



Kansas City

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

**Policy Number:** 2.02.24  
**Origination:** 10/2010

**Last Review:** 10/2014  
**Next Review:** 10/2015

### **Policy**

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Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for cardiac hemodynamic monitoring for the management of heart failure in the outpatient setting. This is considered investigational.

### **When Policy Topic is covered**

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Not Applicable

### **When Policy Topic is not covered**

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

### **Description of Procedure or Service**

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A variety of outpatient cardiac hemodynamic monitoring devices have been proposed to decrease episodes of acute decompensation in patients with heart failure and thus reduce morbidity and improve quality of life. These new outpatient devices include bioimpedance, inert gas rebreathing, and estimating left-ventricular end-diastolic pressure by arterial pressure during Valsalva or use of an implantable pressure sensor.

### **Background**

Patients with chronic heart failure are at elevated risk of developing acute decompensated heart failure, often requiring hospital admission. Patients with a history of acute decompensation have 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 coronary events and dysrhythmias. While precipitating factors are frequently not identified, the most common preventable cause is non-compliance with medication and dietary regimens. (1) Strategies for reducing decompensation, and thusly 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 of symptoms and conventional vital signs, including weight, telephonically or electronically. (2)

Precise measurement of cardiac hemodynamics is often employed in the intensive care setting to carefully manage fluid status in acutely decompensated heart failure. Echocardiography, transesophageal echocardiography (TEE), and Doppler ultrasound are noninvasive methods for monitoring cardiac output on an intermittent basis for the more stable patient, but are not addressed in this policy. A variety of biomarkers and radiological techniques may be utilized in the setting of dyspnea when the diagnosis of acute decompensated heart failure is uncertain.

A number of novel approaches have been investigated as techniques to measure cardiac hemodynamics in the outpatient setting. 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 will be reviewed here: thoracic bioimpedance, inert gas rebreathing, arterial waveform during Valsalva, and 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).

### 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 rebreathe from a rebreathing bag filled with oxygen mixed with a fixed proportion of two inert gases; typically nitrous oxide and sulfur hexafluoride. The nitrous oxide is soluble in blood and is therefore absorbed during the blood's passage through the lungs at a rate that is proportional to the blood flow. The sulfur hexafluoride is insoluble in blood and therefore stays in the gas phase and is used to determine the lung volume from which the soluble gas is removed. These gases and carbon dioxide are measured continuously and simultaneously at the mouthpiece.

### LVEDP 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 left ventricular end diastolic pressure is possible for patients undergoing cardiac catheterization for diagnostic or therapeutic reasons, its invasive nature precludes its 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.

### **Regulatory Status**

The following devices have received specific U.S. Food and Drug Administration (FDA) clearance or approval:

- Non-invasive thoracic impedance plethysmography devices. Multiple thoracic impedance measurement devices that do not require invasive placement have been approved through FDA's 510(k) process, based on substantial equivalence to predicate devices that are used for peripheral

blood flow monitoring. Table 1 includes a representative list of devices, but is not meant to be comprehensive (FDA product code: DSB).

**Table 1: Noninvasive Thoracic Impedance Plethysmography Devices**

Device	Manufacturer	Year of FDA Clearance
TEBCO® (Thoracic Electrical Bioimpedance Cardiac Output)	Hemo Sapiens Inc. (Irvine, CA)	1996
BioZ® Thoracic Impedance Plethysmograph	SonoSite (Bothell, WA)	1997
IQ™ System Cardiac Output Monitor	Renaissance Technology (Newtown, PA)	1998
Sorba Steorra® Non-Invasive Impedance Cardiography	Sorba Medical Systems Inc. (Milwaukee, WI)	2002
Zoe® Fluid Status Monitor	Noninvasive Medical Technologies LLC (Las Vegas, NV)	2004
Cheetah NICOM® system	Cheetah Medical Inc. (Tel Aviv, Israel)	2008
Physioflow® Signal Morphology-based Impedance Cardiography (SM-ICG™)	Vasocom Inc., now Neumedx Inc. (Bristol, PA)	2008

The NEXTFIN HD Continuous Noninvasive Hemodynamic Monitor (BYMEYE B.V., now Edwards Lifesciences, Irvine, CA) uses an inflatable finger cuff with a built-in photoelectric plethysmograph, which calculates estimated cardiac output from continuous blood pressure monitoring; the monitor was cleared by FDA through the 510(k) process in 2007. Other noninvasive monitors that derive cardiac output estimates from measured parameters exist, but not all are designed to be used in the outpatient setting.

In addition, several manufacturers market thoracic impedance measurement devices that are integrated into implantable cardiac pacemakers, cardioverter-defibrillator devices, and cardiac resynchronization therapy devices. With the integrated devices, the electrical resistance of tissue to flow of current is measured using a vector from the right ventricular coil on the lead in the right side of the heart to the implanted cardiac devices; changes in bioimpedance reflect intrathoracic fluid status and are evaluated based on a computer algorithm. These include the CorVue® Thoracic Impedance Monitoring feature (St. Jude Medical, St. Paul, MN) which is integrated in St. Jude Medical's Unify, Fortify, and Quadra family of cardiac rhythm devices, and the OptiVol® Fluid Status Monitor (Medtronic Inc., Minneapolis, MN), which is integrated into multiple Medtronic cardiac rhythm devices. The CorVue device was approved by FDA in 2012 as a premarket approval (PMA) supplement, and the OptiVol Fluid Status Monitor's integration into other devices has been approved through multiple PMA supplements since the device's pivotal trial results in 2008.

- Inert gas rebreathing devices. In March 2006, the "Innocor®" (Innovision, Denmark) inert gas rebreathing device was cleared for marketing by FDA through the 510(k) process. Several other inert gas rebreathing devices have been approved through the same process. FDA determined that this device was substantially equivalent to existing devices for use in computing blood flow. FDA product code: BZG.
- Noninvasive LVEDP measurement devices. In June 2004, the "VeriCor®" (CVP Diagnostics, Boston, MA) 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.

- Implantable pulmonary artery pressure measurement devices. In May 2014, FDA approved the CardioMEMS™ Champion Heart Failure Monitoring System (CardioMEMS, now St. Jude Medical, St. Paul, MN) through the PMA 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)

Several additional devices that monitor cardiac output through measurements of pressure changes in the PA or right ventricular outflow tract have been investigated in the research setting but have not received FDA approval. These include the Chronicle® implantable continuous hemodynamic monitoring device (Medtronic Inc., Minneapolis, MN), which includes a sensor implanted in the right ventricular outflow tract and, and the ImPressure® device (Remon Medical Technologies, Caesara, Israel), which includes a sensor implanted in the PA.

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

## **Rationale**

This policy was created by combining 2 existing policies in 2010; the most recent literature review for this policy was conducted with a search of the MEDLINE database for the period through June 3, 2014.

Evaluation of a diagnostic technology typically focuses on the following 3 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.

## **Literature Review**

### **Noninvasive Thoracic Bioimpedance/Impedance Cardiography**

In 2002, the Agency for Healthcare Research and Quality published a technology assessment on thoracic bioimpedance, which concluded that limitations in available studies did not allow meaningful conclusions concerning the accuracy of thoracic bioimpedance compared with other hemodynamic parameters. (2) The report 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;
- Postheart transplant evaluation;
- Cardiac patients with need for fluid management; and
- Hypertension.

A number of small case series have reported variable results regarding the relationship between measurements of cardiac output determined by thoracic bioelectric impedance and thermodilution

techniques. For example, Belardinelli et al 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.(5) There was a high degree of correlation between cardiac output as measured by thoracic bioimpedance and other invasive measures. Shoemaker et al reported on a multicenter trial of thoracic bioimpedance compared with thermodilution in 68 critically ill patients.(6) Again, the changes in cardiac output, as measured by thoracic bioimpedance closely tracked those measured by thermodilution. In contrast, Sageman and Amundson did not recommend the use of bioimpedance as a postoperative monitoring technique for patients who had undergone coronary artery bypass surgery.(7) In this study of 50 patients, only a poor correlation was found between thermodilution and bioimpedance, due primarily to the postoperative distortion of the patient's anatomy and the presence of endotracheal, mediastinal, and chest tubes. In a study of 34 patients undergoing cardiac surgery, Doering et al also found that there was poor agreement between thoracic bioimpedance and thermodilution in the immediate postoperative period.(8) The COST case series has been published only in abstract form.(9) In this study, cardiac output estimates using thermodilution methods and thoracic bioimpedance were performed in 96 patients undergoing right heart catheterization for a variety of clinical indications. Linear regression analysis revealed an overall correlation of  $r$  (Pearson's correlation coefficient, 0.76). The authors concluded that cardiac output can be reliably measured with either thermodilution or thoracic bioimpedance and that bioimpedance has the additional value of being noninvasive.

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

Packer et al reported on use of ICG to predict decompensation in patients with chronic heart failure.(11) In this study, 212 stable patients with heart failure and a recent episode of decompensation underwent serial evaluation and blinded ICG testing every 2 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 3 ICG parameters was a predictor of an event during the next 14 days ( $p<0.001$ ). 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 with patients at intermediate risk. However, the impact of use of these results on clinical outcomes is not known.

In 2012, Anand et al 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, multisensory system that includes intrathoracic impedance measurements, along with electrocardiographic and accelerometry data.(12,13) The study enrolled 543 patients (206 in the development phase and 337 in the validation phase) with heart failure with ejection fraction less than 40% and a recent heart failure admission, all of whom underwent monitoring for 90 days with the MUSE. There was a high rate of study dropout: 229 patients (42% of the total; 92 development, 137 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), which was defined as any of the following: (1) any heart failure-related hospitalization, emergency department or urgent care visit that required administration of IV diuretics, inotropes, or ultrafiltration for fluid removal; (2) a change in diuretic directed by the health care provider that included 1 or more of the following: a change in the prescribed diuretic type; an increase in dose of an existing diuretic; or the addition of another diuretic; (3) an ADHF event for which death was the outcome. Data from the 206 subjects in the development phase were used to generate a

multiparameter algorithm to predict outcomes that incorporated fluid index, a breath index, and personalization parameters (age, sex, height, weight). 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 an mean advance detection time of 11.5 days, but there was wide variation in this measure, from 2 to greater than 30 days, and it did not differ significantly from less specific algorithms (eg, 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.

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,(14) 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.(15) Thoracic bioimpedance devices that are integrated into implantable cardiac devices are addressed in Policy No. 2.02.10 (Biventricular Pacemakers [Cardiac Resynchronization Therapy] for the Treatment of Heart Failure).

## **Section Summary**

The evidence on thoracic bioimpedance devices consists of nonrandomized studies that correlate measurements with other measures of cardiac function and studies that use bioimpedance measurement as part of an algorithm for predicting future heart failure events. These monitors have also been part of clinical trials in combination with ICD and/or CRT devices. The evidence does not demonstrate that these devices improve clinical outcomes.

### Inert Gas Rebreathing

In contrast to thoracic bioimpedance, relatively little literature has been published on inert gas rebreathing, although a literature search suggests that this technique has been used as a research tool for many years.(16-19) No studies were identified that examined how inert gas rebreathing may be used to improve patient management in the outpatient setting.

### Noninvasive LVEDP Estimation Methods

Studies have shown high correlation between invasive and noninvasive measurement of LVEDP. For example, McIntyre et al reported a comparison of pulmonary capillary wedge pressure (PCWP) measured by right heart catheter and an arterial pressure amplitude ratio during Valsalva. The 2 techniques were highly correlated in both stable and unstable patients ( $R^2$  [coefficient of determination] range, 0.80-0.85).(20) Sharma et al performed simultaneous measurements of the LVEDP based on 3 techniques in 49 patients scheduled for elective cardiac catheterization: direct measurement of LVEDP, considered the criterion standard; indirect measurement using PCWP; and noninvasively using the VeriCor® device.(21) 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 with the criterion standard. In 2012, Silber et al reported on finger photoplethysmography during Valsalva performed in 33 patients before cardiac catheterization.(22) LVEDP greater than 15 mm Hg was identified by finger photoplethysmography during Valsalva with 85% sensitivity (95% confidence interval [CI], 54% to 97%) and 80% specificity (95% CI, 56% to 93%). However, literature searches did not identify any published articles that evaluated the role of noninvasive measurement of the LVEDP on the management of the patient. Therefore, evidence is inadequate to permit scientific conclusions regarding the clinical utility of this technology.

### Implantable Direct Pulmonary Artery Pressure Measurement Methods

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 (RCT) conducted at 64 centers in the United States.(23) This trial was 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. 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 1 previous hospitalization for heart failure in the past 12 months and were classified as having NYHA Class III heart failure for at least 3 months.(24) Left ventricular ejection fraction (LVEF) was not a criterion for participation, but patients were required to be on medication and stabilized for 1 month before participating in the study if LVEF 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 6 months.

The trial's primary efficacy outcome was the rate of heart failure-related hospitalizations in the 6 months after implantation. The primary safety outcomes were device-related or system-related complications and pressure-sensor failures.(24) The investigators reported a statistically significant reduction in readmissions for heart failure at 6 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<0.001). 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<0.001). The primary safety outcome, freedom from device-related complications, was 98.6% with no occurrences of pressure-sensor failure. However, 15 adverse events occurred including 8 which were device-related and 7 which were procedure-related. Additionally, length of stay for these hospitalizations was significantly shorter in the treatment group compared with the control group (2.2 days vs 3.8 days, respectively, p=0.02). There was also benefit reported for other secondary outcomes. There were improvements in the secondary outcomes of mean pulmonary pressure and quality of life at 6 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 safe: freedom from device or system-related complications was 98.6%, with a 95.2% lower confidence bound of 97.3%.

In the Summary of Safety and Effectiveness Data for the CardioMEMS 2014 application, 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."(3) 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 [pulmonary artery] 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 PA 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 PA pressure and no nurse communications).
- Change in heart failure hospitalization rates (HFR) 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 PA 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 PA pressure).

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 with the heart failure hospitalization rates in Treatment group patients whose PA pressures were available throughout the study.

Studies of Other Implantable Devices. Bourge et al and Stevenson et al reported on the COMPASS-HF (Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure Study) randomized trial.(25,26) The COMPASS trial evaluated outcomes on 274 patients implanted with a Medtronic hemodynamic monitoring system. Patients enrolled in the study were stabilized NYHA class III or IV heart failure patients and had at least 1 heart failure-related event within the 6 months before enrollment. LVEF 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 6 months postimplantation. 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 6 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 mm Hg diastolic pressure, event risk was 20% and increased to 34% at 25 mm Hg and to 56% at 33 mm Hg. While pressure readings correlated with event risk, the authors noted optimal filling pressures and needed surveillance for event avoidance have not been established. The Medtronic Chronicle Hemodynamic Monitor was denied U.S. Food and Drug Administration (FDA) approval in March 2007.

In 2011, Adamson et al reported on the Reducing Decompensation Events Utilizing Intracardiac Pressures in Patients With Chronic Heart Failure (REDUCEhf) study that evaluated an ICD coupled with an implantable hemodynamic monitoring (IHM) system.(27) 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 1300 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 was implanted in the right ventricle. Similar to the COMPASS-HF and CHAMPION trials previously discussed, the treatment group of 202 patients received heart failure management that incorporated pressure monitoring information from the IHM compared with 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.

## Section Summary

There are several RCTs of implantable hemodynamic monitoring systems. One of these trials (CHAMPION trial) used an FDA-approved monitor and was powered to report on clinical outcomes. This trial reported a decrease in hospitalizations for patients using the monitor as part of heart failure management compared with usual care. However, this trial had some methodologic limitations, one of which was the 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. A second limitation was the unequal intensity of treatment between groups, with the implantable monitor group having greater frequency of contact with study nurses. Because of these limitations, further high-quality trials are needed to determine whether health outcomes are improved.

### **Ongoing Clinical Trials**

A search of online database [ClinicalTrials.gov](http://ClinicalTrials.gov) identified a number of ongoing comparative studies currently enrolling patients:

- The Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy (LAPTOP-HF) (NCT01121107)—This is a randomized trial to evaluate the safety and clinical effectiveness of an implantable device, the HeartPOD™ System or Promote® LAP System, for left atrial pressure measurements to manage heart failure. Enrollment is planned for 730 subjects; the planned study completion date is June 2017.
- The Prevention of Heart Failure Events with Impedance Cardiography Testing (PREVENT-HF) (NCT00409916) trial will evaluate the impact of incorporating impedance cardiography readings into treatment planning using the BioZ Dx device in 500 patients. The PREVENT-HF trial will follow patients for 24 to 52 weeks and was initially expected to be completed in December 2012. The record on [ClinicalTrials.gov](http://ClinicalTrials.gov) was last updated in 2009, and the listed manufacturer, Cardiodynamics, was purchased by SonoSite.

### **Summary**

Different outpatient cardiac hemodynamic monitoring devices have been proposed to decrease episodes of acute decompensation in patients with heart failure and thus improve quality of life and reduce morbidity. These include bioimpedance, inert gas rebreathing, and estimation of left ventricular end diastolic pressure (LVEDP) by arterial pressure during Valsalva or use of an implantable pressure sensor.

The largest body of evidence is for direct pulmonary pressure monitors, such as the CardioMEMS device that has FDA-approval. Evidence from randomized controlled trials (RCTs) for various pulmonary artery pressure monitors has demonstrated a correlation between increased pressure readings and increased heart failure event risk. One RCT (the CHAMPION trial) noted that the use of pulmonary artery pressure readings may reduce heart failure-related hospitalizations, but this study was subject to a number of potential biases. Therefore, the evidence is insufficient to form conclusions that the CardioMEMS device is associated with improvements in health outcomes. Studies of other implantable direct pulmonary artery pressure measurement devices have not demonstrated significantly improved outcomes.

For other types of hemodynamic monitoring, there is limited available evidence on efficacy. RCTs, as well as studies that specifically address use of ambulatory cardiac hemodynamic monitoring compared with current care are lacking for thoracic bioimpedance, inert gas rebreathing, and arterial pressure/Valsalva techniques.

While some evidence suggests that intensive outpatient pulmonary artery pressure monitoring may reduce hospitalizations for patients with heart failure, definitive evidence that the use of these

technologies improves health outcomes over standard, active heart failure patient management is lacking. Therefore, these technologies are considered investigational.

### **Practice Guidelines and Position Statements**

The 2013 ACCF/AHA Guideline for the Management of Heart Failure offers no recommendations for use of ambulatory monitoring devices.(28,29)

The 2011 update of the National Institute for Health and Clinical Excellence clinical guideline on chronic heart failure management does not include outpatient hemodynamic monitoring as a recommendation.(30)

No other professional society guidelines were found that address thoracic bioimpedance, inert gas rebreathing, arterial pressure/Valsalva, or implantable direct pressure monitoring of the pulmonary artery in the outpatient setting for the management of heart failure.

### **U.S. Preventive Services Task Force Recommendations**

Hemodynamic monitoring in the outpatient setting is not a preventive service.

### **Medicare National Coverage**

In November 2006, the Centers for Medicare and Medicaid Services issued a decision memorandum on the second reconsideration of its coverage policy for thoracic electrical bioimpedance.(31) Medicare's national coverage determination found thoracic bioimpedance to be reasonable and necessary for the following indications:

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

While Medicare allows for coverage of thoracic bioimpedance in these conditions, it acknowledges that there is a "...general absence of studies evaluating the impact of using thoracic bioimpedance for managing patients with cardiac disease..." Medicare concluded in its reconsideration that thoracic bioimpedance use in the management of hypertension is non-covered due to inadequate evidence.

Medicare also specified that thoracic bioimpedance is noncovered "in the management of all forms of hypertension (with the exception of drug-resistant hypertension...)." Medicare specified in its covered indications that:

"Contractors have discretion to determine whether the use of thoracic bioimpedance for the management of drug-resistant hypertension is reasonable and necessary. Drug-resistant hypertension is defined as failure to achieve goal BP in patients who are adhering to full doses of an appropriate three-drug regimen that includes a diuretic."

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

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### **Billing Coding/Physician Documentation Information**

**93701** Bioimpedance-derived physiologic cardiovascular analysis

Prior to 2010, there was a specific category III code for measuring LVEDP:

0086T: Left ventricular fill pressure indirect measurement by computerized calibration by the arterial waveform response to Valsalva maneuver.

After January 1, 2010, this testing should be reported using the unlisted code:

93799: Unlisted cardiovascular service or procedure.

There is no specific code for implantable direct pressure monitoring of the pulmonary artery. The unlisted code 93799 would be used.

Category III codes 0104T (Inert gas rebreathing for cardiac output measurement; during rest) and 0105T (Inert gas rebreathing for cardiac output measurement; during exercise) were deleted January 1, 2011.

### **Policy Implementation/Update Information**

10/1/10 This new policy is a combination of the 2 policies 2.02.12 - Noninvasive Measurements of Cardiac Hemodynamics in the Ambulatory-Outpatient Setting AND 2.02.21 - Non-invasive Measurement of Left Ventricular End Diastolic Pressure (LVEDP) in the Outpatient Setting. (Upon approval of this policy, the above policies will be archived.)The policy statements are unchanged. Implantable direct pressure monitoring of the pulmonary artery

added to the policy as investigational.  
10/1/11 No policy statement changes.  
10/1/12 No policy statement changes.  
10/1/13 No policy statement changes.  
10/1/14 No policy statement changes.

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