of its lack of a mortality benefit in multiple RCTs, particularly in light of approved expanded use in individuals with NYHA class II heart failure.

Vaduganathan (2017) analyzed mandatory and voluntary reports of device-related malfunctions reported to FDA to identify CardioMEMS system–related adverse events within the first 3 years of FDA approval.(33) From among the more than 5500 CardioMEMS implants in the first three 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 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)	Retrospective matched cohort	U.S./AHRQ	2014-2019	Individuals with ICD codes consistent with use of procedure	CardioMEMS implant	6 mo
Abraham et al (2019)	Retrospective matched cohort	U.S./Medicare /Abbott	2014-2016	Individuals with CPT codes consistent with the use of procedure and at least 1 HFH within the previous 12 months	CardioMEMS implant	12 mo
Pre-post Studies						
Cowie et al (2021)	Post-approval multicenter study	U.K/Abbott	2017-2019	Individuals with NYHA class III HF and at least 1 HFH within the previous 12 months	CardioMEMS implant	12 and 24 mo

Shavelle et al (2020); Heywood et al (2023)	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 previous 12 months.	CardioMEMS implant	12 mo and 24 mo
Angermann et al (2020)	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	CardioMEMS implant; communications with trained non-physician staff	12 mo
Desai et al (2017)[15]	Retrospective cohort	U.S./ Medicare	2014-2015	Individuals with inpatient CPT codes consistent with use of procedure	CardioMEMS implant	• 6-mo preimplant and postimplant data (n=1114) • 12-mo preimplant and postimplant data (n=480)
Post-marketing Safety Studies						
Lin et al (2022)	Post-marketing MAUDE database analysis	U.S./FDA and Abbott	2014-2020	Mandatory reports of CardioMEMS-related adverse events	CardioMEMS implant	NA
Vaduganathan et al (2017)	Post marketing surveillance study	U.S./FDA and Abbott	2014-2017	Individuals reporting Cardio-MEMS related adverse event	CardioMEMS implant	Not applicable

FDA: U.S. Food and Drug Administration. HFH: heart failure-related hospitalization; NYHA: New York Heart Association,

Table 8. Summary of Key Nonrandomized Study Results

Study	HFH at 6 Months	HFH at 12 Months	Safety
COMPARATIVE STUDIES			
Kishino et al (2022)	728	NR	In-hospital mortality at 30 days (7% vs. 3.6%; p=.002); acute kidney injury (43.8% vs. 34.7%; p<.001); acute kidney injury requiring hemodialysis (3.5% vs. 1.8%; p=.019); transfusions (9.8% vs. 3.4%; p<.001).
HR (95% CI); p-value	0.80 (0.71 to 0.91);.001	NR	
Abraham et al (2019)	NR	1087	NR
HR (95% CI); p-value	NR	0.76 (0.65 to 0.89); <.001	NR

PRE-POST STUDIES			
Cowie et al (2021)	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)	NR	628 (12 mo)	NR
Heywood et al (2023)	NR	307 (24 mo)	Freedom from DSRC at 2 yr: 99.6%
HR (95% CI); p-value	NR	0.43 (0.39 to 0.47); <.0001 (12 mo) 0.30 (0.25 to 0.35); < .0001 (24 mo)	Freedom from DSRC: 99.6% Freedom from pressure sensor failure: 99.9%
Angermann et al (2020)	**198**	**234[a]; 180[b]**	**236**
HR (95% CI); p-value	NR	0.38 (0.31 to 0.48); <.0001[a] 0.34 (0.26 to 0.44); <.0001[b]	DSRC: 1.7% Pressure sensor failure: 0.4% SAE: 21/236 (8.9%) Delivery system-related events: 4 Implant procedure-related events: 21 Pulmonary artery perforation: 1 (0.4%) Procedure-related cardiac deaths: 3 (1.3%)
Desai et al (2017)	1114	480	NR
Preimplant, n	1020	696	NR
Postimplant, n	381	300	NR
HR (95% CI); p-value	0.55 (0.49 to 0.61); <0.001	0.66 (0.57 to 0.76); <.001	NR
POSTMARKETING SAFETY STUDIES			
Lin et al (2022)			2858 (99.9%) mandatory CardioMEMS reports
AE cohort identified from MAUDE database	NR	NR	Inaccurate measurements requiring replacement of the external CardioMEMS unit (n=1109; 38.8%); repeat noninvasive testing (n=314; 11.0%); repeat right heart catheterization (n=677; 23.7%); surgery (n=23; 0.8%); hemoptysis (n=70; 2.4%); heart failure exacerbation (n=43; 1.5%); significant bleeding at the site of catheterization (n=24; 0.8%); death or transition to end-of-life care as terminal event (167; 5.8%).
Vaduganathan et al (2017)			Estimated 5500 received CardioMEMS
AE cohort identified from MAUDE database	NR	NR	155 (2.8%) AEs; 28 pulmonary artery injury or hemoptysis (0.5%), and 2 (0.4%) deaths

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

Table 9. Nonrandomized Study Relevance Limitations

Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Comparative Studies					
Kishino et al (2022)	3. NYHA Class data not reported. Database		2. While propensity scoring was applied for several patient factors, residual	Kishino et al (2022)	3. NYHA Class data not reported.

	data may lack complete medical history information.		confounding by unmeasured covariates remains possible. Database data may lack complete medical history data.	Database data may lack complete medical history information
Abraham et al (2019)	3. NYHA Class data not reported. Medicare claims data may lack complete medical history information.	1. Details regarding the frequency of nursing and/or provider communications were not described.	2. While propensity scoring was applied for several patient factors, residual confounding by unmeasured covariates remains possible. Medicare claims data may lack complete medical history data.	
Pre-post Studies				
Cowie et al (2021)		1. Details regarding the frequency of nursing and/or provider communications were not described.		
Shavelle et al (2020); Heywood et al (2023)		1. Details regarding the use of nursing and/or provider communications were not described.		
Angermann et al (2020)		3. Frequency of nursing communications varied based on patient NYHA Class.		
Desai et al (2017)	3. NYHA Class data not reported. Medicare claims data may lack complete medical history information.			
Post-marketing Safety Studies				
Lin et al (2022)				
Vaduganathan et al (2017)				

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

Table 10. Nonrandomized Study Design and Conduct Limitations

Trial	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Comparative Studies						
Kishino et al (2022)	1-2. Participants were not randomly allocated and allocation was not concealed.	1. Physicians were not blinded to treatment assignment. Events were not formally adjudicated and were limited by retrospective claims data.				
Abraham et al (2019)	1-2. Participants were not randomly allocated and allocation was not concealed. 4. While propensity scoring was applied for several patient factors, residual confounding by unmeasured covariates remains possible. Medicare claims data may lack complete medical history data.	1. Physicians were not blinded to treatment assignment. Events were not formally adjudicated and were limited by retrospective claims data.				
Pre-post Studies						
Cowie et al (2021)	1-2 Participants were not randomly allocated and allocation was not concealed. 4. Assessing HFH as a study entry requirement and endpoint may reflect a bias of prior hospitalization in favor of any intervention	1. Physicians were not blinded to treatment assignment. Events were adjudicated by treating physicians.	2. Only results for patients with follow-up completed before COVID-19 have been reported.			
Shavelle et al (2020)	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)	1-2. Participants were not randomly allocated and allocation was not concealed.	1. Physicians were blinded to treatment assignment.				

	4. Assessing HFH as a study entry requirement and endpoint may reflect a bias of prior hospitalization in favor of any intervention.	Outcome adjudication was unclear.	
Desai et al (2017)	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.	
Post marketing Safety Studies			
Lin et al (2022)	1-2. Participants were not randomly allocated and allocation was not concealed.	1. Physicians were not blinded to treatment assignment. No formal outcome adjudication was used due to limitations with self-reports.	1. Voluntary reporting of adverse events limits the interpretation of results as all events are not captured.
Vaduganathan et al (2017)	1-2. Participants were not randomly allocated and allocation was not concealed.	1. Physicians were not blinded to treatment assignment. No formal outcome adjudication was used due to limitations with self-reports.	1. Voluntary reporting of adverse events limits the interpretation of results as all events are not captured.

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

Section Summary: Implantable Pulmonary Artery Pressure Monitoring (CardioMEMS Device)
The pivotal CHAMPION RCT reported a statistically significant 28% decrease in heart failure–related hospitalizations 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 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 open access phase of the GUIDE-HF RCT and the German non-industry-sponsored PASSPORT-HF trial.

NONINVASIVE THORACIC BIOIMPEDANCE/IMPEDANCE CARDIOGRAPHY

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

The following PICOs were used to select literature to inform this review.

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

Interventions
The test being considered is thoracic bioimpedance.

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

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

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

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

Study Selection Criteria
Remains as described above.

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.(34)

Review of Evidence

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

Several studies were excluded from the evaluation of the clinical validity of thoracic bioimpedance testing because they did not include information needed to assess clinical validity.(35-37)

Packer et al (2006) reported on the use of impedance cardiography measured by BioZ impedance cardiography monitor to predict decompensation in patients with chronic heart failure.(38) In this study, 212 stable patients with heart failure and a recent episode of decompensation underwent serial evaluation and blinded impedance cardiography testing every 2 weeks for 26 weeks and were followed for the occurrence of death or worsening heart failure requiring hospitalization or emergent care. Results are summarized in Table 12. A composite score of three impedance cardiography 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)	212	212	None	59 patients had 104 episodes of decompensated HF including 16 deaths, 78 hospitalizations, 10 ED visits	1.0 (0.5 to 1.9)	3.5 (2.4 to 4.8)	8.4 (5.8 to 11.6)

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

Section Summary: Clinically Valid

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

Clinically Useful

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

Direct Evidence

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

Amir et al (2017) reported on the results of a prospective study in which 59 patients recently hospitalized for heart failure were selected for remote dielectric sensing (ReDS)-guided treatment for 90 days.(39) The number of heart failure hospitalizations during 90-day ReDS-guided therapy was compared with hospitalizations in the preceding 90 days before enrollment and the 90 days following discontinuation of ReDS monitoring. During treatment, patients were equipped with the ReDS wearable vest, which was worn once a day at home to measure lung fluid content. Study characteristics and results are summarized in Tables 13 and 14. The rate of heart failure hospitalizations was lower during the ReDS-guided follow-up compared with pre- and post-treatment periods. Interpretation of results is uncertain due to the lack of concurrent control and randomization, short-term follow-up, large CIs, and lack of clarity about lost-to-follow-up during the post-ReDS period. An RCT comparing ReDS monitoring with the standard of care (SMILE; NCT02448342) was initiated but terminated before its completion.

Table 12. Summary of Key Nonrandomized Study Characteristics

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

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

Table 13. Summary of Key Nonrandomized Study Results

Study	Heart Failure-Related Hospitalizations (events/patient/3 mo)	Deaths
Amir et al (2017)	50	50
Pre-90-day period (control)	0.04	0
90-day treatment period	0.30	2
Post-90-day period (control)	0.19	2
Hazard ratio (95% confidence interval); p	0.07 (0.01 to 0.54); 0.01[a] 0.11 (0.014 to 0.88); 0.037[b]	

[a] Treatment vs pretreatment period. [b] Treatment vs posttreatment period.

Chain of Evidence

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

Section Summary: Clinical Utility

The clinical utility of using thoracic bioimpedance for patients with chronic heart failure who are at risk of developing ADHF has not been established. One prospective longitudinal study reported that ReDS-guided management reduced heart failure readmissions in ADHF patients recently discharged from the hospital. However, interpretation of results is uncertain due to the lack of concurrent controls and randomization, short-term follow-up, large CIs, and lack of clarity about lost-to-follow-up during the post-ReDS monitoring period. An RCT comparing ReDS monitoring with the standard of care was initiated but terminated before its completion.

INERT GAS REBREATHING

Clinical Context and Test Purpose

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

The following PICOs were used to select literature to inform this review.

Populations
The relevant population of interest are 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 two inert gases, typically nitrous oxide and sulfur hexafluoride. The nitrous oxide is soluble in blood and is therefore absorbed during the blood's passage through the lungs at a rate 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.

Patients with heart failure are managed by cardiologists in an outpatient clinical setting.

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 breathing in this population were not found. Generally, demonstration of outcomes over a one-year period is meaningful for interventions.

Study Selection Criteria
Remains as described above.

Review of Evidence

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

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

Section Summary: Clinically Valid
The clinical validity of using inert gas breathing for patients with chronic heart failure who are at risk of developing ADHF has not been established.

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

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

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

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

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

NONINVASIVE LEFT VENTRICULAR END-DIASTOLIC PRESSURE ESTIMATION

Clinical Context and Test Purpose

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

The following PICOs were used to select literature to inform this review.

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

Interventions
The test being considered is noninvasive LVEDP estimation.

LVEDP is elevated with acute decompensated heart failure. While direct catheter measurement of LVEDP is possible for 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 in this population were not found. Generally, demonstration of outcomes over a 1-year period is meaningful for interventions.

Study Selection Criteria
Remains as described above.

Review of Evidence

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

Silber et al (2012) reported on finger photoplethysmography during the Valsalva maneuver performed in 33 patients before cardiac catheterization.(40) LVEDP was measured via a catheter placed in the left ventricle and used as the reference standard. For identifying LVEDP greater than 15 mm Hg, finger photoplethysmography during the Valsalva maneuver was 85% sensitive (95% CI, 54% to 97%) and 80% specific (95% CI, 56% to 93%).

Section Summary: Clinically Valid
Only 1 study was identified assessing the use of LVEDP monitoring in this patient population; it reported an 85% sensitivity and an 80% specificity to detect LVEDP greater than 15 mm Hg.

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

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

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

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

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

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

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 2 meta-analyses, 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 approval. The pivotal CHAMPION RCT reported a statistically significant 28% decrease in heart failure–related hospitalizations 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 Food and Drug Administration. 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 heart-failure related hospitalizations 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 prespecify sensitivity analyses to assess the impact of COVID-19 on the trial. For the 72% of patients who completed follow-up prior to the public health emergency declaration in March 2020, a statistically significant 19% reduction in the primary endpoint was reported, driven by a 28% reduction in HFH. However, lifestyle changes during the COVID-19 pandemic such as changes in physical activity, exposure to infections, willingness to seek medical care, and adherence to

medications are unmeasured and add imprecision to treatment effect estimates, as do alterations in provider behaviors. Enrollment of NYHA Class II patients was significantly enriched in the first 500 patients, potentially impacting the pre-COVID-19 analysis. The MONITOR-HF trial, an open-label RCT conducted in the Netherlands, showed that hemodynamic monitoring significantly improved quality of life on the Kansas City Cardiomyopathy Questionnaire (KCCQ) and reduced HFH but did not impact mortality at 1 year follow-up. Overall, the beneficial effect of CardioMEMS, if any, appears to be on the hospitalization outcome of the composite. Both urgent heart failure visits and death outcomes had hazard ratios favoring the control group with wide confidence intervals including the null value in pre-COVID-19, during-COVID-19, and overall analyses of the GUIDE-HF trial. The MONITOR-HF trial found improvement in quality of life on the KCCQ for the CardioMEMS group relative to the control, but no significant differences were observed in secondary quality of life and functional status outcomes in the other included trials. While the HFH reduction of 28% found in the pre-COVID-19 analysis is consistent with findings from the CHAMPION trial, it is unclear whether physician knowledge of treatment assignment biases the decision to hospitalize and administer intravenous diuretics. The 2 included meta-analyses showed a reduction in HFHs with hemodynamic monitoring in heart failure patients but had discordant findings regarding the impact on mortality. One meta-analysis found no pooled difference in mortality between hemodynamic monitoring and control groups; however, a patient-level meta-analysis revealed a significant 25% decrease in mortality associated with hemodynamic monitoring in patients with heart failure with reduced ejection fraction. Given that the intervention is invasive and intended to be used for a highly prevalent condition and, in light of the conflicting evidence of benefit on mortality and functional outcomes, the lack of periprocedural safety data, and unclear impact of COVID-19 on remote monitoring in the GUIDE-HF trial, the net benefit of the CardioMEMS 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. 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 impedance, with inert gas rebreathing, or of arterial pressure during the Valsalva maneuver, the evidence includes uncontrolled prospective studies and case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. There is a lack of RCT evidence evaluating whether the use of these technologies improves health outcomes over standard active management of heart failure patient. The case series have reported physiologic measurement–related outcomes and/or associations between monitoring information and heart failure exacerbations, but do not provide definitive evidence on device efficacy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

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

Supplemental Information

PRACTICE GUIDELINES AND POSITION STATEMENTS

American College of Cardiology et al

The 2013 American College of Cardiology and the American Heart Association Task Force issued joint guidelines on the management of heart failure. They indicated that “there has been no established role for routine or periodic invasive hemodynamic measurements in the management of heart failure (HF). Most drugs used for the treatment of HF are prescribed on the basis of their ability to improve symptoms or survival rather than their effect on hemodynamic variables. The initial and target doses of these drugs are generally selected on the basis of controlled trial experience rather than changes produced in cardiac output or pulmonary capillary wedge pressure.”(46)

In 2017 the American College of Cardiology, the American Heart Association, and the Heart Failure Society of America updated their joint guidelines on the management of heart failure and offered no recommendations for the use of ambulatory monitoring devices.(41)

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)

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).

National Institute for Health and Clinical Excellence

In 2021, the National Institute for Health and Care Excellence (NICE) issued a new interventional procedures guidance regarding the use of percutaneous implantation of

pulmonary artery pressure sensors for monitoring the treatment of chronic heart failure.(43) The Institute's recommendation stated that "Evidence on the safety and efficacy of percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure is adequate to support using this procedure provided that standard arrangements are in place for clinical governance, consent, and audit."

Heart Failure Society of America

In 2018, the Heart Failure Society of America Scientific Statements Committee published a white paper consensus statement on remote monitoring of patients with heart failure.(44)

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

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 16.

Table 16. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Estimated Completion
Ongoing			
NCT04223271[a]	Heart Failure Event Advance Detection Trial (HEAD start)	165	Apr 2021 (unknown)
NCT02954341[a]	CardioMEMS HF SystemOUS Post Market Study	300	Dec 2023 (ongoing)
NCT03387813[a]	Hemodynamic-GUIDEd Management of Heart Failure	2358	Aug 2023 (ongoing)
NCT04398654	Pulmonary Artery Sensor System Pressure Monitoring to Improve Heart Failure (HF) Outcomes (PASSPORT-HF)	554	Dec 2026 (recruiting)
NCT04441203	Patient SELF-management With HemodynamIc Monitoring: Virtual Heart Failure Clinic and Outcomes (SELF-HF)	150	Jun 2024 (recruiting)
NCT04012944[a]	A Prospective, Multi-Center, Open-Label, Single-Arm Clinical Trial Evaluating the Safety and Efficacy of the Cordella™ Pulmonary Artery Sensor System in New York Heart Association (NYHA) Class III Heart Failure Patients (SIRONA 2 Trial)	81	Jul 2025
NCT03020043	CardioMEMS Registry of the Frankfurt Heart Failure Center	500	Dec 2025 (recruiting)
NCT04089059[a]	PROACTIVE-HF IDE Trial Heart Failure NYHA Class III	457	April 2028
NCT05934487[a]	PROACTIVE-HF-2 Trial Heart Failure NYHA Class II and III	1650	Sept 2029

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

Government Regulations
National:

Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB) Manual 100-3. Ch 1; Part 1; sec 20.16. Effective date: 11/24/06; Implementation date: 1/16/07.

Under a previous coverage determination, effective for services performed on and after July 1, 1999, use of TEB was covered for the "noninvasive diagnosis or monitoring of hemodynamics in patients with suspected or known cardiovascular disease." In reconsidering this policy, the Centers for Medicare & Medicaid Services (CMS) concluded that this use was neither sufficiently defined nor supported by available clinical literature to offer the guidance necessary for practitioners to determine when TEB would be covered for patient management. Therefore, CMS revised its coverage policy language in response to a request for reconsideration to offer more explicit guidance and clarity for coverage of TEB based on a complete and updated literature review.

Nationally Covered Indications:
TEB is covered for the following uses:

- Differentiation of cardiogenic from pulmonary causes of acute dyspnea when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.
- Optimization of atrioventricular interval for patients with A/V sequential cardiac pacemakers when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.
- Monitoring of continuous inotropic therapy for patients with terminal congestive heart failure, when those patients have chosen to die with comfort at home, or for patients waiting at home for a heart transplant.
- Evaluation for rejection in patients with a heart transplant as a predetermined alternative to myocardial biopsy. Medical necessity must be documented should a biopsy be performed after TEB.
- Optimization of fluid management in patients with congestive heart failure when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.

Nationally Non-Covered Indications:
TEB is non-covered when used for patients:

- With proven or suspected disease involving severe regurgitation of the aorta;
- With minute ventilation (MV) sensor function pacemakers, since the device may adversely affect the functioning of that type of pacemaker;
- During cardiac bypass surgery; or,
- In the management of all forms of hypertension (with the exception of drug resistant hypertension as outlined below).
    - Medicare Administrative Contractors have discretion to determine whether the use of TEB 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. Effective November 24, 2006, after reconsideration of Medicare policy, CMS will continue current Medicare policy for TEB.
- All other uses of TEB not otherwise specified remain non-covered.

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

Medicare Coverage of Clinical Trials
CMS may consider for Medicare coverage certain devices with an FDA-approved investigational device exemption (IDE) that have been categorized as Category B (Nonexperimental/investigational) device.

Category B (Nonexperimental/investigational) device refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety of that device type have been resolved), or it is known that the device type can be safe and/or effective (e.g., FDA premarket approval or clearance for that device type has been granted). Clinical trials are most often conducted to support a PMA.

Abbotts "Hemodynamic guided management of HF" clinical trial (NCT03387813; Actual completion date: May 17, 2023) is listed as a category B on Medicare's website for approved studies. The covered trial is investigating the effectiveness of the CardioMems HF system in an expanded population which includes patients with New York Heart Association Class II, III, or IV HF who have an elevated N-terminal pro-Brain Natriuretic Peptide or an elevated Brain Natriuretic Peptide and/or a prior HF hospitalization. The current FDA PMA population includes NYHA Class III HF patients who have been hospitalized for HF in the last year. Last updated August 9, 2023. No results have been posted.

Endotronix, Inc's clinical trials for the use of the Cordella™ Pulmonary Artery Sensor System in New York Heart Association (NYHA) class II (NCT05934487) and III (NCT04089059) heart failure patients is listed as a category B on Medicare's website for approved studies. The covered trials are investigating the effectiveness of the Cordella PA Sensor to demonstrate safety and efficacy in NYHA Class II and III HF individuals.

- NCT04089059: CMS approval date of October 30, 2019; Estimated completion date of April 2028.
- NCT05934487: CMS approval date of December 12, 2023; Estimated study completion date Sept 2029)

NCA: Proposed Decision Memo. CAG-00466N; Tracking sheet posted: April 30, 2024.
Implanted Pulmonary Artery Pressure Sensor for Heart Failure Management.
The Centers for Medicare & Medicaid Services (CMS) proposes to cover implantable pulmonary artery pressure sensor(s) (IPAPS) for heart failure (HF) management.

- First Comment Period: April 30, 2024 – May 30, 2024
- Second Comment Period: October 30, 2024 – November 29, 2024
- January 28, 2024 - CMS estimates posting final Decision Memorandum.

See proposal for potential criteria and additional information.

Local:

There is no local coverage determination on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Remote Patient Monitoring

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 11/12/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/14	4/8/14	4/15/14	Joint policy established Policy adopted from BCBSA. This policy will replace the JUMP policies “Left Ventricular Fill Pressure (Indirect Measurement by Arterial Waveform Response to Valsalva Maneuver)” and “Electrical Bioimpedance and Inert Gas Rebreathing as Measures of Cardiac Hemodynamics.”
7/1/15	4/24/15	5/8/15	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
11/1/16	8/16/16	8/16/16	Routine maintenance
11/1/17	8/15/17	8/15/17	• Routine maintenance • Added codes C2624 and C9741
11/1/18	8/21/18	8/21/18	Routine maintenance
11/1/19	8/20/19		• Routine maintenance • 33289 and 93264 added via code update (EI) • C9741 deleted effective 1/1/19
11/1/20	8/18/20		Routine maintenance
11/1/21	8/17/21		• Routine maintenance • Medicare info added r/t approved studies
7/1/22	4/19/22		• Off cycle review regarding push to cover; reviewed National and Local Medicare Determination, National commercial plans, FDA history and new literature • Clarification added to Regulatory and Governmental sections r/t FDA PMA for CardioMems, and Medicare covered clinical trial
5/1/23	2/21/23		• Routine maintenance (slp) • AHA indicates there is weak evidence using a moderate quality

			of evidence for the efficacy of CardioMEMS • FDA expands approval of CardioMEMS to NYHA Class II-III pts who have been hospitalized at least 1 time in prior year and/or had elevated BNPs • Vendor managed: N/A
3/1/24	12/19/23		• Routine maintenance (slp) • Vendor managed: N/A
3/1/25	12/17/24		• Routine maintenance (slp) • Vendor managed: N/A • Updated FDA PMA for Cordella

Next Review Date: 4th Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: CARDIAC HEMODYNAMIC MONITORING FOR THE MANAGEMENT OF HEART FAILURE IN THE OUTPATIENT SETTING

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.