

# Regence

Medical Policy Manual

Medicine, Policy No. 33

## ***Cardiac Hemodynamic and Thoracic Fluid Index Monitoring for the Management of Heart Failure in the Outpatient Setting***

**Effective:** July 1, 2025

**Next Review:** April 2026

**Last Review:** May 2025

### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

Various cardiac hemodynamic monitoring techniques have been investigated as ambulatory approaches to measure cardiac hemodynamics in patients with chronic heart failure who are at risk for acute decompensated heart failure.

### **MEDICAL POLICY CRITERIA**

In the ambulatory care and outpatient setting, cardiac hemodynamic and thoracic fluid index monitoring for the management of heart failure is considered **investigational** utilizing any method, including but not limited to the following:

- A. Thoracic bioimpedance, including the thoracic fluid index
- B. Inert gas rebreathing
- C. Arterial pressure/Valsalva
- D. Implantable direct pressure monitoring of the pulmonary artery
- E. Left atrial pressure monitoring
- F. Implanted Inferior Vena Cava Sensor

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

## CROSS REFERENCES

1. [Intracardiac Ischemia Monitoring](#), Surgery, Policy No. 208

## BACKGROUND

Reasons for the transition from a stable, chronic state to an acute, decompensated state include disease progression, as well as acute coronary events and dysrhythmias. While precipitating factors are frequently not identified, the most common preventable cause is noncompliance with medication and dietary regimens.<sup>[1]</sup>

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 office or in home, or via transmission telephonically or electronically of symptoms and conventional vital signs, including weight.<sup>[2]</sup>

A number of novel approaches have been investigated as techniques to measure cardiac hemodynamics in the outpatient setting with a goal of early identification of patients at imminent risk of heart decompensation. It is postulated that real-time values of cardiac output or left ventricular end diastolic pressure (LVEDP) will supplement the characteristic signs and symptoms and improve the clinician's ability to intervene early to prevent acute decompensation. Four methods of measurement of cardiac hemodynamics in the outpatient setting are reviewed in this policy:

- Noninvasive thoracic bioimpedance
- Inert gas rebreathing
- Noninvasive arterial waveform during Valsalva
- Implantable pressure monitoring devices.

### THORACIC BIOIMPEDANCE

Bioimpedance is defined as the electrical resistance of tissue to the flow of current. 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 at each beat of the heart, are inversely related to pulsatile changes in volume and velocity of blood in the aorta. Cardiac output is the product of stroke volume by heart rate, and thus can be calculated from bioimpedance. Cardiac output is generally reduced in patients with systolic heart failure. Acute decompensation is characterized by worsening of cardiac output from the patient's baseline status. The technique is alternatively known as impedance plethysmography and impedance cardiography (ICG). This measure can be used to calculate the thoracic fluid index.

### INERT GAS REBREATHING

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

typically nitrous oxide and sulfur hexafluoride. The nitrous oxide is soluble in blood and is therefore absorbed during the blood's passage through the lungs at a rate that is proportional to the blood flow. The sulfur hexafluoride is insoluble in blood and therefore stays in the gas phase and is used to determine the lung volume from which the soluble gas is removed. These gases and carbon dioxide are measured continuously and simultaneously at the mouthpiece.

## **LEFT VENTRICULAR END DIASTOLIC PRESSURE ESTIMATION METHODS**

### **Arterial Pressure During Valsalva to Estimate LVEDP**

Left-ventricular end-diastolic pressure (LVEDP) is elevated in the setting of 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.

### **PULMONARY ARTERY PRESSURE MEASUREMENT TO ESTIMATE LVEDP**

LVEDP can also be approximated by direct pressure measurement of an implantable sensor in the pulmonary artery wall. The sensor is implanted via right heart catheterization and transmits pressure readings wirelessly to external monitors.

### **LEFT ATRIAL PRESSURE (LAP) MONITORING**

LAP monitoring systems are currently being studied for permanent implantation as a method for physician-directed patient self-management in patients with advanced heart failure. A sensor module is implanted in the atrial septum via right heart catheterization under echocardiographic guidance.

### **IMPLANTED INFERIOR VENA CAVA SENSOR MONITORING**

The FIRE1 or NORM system is an implantable hemodynamic monitoring technology designed to continuously track the variation of the inferior vena cava cross sectional area as an indicator of fluid accumulation across the respiratory cycle. The patient wears a specialized monitoring belt that activates the implanted sensor, which then transmits the collected hemodynamic data wirelessly to their healthcare provider for review and analysis. This system is currently being studied as an option for remote monitoring of patients with heart failure.

## **REGULATORY STATUS**

Several impedance plethysmographs and inert gas rebreathing devices have received U.S. Food and Drug Administration (FDA) 510(k) approval (i.e., Innocor®).<sup>[3]</sup>

Several noninvasive LVEDP measurement devices received FDA 510(k) approval, however not all devices have been clinically validated.

Several wireless abdominal aortic aneurysm (AAA) pressure measurement devices received FDA 510(k) approval for use in monitoring endovascular pressure during AAA repair. However, no device has been cleared for marketing for the indication of determining LVEDP or managing heart failure.

The FDA approved the CardioMEMS™ (Champion Heart Failure Monitoring System) through the premarket approval (PMA) process.<sup>[4]</sup> The device consists of an implantable pulmonary artery sensor, implanted in the distal pulmonary artery, a transvenous delivery system, and an electronic sensor that processes signals from the sensor and transmits pulmonary artery pressure measurements to a secure off-site database. Several additional devices that monitor cardiac output through measurements of pressure changes in the pulmonary artery or right ventricular outflow tract have been investigated in the research setting, but have not received FDA approval (e.g., Chronicle®, ImPressure®)

There are no left atrial pressure monitoring systems (e.g., the HeartPOD™ System or Promote® LAP System) with FDA approval for use outside the clinical trial setting.

The µCor Heart Failure and Arrhythmia Management System by ZOLL Manufacturing has received 510(k) approval to periodically record, store, and transmit Thoracic Fluid Index and to continuously record and store, and periodically transmit ECG, heart rate, respiration rate, activity and posture data.<sup>[5]</sup> The µCor Heart Failure and Arrhythmia Management System is indicated in patients 21 years and older who 1. require monitoring for the detection of non-lethal cardiac arrhythmias or 2. require fluid management.

There are no IVC monitoring systems (e.g., the FIRE1 or NORM system) with FDA approval for use outside of the clinical trial setting.

**Note:** This policy only addresses use of these techniques in ambulatory care and outpatient settings. It does not address the following:

- Measurement of cardiac hemodynamics in the intensive care setting to carefully manage fluid status in acutely decompensated heart failure
- Echocardiography, transesophageal echocardiography (TEE), and Doppler ultrasound, which are noninvasive methods for monitoring cardiac output on an intermittent basis for the more stable patient.

## EVIDENCE SUMMARY

Evaluation of a diagnostic technology typically focuses on the following three characteristics: (1) technical performance; (2) diagnostic parameters (sensitivity, specificity, and positive and negative predictive value) in different populations of patients; and (3) demonstration that the diagnostic information can be used to improve patient outcomes. Additionally, when considering invasive monitoring, any improvements in patient outcomes must be outweighed by surgical and device-related risks associated with implantable devices.

Randomized controlled trials (RCTs) comparing patients with chronic heart failure (CHF) who are managed with versus without measurement of cardiac hemodynamics (i.e., ICG, inert gas rebreathing, arterial waveform during Valsalva, implantable pressure monitoring device) are necessary to establish the clinical utility of these techniques in an outpatient setting.

## SYSTEMATIC REVIEW

Halawa (2019) published the results of a systematic review (SR) with meta-analysis of the effect of continuous hemodynamic monitoring using implantable devices on heart failure clinical outcomes.<sup>[6]</sup> The SR included 5,454 patients from 14 studies comparing device-monitored patients with a control group. The device group included a total of 2,895 patients (640 in pressure sensor subgroup and 2,255 in the impedance monitoring group) and the

control group included a total of 2,559 patients (650 in pressure sensor subgroup and 1,909 in the impedance monitoring subgroup). Of these 14 studies, 11 were RCTs and three were observational studies (one case-control, one case-series and one prospective study). Pooled outcomes were assessed in a random-effects meta-analysis. Follow-up times varied from six to 15 months across studies. No evidence of high of risk bias was found in regards to population selection, randomization, concealment allocation, groups comparability, adequate follow up or attrition biases, although most of the randomized trials were single or non-blinded and two studies had lost follow-up in greater than 20% of the study population. No difference in heart failure related admissions rate [odds ratio (OR) 1.25, 95% CI: 0.92-1.69, P=0.15], all-cause mortality (OR 1.21, 95% CI: 0.91-1.61, P=0.20), or combined admission rate and all-cause mortality (OR 1.21, 95% CI: 0.89-1.64, P=0.22) were found between the device-monitored and the control group. Subgroup analysis of data from four studies found monitoring with a pressure sensor to be associated with lower heart failure admissions rate (OR 1.63, 95% CI: 1.10–2.41, P=0.02) and lower combined heart failure admissions rate and all-cause mortality (OR 1.58, 95% CI: 1.07–2.34, P=0.02). However, there was no difference in all-cause mortality in this subgroup analysis (OR 1.04, 95% CI: 0.62–1.74, P=0.89). Subgroup analysis of impedance monitoring devices found no differences in heart failure admissions rate (OR 1.09, 95% CI: 0.74–1.60, P=0.67), all-cause mortality (OR 1.29, 95% CI: 0.89–1.86, P=0.18) or combined heart failure admissions rate and all-cause mortality (OR 1.05, 95% CI: 0.71–1.55, P=0.82). In summary, in this SR of over 5,000 patients across 14 studies, implantable cardiac monitoring devices were not associated with significant effects on readmission or mortality rates in heart failure patients.

## **THORACIC BIOIMPEDANCE/IMPEDANCE CARDIOGRAPHY (ICG)**

### **Technology Assessments**

In 2002, the Agency for Healthcare Research and Quality (AHRQ) published a technology assessment on thoracic bioimpedance, which concluded that limitations in available studies did not allow the agency to draw meaningful conclusions about the accuracy of thoracic bioimpedance compared to other hemodynamic parameters.<sup>[7]</sup> The agency also found a lack of studies focusing on clinical outcomes and little evidence to draw conclusions on patient outcomes for the following clinical areas:

- Monitoring in patients with suspected or known cardiovascular disease;
- Acute dyspnea;
- Pacemakers;
- Inotropic therapy;
- Post-heart transplant evaluation;
- Cardiac patients with need for fluid management; and
- Hypertension.

### **Randomized Controlled Trials**

There are no RCTs comparing patients who are managed with versus without ICG as a technique to measure cardiac hemodynamics and improve CHF-related health outcomes in the outpatient setting.

### **Nonrandomized Studies**

The majority of non-randomized studies of ICG consist of small case series that have examined and reported variable results regarding the relationship between measurements of cardiac output determined by thoracic bioelectric impedance and thermodilution techniques:

Anand (2012) reported results of the Multi-Sensor Monitoring in Congestive Heart Failure (MUSIC) Study, a nonrandomized prospective study designed to develop and validate an algorithm for the prediction of acute heart failure decompensation using a clinical prototype of the MUSE system.<sup>[8, 9]</sup> This system included intrathoracic impedance measurements, along with electrocardiographic and accelerometry data. The study enrolled 543 patients with heart failure with ejection fraction less than 40% and a recent heart failure admission, all of whom underwent monitoring for 90 days with MUSE. The investigators reported a high rate of study dropout: 229 patients (42% of the total; 92 in development, 137 in validation) were excluded from the analysis, primarily due to withdrawal of consent or failure of the prototype device to function. Subjects were assessed for the development of an acute heart failure decomposition event (ADHF). When the algorithm was applied to the validation cohort, it had a sensitivity of 63%, specificity of 92%, and a false positive rate of 0.9 events per patient-year. The algorithm had a mean advance detection time of 11.5 days, but there was wide variation in this measure, from two to greater than 30 days, and it did not differ significantly from less specific algorithms (e.g., based on fluid index alone). The high rate of study dropout makes it difficult to generalize these results. Further research is needed to determine whether prediction of heart failure decomposition is associated with differences in patient outcomes.

In a sub-analysis of 170 subjects from the ESCAPE study, a multicenter randomized trial assessed pulmonary artery catheter-guided therapy in patients with advanced heart failure.<sup>[10]</sup> Kamath (2009) compared cardiac output estimated by the BioZ device to subsequent heart failure death or hospitalization and to directly-measured hemodynamics from right heart catheterization in a subset of patients (n=82). There was modest correlation between ICG and invasively measured cardiac output ( $r$  0.4 to 0.6), but no significant association between ICG measurements and subsequent heart failure death or hospitalization.

Packer (2006) reported on use of ICG to predict risk of decompensation in patients with CHF.<sup>[11]</sup> In this study, 212 stable patients with heart failure and a recent episode of decompensation underwent serial evaluation and blinded ICG testing every two weeks for 26 weeks and were followed up for the occurrence of death or worsening heart failure requiring hospitalization or emergent care. During the study, 59 patients experienced 104 episodes of decompensated heart failure: 16 deaths, 78 hospitalizations, and 10 emergency visits. A composite score of three ICG parameters was a strong predictor of an event during the next 14 days ( $p=0.0002$ ). Patients noted to have a high-risk composite score at a visit had a 2.5 times greater likelihood of a near-term event, and those with a low-risk score had a 70% lower likelihood when compared to ones at intermediate risk. However, the impact of use of these results on clinical outcomes is not known

Belardinelli (1996) compared the use of thoracic bioimpedance, thermodilution, and the Fick method to estimate cardiac output in 25 patients with documented coronary artery disease and a previous myocardial infarction.<sup>[12]</sup> There was a high degree of correlation between cardiac output as measured by thoracic bioimpedance and other invasive measures.

Shoemaker (1994) reported on a multicenter trial of thoracic bioimpedance compared to thermodilution in 68 critically ill patients.<sup>[13]</sup> Again, the changes in cardiac output as measured by thoracic bioimpedance closely tracked those measured by thermodilution.

A number of studies have evaluated the impact of thoracic bioimpedance devices that are integrated into implantable cardioverter defibrillator (ICD), cardiac resynchronization therapy (CRT), or cardiac pacing devices. These include the Fluid Accumulation Status Trial (FAST), a prospective trial to evaluate the use of intrathoracic impedance monitoring with ICD or CRT devices in patients with heart failure,<sup>[14]</sup> and the Sensitivity of the InSync Sentry for Prediction of Heart Failure (SENSE-HF) study, which evaluated the sensitivity of the OptiVol fluid trends feature in predicting heart failure hospitalizations.<sup>[15]</sup>

## **INERT GAS REBREATHING (IGR)**

Although a literature search suggests that IGR has been used as a research tool for many years,<sup>[16-20]</sup> few studies have been published on this technique as a method of monitoring CHF patients in the outpatient setting. A literature search did not identify clinical utility studies exploring how inert gas rebreathing may be used to guide patient management and improve health outcomes in the outpatient setting.

## **NONINVASIVE LVEDP ESTIMATION METHODS**

There are no clinical utility studies that examined how use of arterial pressure during Valsalva to estimate LVEDP impacts patient management and health outcomes in outpatient setting.

Non-randomized studies have suggested high correlation between invasive and non-invasive measurement of LVEDP; however, these studies do not address clinical utility.

Silber (2012) recorded a finger photoplethysmography (PPG) waveform during a Valsalva effort in 33 subjects prior to cardiac catheterization.<sup>[21]</sup> Pulse amplitude ratio (PAR) was calculated (PPG waveform amplitude just prior to release of expiratory effort divided by the waveform amplitude at baseline). PAR was significantly correlated with LVEDP ( $r=0.68$ ,  $p<0.0001$ ). For identifying LVEDP > 15 mmHg, PAR > 0.4 was 85% sensitive (95% confidence interval [CI] 54% to 97%) and 80% specific (95% CI 56% to 93%).

Sharma (2002) performed simultaneous measurements of the LVEDP based on three techniques: direct measurement of LVEDP, considered the gold standard; indirect measurement using pulmonary capillary wedge pressure (PCWP); and non-invasively using the VeriCor® device in 49 patients scheduled for elective cardiac catheterization.<sup>[22]</sup> The VeriCor® measurement correlated well with the direct measures of LVEDP ( $r=0.86$ ) and outperformed the PCWP measurement, which had a correlation coefficient of 0.81 compared to the gold standard.

McIntyre (1992) reported a comparison of pulmonary capillary wedge pressure (PCWP) measured by right heart catheter and an arterial pressure amplitude ration during Valsalva. The two techniques were highly correlated in both stable and unstable patients ( $R^2$  [coefficient of determination]=0.80 to 0.85).<sup>[23]</sup>

## **IMPLANTABLE DIRECT PULMONARY ARTERY PRESSURE MEASUREMENT METHODS**

### **Systematic Reviews**

Lindenfeld (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  $\leq 40\%$ .<sup>[24]</sup> 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.

Iaconelli (2023) published a systematic review and meta-analysis of RCTs evaluating the use of implantable hemodynamic monitoring devices to guide the management of heart failure.<sup>[25]</sup> 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 to 1.26;  $p = .48$ ). Changes in treatment guided by hemodynamic monitoring resulted in small reductions in mean pulmonary artery pressure less than 1 mmHg as a daily average.

Adamson (2017) published a meta-analysis evaluating remote monitoring of hemodynamic pressures for patients with CHF.<sup>[26]</sup> The meta-analysis included five studies: three were the prospective RCTs CHAMPION (n=550), COMPASS-HF (n=274), and REDUCEhf (n=400) described below, and the other two were smaller observational studies (n=32 and 40). The three RCTs all evaluated different types of monitors, and average follow-up ranged from six months (COMPASS-HF) to 18 months (CHAMPION). Although the REDUCEhf study did not show a reduction in hospitalizations with monitoring (HR 0.99), the meta-analysis demonstrated a reduction in hospitalizations (random effects model hazard ratio [HR] 0.62, 95% CI 0.50 to 0.78) similar to that seen in the CHAMPION (HR 0.63, 95% CI 0.52 to 0.77) and COMPASS-HF (HR 0.54, 95% CI 0.42 to 0.97) trials. No evaluations of study quality were performed.

## **Randomized Controlled Trials**

### CardioMEMS™ Device

The CHAMPION (CardioMEMS™ Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Patients) Trial Study was a prospective, single-blind, randomized, controlled trial designed to evaluate the safety and efficacy of an implanted, passive, wireless, pulmonary artery pressure monitor developed by CardioMEMS™ for the ambulatory management of heart failure patients.<sup>[27]</sup> However, in December 2011 the FDA advisory committee recommended against approval of the CardioMEMS™ pulmonary artery pressure monitoring device because of the inability to determine whether the potential benefits outweigh the potential risks.

The CardioMEMS™ device is implanted using a heart catheter system fed through the femoral vein and requires patients have an overnight hospital admission for observation after implantation. The CHAMPION study enrolled 550 patients who had at least one previous hospitalization for heart failure in the past 12 months and were classified as having New York Heart Association (NYHA) Class III heart failure for at least three months. Left ventricular ejection fraction was not a criterion for participation but patients were required to be on



medication and stabilized for one month before participating in the study if left ventricular ejection fraction was reduced. All enrolled patients received implantation of the CardioMEMS™ pulmonary artery radiofrequency pressure sensor monitor and standard of care heart failure disease management. Heart failure disease management followed American College of Cardiology and American Heart Association guidelines along with local disease management programs. Patients were randomized by computer in a 1:1 ratio to the treatment group (n=270) in which treating providers used data from the pulmonary artery pressure sensor in patient management or the control group (n=280) in which providers did not incorporate pulmonary artery pressure sensor data into patient management. All patients took daily pulmonary artery pressure readings but were masked to their treatment groups for the first six months.

In the Summary of Safety and Effectiveness Data for the CardioMEMS™ 2014 application, the FDA noted that “trial conduct included subject-specific treatment recommendations sent by nurses employed by the CardioMEMS™ to the treating physicians. These subject-specific recommendations were limited to subjects in the treatment arm of the study. The possible impact of nurse communications was determined to severely limit the interpretability of the data in terms of effectiveness.”<sup>[4]</sup> In response, the manufacturer continued to follow all patients implanted with the device during an open access period, in which all patients were managed with pulmonary artery pressure monitoring, and no nurse communication occurred. Follow up data were available for 347 patients. For these patients, the following comparisons in heart failure-related hospitalization rates were reported to attempt to ensure that outcomes with the CardioMEMS™ device during the open access period (“Part 2”) were similar to those in the randomized period (“Part 1”):

- Former Control vs. Control: To determine whether the heart failure hospitalization rate was lower in the Former Control group than the Control group, when physicians of Former Control patients received access to PA pressures (neither had nurse communications).
- Former Treatment to Treatment: To evaluate whether heart failure hospitalization rates remain the same in subjects whose physician’s access to pulmonary artery pressures remained unchanged, but no longer received nurse communications.
- Former Control to Former Treatment: To demonstrate that the rates of heart failure hospitalizations were similar during Part 2 when both groups were managed in an identical fashion (access to pulmonary artery pressure and no nurse communications).
- Change in heart failure hospitalization rates in the control group (Part 2 vs. Part 1) compared to the change in heart failure hospitalization rates in the treatment group (Part 2 vs. Part 1): To demonstrate that the magnitude of change in HFR hospitalization rates after the transition from Control to Former Control (Part 1 vs. Part 2, initiation of physician access to pulmonary artery pressures in Part 2) was greater than the magnitude of change in HFR hospitalization rates after the transition from Treatment to Former Treatment (Part 1 vs. Part 2, no change in physician access to pulmonary artery pressure).

The FDA concluded that these longitudinal analyses indicated that heart failure hospitalization rates in Former Control patients in Part 2 of the study decreased to levels comparable to the heart failure hospitalization rates in Treatment group patients whose pulmonary artery pressures were available throughout the study.

Limitations of the CHAMPION trial include the following:

- Lack of double-blinding: while the patients were blinded and efforts to maintain patient masking were undertaken, the clinicians were not blinded to treatment assignment. The unblinded clinicians were presumably also making decisions on whether to hospitalize patients, and these decisions may have been influenced by knowledge of treatment assignment.
- The design of this trial does not allow comparison of the incremental risk of implanting a device compared to no implantation, since all patients had a device implanted.

Use of hospital admission rate as a surrogate outcome; the correlation between the hospital admission rate and patient-relevant health outcomes, such as cardiac events or survival, has not been determined. Hence, the true estimate of effect on relevant health outcomes is unclear.

The primary efficacy outcome of the CHAMPION trial was the rate of heart failure-related hospitalizations in the six months after implantation. The primary safety outcomes were device-related or system-related complications (DSRC) and pressure-sensor failures.<sup>[28]</sup> The investigators reported a statistically significant reduction in readmissions for heart failure at six months by 30% in the treatment group (n=83) over the control group (n=120) (HR 0.70, 95% CI 0.60 to 0.84, p<0.0001). This benefit was maintained over the entire randomized follow-up (mean 15 months) (153 vs. 253 hospitalizations, respectively) (HR 0.64, 95% CI 0.55 to 0.75, p<0.0001). Results have not been formally published. For the primary safety outcomes, freedom from device-related complications was 98.6% with no occurrences of pressure-sensor failure. However, 15 adverse events occurred, including eight which were device-related and seven which were procedure-related. Additionally, length of stay for these hospitalizations was significantly shorter in the treatment group when compared to the control group (2.2 days vs. 3.8 days, respectively, p=0.02). There were also improvements in the secondary outcomes of mean pulmonary pressure and QOL at six months. There was no difference in overall mortality, although the trial was not designed with sufficient power to evaluate mortality benefit. There were 15 deaths in the treatment group and 26 deaths in the control group at 6 months (HR 0.77, 95% CI 0.40 to 1.51, p=0.45). During the randomized portion of the trial, the device was generally considered safe: freedom from device or system-related complications was 98.6%, with a 95.2% lower confidence bound of 97.3%.

Consecutive analyses from the CHAMPION study, described below, have reported the efficacy of the CardioMEMS™ in the remote monitoring of patients with heart failure and in providing adequate information to optimally manage such patients, resulting in significant hospitalization rate reduction. Overall, the reports from the CHAMPION study encourage the use of CardioMEMS™, however, larger populations are needed to definitively prove its value. These consecutive reports are described below.

In another follow-up report from the CHAMPION trial, investigators analyzed data to understand what interventions produced the significant reduction in heart failure hospitalizations in the active monitoring group.<sup>[29]</sup> At six-month follow-up, the active monitoring group experienced a higher frequency of medications adjustments; and significant increases in the doses of diuretics, vasodilators, and beta blockers and aldosterone antagonists, compared to those in the control group receiving management based on clinical symptoms alone.

An 18-month follow-up report of the CHAMPION trial was published in 2016.<sup>[30]</sup> This publication included data on 13 months of open-label follow-up for 347/550 (63%) of the original randomized patients. For patients who were originally randomized to the control group,

information from the monitoring device was available during this phase. The rate of hospitalizations was significantly decreased in this group (hazard ratio 0.52, 95% CI 0.40 to 0.69,  $p<0.001$ ) compared to the control group in the follow-up open access period, when monitoring information was no longer blinded. Quality of life assessed at 12-month follow-up was also significantly lower in the treatment group compared to controls ( $p=0.267$ ). Adverse events reported included Eight (1%) device-related or system related complications and seven (1%) procedure-related complications.

Varma (2021) published the results of an analysis of the cardiac resynchronization therapy subjects included in the CHAMPION trial, which compared remotely managed pulmonary artery (PA) pressure-guided management (treatment) or usual heart failure (HF) care (control) in these patients.<sup>[31]</sup> During the 18 months of follow-up, HF hospitalizations were 30% lower in treatment ( $n=91$ , 62 events, 0.46 events/patient-year) compared to control patients ( $n=99$ , 93 events, 0.68 events/patient-year, hazard ratio, 0.70; 95% CI, 0.51–0.96;  $p=0.028$ ). Treatment patients had more medication up-/down-titrations (847 versus 346 in control,  $p<0.001$ ), mean PA pressure reduction (area under the curve  $-413.2\pm123.5$  versus  $60.1\pm88.0$  in control,  $p<0.01$ ), and quality of life improvement (Minnesota Living with Heart Failure Questionnaire decreased  $-13.5\pm23$  versus  $-4.9\pm24.8$  in control,  $p<0.01$ ). In addition to the limitations of the clinical trial discussed above, the ability to generalize the results of this exploratory analysis is limited by the retrospective study design. This study was supported by CardioMEMS Inc., and several of the study authors report financial ties to the company.

Another subgroup analysis, by Givertz (2017), evaluated the 456 patients from the CHAMPION trial that had heart failure with reduced ejection fraction (HFrEF).<sup>[32]</sup> This showed similar results to those of the main study, in terms of reduced hospitalizations in the treatment group compared with controls, and provides evidence that the effects of the technology are not due only to the enforcement of guideline-directed medical therapy. However, the study was unable to demonstrate a significant mortality benefit, and as with the main study there were several limitations, including loss to follow-up and lack of double-blinding.

Krahnke (2015) published a subgroup analysis of the CHAMPION trial evaluating outcomes for heart failure patients with chronic obstructive pulmonary disease (COPD).<sup>[33]</sup> Of the total study population, 187 were classified as having COPD; these patients were more likely to have coronary artery disease and a history of myocardial infarction, diabetes, and atrial fibrillation. COPD-classified patients in the intervention group had lower rates of heart failure hospitalization than those in the control group (0.55 vs. 0.96; HR 0.59, 95% CI 0.44 to 0.81,  $p<0.001$ ). Rates of respiratory hospitalizations were lower in COPD-classified patients in the intervention group (0.12 vs. 0.31; HR 0.38, 95% CI 0.21 to 0.71,  $p=0.002$ ). Rates of respiratory hospitalizations did not differ significantly between intervention and control group patients for non-COPD patients.

Adamson (2014) reported longer-term outcomes in the same population as the CHAMPION study ( $n=550$ ).<sup>[34]</sup> Of these enrollees, 119 had left ventricular ejection fraction (EF) of  $\geq 40\%$ , and 430 patients had low left ventricular EF ( $<40\%$ ). After implantation of the pressure sensor by right heart catheterization, patients were randomized in a single-blind manner to a treatment group in which daily pressure readings were used to treat heart failure or to a control group with standard heart failure management including weight monitoring, but no pressure readings. For preserved EF patients, the rate of hospitalization due to heart failure was 46% lower in the treatment group compared with controls ( $p<0.0001$ ). After an average follow-up period of 17.6 months, the hospitalization rate was 50% lower than controls ( $p<0.0001$ ). In addition, a greater

number of changes of diuretic and vasodilator medications were made in the treatment group based on pulmonary artery pressure readings compared with controls.

## Nonrandomized Studies

The outcomes of two prospective, single-arm, non-randomized multicenter studies on pulmonary artery pressure-guided therapy (CardioMEMS™) in patients with heart failure were published in 2020. One study published by Angermann (the CardioMEMS European Monitoring Study for Heart Failure [MEMS-HF] study) evaluated patient outcomes over 12 months in Germany (26 centers), The Netherlands (4 centers) and Ireland (1 center).<sup>[35]</sup> Co-primary safety endpoints were device- or system-related complications (DSRC) defined as serious adverse events definitely or possibly related to the pulmonary artery pressure (PAP) sensor or external electronics that was treated invasively or resulted in patient death or explant of the device. Mean daily adherence to pulmonary artery pressure transmission was  $78.1 \pm 23.5\%$  (median, 87.6% [interquartile range, 69.4% to 94.9%]). At 12-month follow-up, 235/239 patients [98.3%, 95% confidence interval (CI) 95.8–100.0%] were free from DSRC and 233/234 (99.6%, 95% CI 97.6–100.0%) were free from pressure sensor failure. The survival rate was 86.2%. At 12 months post- vs. pre-implant, heart failure hospitalization (HFH) decreased by 62% (0.60 vs. 1.55 events/patient-year; hazard ratio 0.38, 95% CI 0.31–0.48;  $p < 0.0001$ ), Kansas City Cardiomyopathy Questionnaire (KCCQ) overall/clinical summary scores increased from  $47.0 \pm 24.0/51.2 \pm 24.8$  to  $60.5 \pm 24.3/62.4 \pm 24.1$  ( $p < 0.0001$ ), and the 9-item Patient Health Questionnaire sum score improved from  $8.7 \pm 5.9$  to  $6.3 \pm 5.1$  ( $p < 0.0001$ ). Also in 2020, Shavelle published a prospective, open-label, observational, single-arm trial of 1200 patients from 104 centers within the United States (CardioMEMS™ post-approval study).<sup>[36]</sup> The primary effectiveness end point was the annualized HFH rate at one year, compared with the HFH rate in the year before enrollment. 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. There were 1600 HFH (1.25 events/patient-years before) compared with 628 HFH (0.54 events/patient-years after implant) indicating a risk reduction of 57% (hazard ratio [HR] 0.43 [95% CI, 0.39–0.47];  $p < 0.0001$ ). During the study, 94.1% of patients had a medication change, with an average of 1.6 medication changes per month. Medication changes related to an increase or decrease in pulmonary artery pressure were implemented in 81.8% and 55.8% of patients, respectively. There were five device- or system-related complications (0.4%); freedom from device- or system-related complications was 99.6% and there was one pressure sensor failure (0.1%). Although these registry studies provide valuable information regarding feasibility and safety of the technology based on historical events for within-patient comparisons, study generalizability is limited by the lack of a randomized control group and the potential influence of both information and survivor bias. Both studies were funded by the device manufacturer (Abbott) and study authors were employed by or received research support from Abbott during the study period.

Abraham (2019) published a retrospective matched cohort study of Medicare beneficiaries who received the CardioMEMS™ device between 2014 and 2016.<sup>[37]</sup> Patients were matched to 1087 controls by demographics, history and timing of heart failure-related hospitalizations, and number of all-cause hospitalization (ACH). Propensity scoring based on arrhythmia, hypertension, diabetes, pulmonary disease, and renal disease was used for additional matching. Follow-up was censored at death, ventricular assist device implant, or heart transplant. At 12 months postimplantation, 616 and 784 heart failure-related hospitalizations occurred in the treatment and control cohorts, respectively. The rate of heart failure-related hospitalizations was lower in the treatment cohort at 12 months (HR, 0.76; 95% CI, 0.65 to

0.89;  $p < 0.001$ ). Percentage of days lost to heart failure-related hospitalizations (HR, 0.73; 95% CI, 0.64 to 0.84;  $p < 0.001$ ) and all-cause hospitalization or death (HR, 0.77; 95% CI, 0.68 to 0.88;  $p < 0.001$ ) were both significantly lower in the treatment group. The treatment cohort had 241 deaths and 20 ventricular assist device implants or heart transplants; over the same period, the control cohort had 325 deaths and 13 ventricular assist device implants or heart transplants. Mean (standard deviation [SD]) length of hospital stay was 6.6 (6.5) and 6.5 (5.8) days in the control and treatment cohorts, respectively ( $p = 0.70$ ). Mean (SD) total days spent in hospital for heart failure was 3.7 (9.5) and 4.4 (10.3), respectively. The percentage of days lost owing to heart failure-related hospitalization or death was reduced in the treatment cohort (relative risk [RR], 0.73; 95% CI, 0.63 to 0.83). Limitations of this study include lack of medical history data, including ejection fraction, natriuretic peptide levels, renal function, and medication use. Residual confounding by unmeasured covariates remains possible, including the role of heightened health care team involvement in implanted patients.

### Chronicle Devices

Adamson (2011) reported on the Reducing Decompensation Events Utilizing Intracardiac Pressures in Patients With Chronic Heart Failure (REDUCEhf) study that evaluated an implantable cardioverter-defibrillator (ICD) coupled with an implantable hemodynamic monitoring (IHM) system.<sup>[38]</sup> The REDUCEhf study was a prospective, randomized, multicenter, single-blinded trial of 400 patients with NYHA class II or III symptoms who were hospitalized for heart failure within the past 12 months and qualified for an ICD. The study had expected to enroll 1,300 patients, but after ICD lead failures had been reported in other studies, enrollment was limited to 400 patients. After the ICD was placed, an IHM sensor (Chronicle, Medtronic) was implanted in the right ventricle. Similar to the COMPASS-HF and CHAMPION trials above, the treatment group of 202 patients received heart failure management that incorporated pressure monitoring information from the IHM compared to the control group of 198 patients that did not use pressure monitoring information in treatment planning. After 12 months of follow-up, rates of heart failure hospitalizations, emergency department visits, and urgent clinic visits did not differ between groups (HR 0.99, 95% CI 0.61 to 1.61,  $p = 0.98$ ). While the study was underpowered to detect differences in these events because of limited enrollment, there were no trends favorable to the monitoring group to suggest that the lack of difference was due to inadequate power.

COMPASS-HF (Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure Study) trial evaluated outcomes on 274 patients implanted with a Medtronic hemodynamic monitoring system.<sup>[39, 40]</sup> Patients enrolled in the study were stabilized NYHA class III or IV heart failure patients and had at least one heart failure-related event within the six months prior to enrollment. Left ventricular ejection fraction was not a criterion. Similar to the CHAMPION trial, all patients were implanted with the monitoring device and received standard heart failure disease treatment during the first six months post-implantation. One-half of the patients were randomized to incorporate pressure monitoring data into heart failure management, while information from the other half of patients was not used in treatment decisions. The authors of this article reported 100 of 261 patients (38%) from both treatment groups had heart failure-related events during the six months follow-up despite weight-guided management. Separate reports on heart failure events by treatment group were not provided. Heart failure event risk increased with higher readings of chronic 24-hour estimated pulmonary artery pressure and at 18 mmHg diastolic pressure, event risk was 20% and increased to 34% at 25mm Hg and to 56% at 33mm Hg. While pressure readings correlated with event risk, the authors noted optimal filling pressures and needed surveillance for event avoidance have not

been established. In March 2007, the FDA advisory panel voted against approval of the Medtronic Chronicle Hemodynamic Monitor, citing concerns about the lack of clinical effectiveness.

## **Nonrandomized Studies**

Several nonrandomized studies of the CardioMEMS™ device have been published. Heywood (2017) reported on the first 2000 consecutive patients in the remote monitoring database (St. Jude Medical) with at least six months of follow-up.<sup>[41]</sup> The authors reported that the patients in the database had higher baseline PA pressures and had greater reductions in PA pressure than the CHAMPION patients. Desai (2017) published a retrospective cohort study using data from U.S. Medicare claims between June 2014 and December 2015.<sup>[42]</sup> This study found that there was a lower number of hospitalizations in the six months following implantation than in the six months before, however there was no control group so it is unclear if the reduction was due to device implantation. Vaduganathan (2017) published a brief report of the adverse events associated with CardioMEMS™ from the Manufacturer and User Facility Device Experience (MAUDE) database.<sup>[43]</sup> The authors identified 155 reports of 177 adverse events from May 2014 to May 2017, and estimated that more than 5,500 devices were implanted in the U.S. during this period. Limitations of the dataset included underreporting, delayed or selective reporting, and lack of event adjudication.

## **LEFT ATRIAL PRESSURE MONITORING**

Left atrial pressure (LAP) monitoring is currently being studied in the LAPTOP-HF trial. Published data is limited to small feasibility studies that do not permit conclusions about the technical and diagnostic performance, clinical utility, rate of adverse events, or net health outcomes compared with left ventricular pressure monitoring or no monitoring. In addition, there are currently no LAP monitoring systems with approval from the U.S. Food and Drug Administration (FDA) for use outside the clinical trial setting.

## **THORACIC FLUID INDEX**

A literature search did not identify clinical utility studies that examine how remote monitoring of thoracic fluid index may be used to guide patient management and improve health outcomes in the outpatient setting.

## **IMPLANTED INFERIOR VENA CAVA SENSOR MONITORING**

### **Non-Randomized Studies**

Uriel (2025) published a prospective, multicenter, single-arm Early Feasibility Study evaluating a novel implantable sensor designed to measure inferior vena cava (IVC) area for monitoring congestion in heart failure patients. The study enrolled 15 heart failure patients (mean age 66±12 years, 47% female, 87% NYHA class III) who had experienced a heart failure event in the previous 12 months. All patients met the primary safety and effectiveness endpoints, with sensor-derived IVC measurements showing excellent agreement with computed tomography ( $R^2=0.99$ , mean absolute error=11.15 mm<sup>2</sup>). Patient adherence to daily readings was high (median 98%, IQR: 86%-100% per patient-month), and significant improvements in NYHA class were observed, though improvements in KCCQ were non-significant. Limitations include the small sample size, single-arm design without a control group, and the relatively short

follow-up period of 3 months, suggesting the need for larger studies to establish the sensor's long-term efficacy in remote heart failure management.

There is not enough evidence to determine how IVC sensor monitoring may be used to guide patient management and improve health outcomes in the outpatient setting.

## PRACTICE GUIDELINE SUMMARY

### HEART FAILURE SOCIETY OF AMERICA

The Heart Failure Society of America Scientific Statements Committee published a white paper on the remote monitoring of patients (RPM) with heart failure in 2018, which stated:<sup>[44]</sup>

“Based on available evidence, routine use of external RPM devices is not recommended. Implanted devices that monitor pulmonary arterial pressure and/or other parameters may be beneficial in selected patients or when used in structured programs, but the value of these devices in routine care requires further study.”

### AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION/AMERICAN HEART ASSOCIATION

The updated 2022 American College of Cardiology Foundation/American Heart Association (ACCF/AHA) Guidelines for the Diagnosis and Management of Heart Failure in Adults<sup>[45]</sup> which provides no recommendations for the use of ambulatory monitoring devices and includes invasive (e.g., pulmonary artery pressure monitoring catheter) or noninvasive remote monitoring in the list of topics with evidence gaps and future research directions.

## SUMMARY

There is not enough research to show that cardiac hemodynamic or thoracic fluid index monitoring improves health outcomes for people with heart failure in the outpatient/ambulatory care setting. No U.S. clinical guidelines based on research recommend cardiac hemodynamic or thoracic fluid index monitoring for people with heart failure. Therefore, cardiac hemodynamic and thoracic fluid index monitoring for the management of heart failure in the outpatient/ambulatory care setting are considered investigational.

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## CODES

Codes	Number	Description
CPT	33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization,

Codes	Number	Description
		radiological supervision and interpretation, and pulmonary artery angiography, when performed
	93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional
	93701	Bioimpedance-derived physiologic cardiovascular analysis
	93799	Unlisted cardiovascular service or procedure
	0607T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequencyderived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; set-up and patient education on use of equipment
	0608T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequencyderived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; analysis of data received and transmission of reports to the physician or other qualified health care professional
	0981T	Transcatheter implantation of wireless inferior vena cava sensor for long-term hemodynamic monitoring, including deployment of the sensor, radiological supervision and interpretation, right heart catheterization, and inferior vena cava venography, when performed
	0982T	Remote monitoring of implantable inferior vena cava pressure sensor, physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial set-up and patient education on use of equipment
	0983T	Remote monitoring of an implanted inferior vena cava sensor for up to 30 days, including at least weekly downloads of inferior vena cava area recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional
HCPCS	C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components

**Date of Origin:** November 1997