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

Policy # 00287
Original Effective Date: 01/31/2005
Current Effective Date: 07/11/2018

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Note: Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure is addressed separately in medical policy 00009.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers cardiac hemodynamic monitoring for the management of heart failure utilizing thoracic bioimpedance, inert gas rebreathing, arterial pressure during the Valsalva maneuver, and implantable direct pressure monitoring of the pulmonary artery (PA) in the ambulatory care and outpatient setting to be **investigational.***

Background/Overview

CHRONIC HEART FAILURE

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

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

Precise measurement of cardiac hemodynamics is often employed in the intensive care setting to carefully manage fluid status in acutely decompensated heart failure. Transthoracic echocardiography, transesophageal echocardiography, and Doppler ultrasound are noninvasive methods for monitoring cardiac output on an intermittent basis for the more stable patient but are not addressed herein. A variety of biomarkers and radiologic techniques may be used for dyspnea when the diagnosis of ADHF is uncertain.

The criterion standard for hemodynamic monitoring is PA catheters and central venous pressure catheters. However, they are invasive, inaccurate, and inconsistent in predicting fluid responsiveness. Several studies

have demonstrated that catheters fail to improve outcomes in critically ill patients and may be associated with harm. To overcome these limitations, multiple techniques and devices have been developed that use complex imaging technology and computer algorithms to estimate fluid responsiveness, volume status, cardiac output and tissue perfusion. Many are intended for use in outpatient settings but can be used in the emergency department, intensive care unit, and operating room. Four methods are reviewed here: implantable pressure monitoring devices, thoracic bioimpedance, inert gas rebreathing, and arterial waveform during the Valsalva maneuver. Use of last three is not widespread because of several limitations including use proprietary technology making it difficult to confirm their validity and lack of large randomized controlled trials (RCTs) to evaluate treatment decisions guided by these hemodynamic monitors.

Left Ventricular End-Diastolic Pressure Estimation

Pulmonary Artery Pressure Measurement to Estimate Left Ventricular End-Diastolic Pressure

Left ventricular end-diastolic pressure (LVEDP) can be approximated by direct pressure measurement of an implantable sensor in the PA wall or right ventricular outflow tract. The sensor is implanted via right heart catheterization and transmits pressure readings wirelessly to external monitors. One device, the CardioMEMS Champion Heart Failure Monitoring System, has approval from the U.S. Food and Drug Administration (FDA) for the ambulatory management of heart failure patient. The CardioMEMS device is implanted using a heart catheter system fed through the femoral vein and generally requires patients have an overnight hospital admission for observation after implantation.

Thoracic Bioimpedance

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

Inert Gas Rebreathing

Inert gas rebreathing is based on the observation that the absorption and disappearance of a blood-soluble gas are proportional to cardiac blood flow. The patient is asked to breathe and rebreathe from a bag filled with oxygen mixed with a fixed proportion of 2 inert gases, typically nitrous oxide and sulfur hexafluoride. The nitrous oxide is soluble in blood and is therefore absorbed during the blood's passage through the lungs at a rate proportional to the blood flow. The sulfur hexafluoride is insoluble in blood and therefore stays in the gas phase and is used to determine the lung volume from which the soluble gas is removed. These gases and carbon dioxide are measured continuously and simultaneously at the mouthpiece.

Arterial Pressure During Valsalva Maneuver to Estimate LVEDP

LVEDP is elevated with ADHF. 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Noninvasive LVEDP Measurement Devices

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

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

FDA product code: DXN.

Thoracic Bioimpedance Devices

Multiple thoracic impedance measurement devices that do not require invasive placement have been cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices used for peripheral blood flow monitoring. Table 1 presents an inexhaustive list of representative devices (FDA product code: DSB).

Table 1. Noninvasive Thoracic Impedance Plethysmography Devices

Device	Manufacturer	Clearance Date
BioZ®‡ Thoracic Impedance Plethysmograph	SonoSite	2009
Zoe®‡ Fluid Status Monitor	Noninvasive Medical Technologies	2004
Cheetah Starling SV	Cheetah Medical	2008
PhysioFlow®‡ Signal Morphology-based Impedance Cardiography (SM-ICG™‡)	Vasocom, now NeuMeDx	2008
ReDSTM Wearable System	Sensible Medical Innovations	2015
Device	Manufacturer	Clearance Date
BioZ Thoracic Impedance Plethysmograph	SonoSite	2009
Zoe Fluid Status Monitor	Noninvasive Medical Technologies	2004

Also, several manufacturers market thoracic impedance measurement devices integrated into implantable cardiac pacemakers, cardioverter defibrillator devices, and cardiac resynchronization therapy devices.

Thoracic bioimpedance devices integrated into implantable cardiac devices are addressed in medical policy 00009.

Inert Gas Rebreathing Devices
In 2006, the Innocor®‡ (Innovision), an inert gas rebreathing device, was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent to existing inert gas rebreathing devices for use in computing blood flow. FDA product code: BZG.

Implantable Pulmonary Artery Pressure Sensor Devices
In 2014, the CardioMEMS™‡ Champion Heart Failure Monitoring System (CardioMEMS, now St. Jude Medical) was cleared for marketing by FDA through the premarket approval process. This device consists of an implantable PA sensor, which is implanted in the distal PA, a transvenous delivery system, and an electronic sensor that processes signals from the implantable PA sensor and transmits PA pressure measurements to a secure database. The device originally underwent FDA review in 2011, at which point FDA found no reasonable assurance that the monitoring system would be effective, particularly in certain subpopulations, although FDA agreed this monitoring system was safe for use in the indicated patient population.

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

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

Centers for Medicare and Medicaid Services (CMS)
In 2014, the CMS updated its 2006 decision memorandum on thoracic electrical bioimpedance. 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 atrioventricular 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 permits coverage of thoracic bioimpedance in these conditions, it has acknowledged that there is a "…general absence of studies evaluating the impact of using thoracic bioimpedance for managing

patients with cardiac disease…." Medicare does not cover the use of thoracic bioimpedance in the management of hypertension due to inadequate evidence.

Medicare has also specified that thoracic bioimpedance is not covered for "the management of all forms of hypertension (with the exception of drug-resistant hypertension…)." Further, Medicare specified that:

> "[Contractors] have discretion to determine whether the use of TEB [thoracic bioimpedance] for the management of drug-resistant hypertension is reasonable and necessary. Drug resistant hypertension is defined as failure to achieve goal blood pressure in patients who are adhering to full doses of an appropriate 3-drug regimen that includes a diuretic."

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

Effective April 7, 2016, Novitas Solutions issued a noncoverage local coverage determination (ID L36419) for outpatient wireless PA pressure monitoring for heart failure (CardioMEMS).

Rationale/Source

For the first indication, because there is direct evidence from a large RCT, we focus on it and assess the evidence it provides on clinical utility.-Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The RCT is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

For indications 2, 3, and 4, we assess the evidence as a medical test. Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

IMPLANTABLE PULMONARY ARTERY PRESSURE MONITORING
CardioMEMS Device

Abraham et al (2011, 2016) have reported on the results of the CHAMPION single-blind RCT in which all enrolled patients were implanted with the CardioMEMS device. Patients were randomized to the CardioMEMS group, in which daily uploaded PA pressures were used to guide medical therapy, or to the control group, in which daily uploaded pressures were not made available to investigators and patients continued to receive standard of care management, which included drug adjustments in response to patients' clinical signs and symptoms. An independent clinical end points committee, blinded to the treatment groups, reviewed abstracted clinical data and determined if hospitalization was related to heart failure hospitalization. The randomized phase ended when the last patient enrolled completed at least 6 months of study follow-up (average, 18 months) and was followed in an open-access phase during which investigators had access to PA pressure for all patients (former control and treatment group). The open-access phase lasted for an average of 13 months. In the randomized phase of the trial, if the investigator did not document a medication change in response to an abnormal PA pressure elevation, a remote CardioMEMS nurse could send communications to the investigator related to clinical management. No such activity occurred in the nonrandomized phase. Trial characteristics and results are summarized in Tables 2 and 3. The trial met its primary efficacy end point, with a statistically significant 28% relative reduction in the rate of heart failure–related hospitalizations at 6 months. However, members of the U.S. FDA advisory committee in 2011 were unable to distinguish the effect of the device from the effect of nurse communications, and so FDA denied approval of CardioMEMS and requested additional clarification from the manufacturer. Subsequently, FDA held a second advisory committee meeting in 2013 to review additional data (including open-access phase) and address previous concerns related to impact of nurse communication on the CHAMPION trial.

The 2 major limitations in the early data were related to the potential impact of nurse communication and lack of treatment effect in women.

The sponsor conducted multiple analyses to address the impact of nurse intervention on heart failure-related hospitalizations. These analyses included: (1) independent auditing of all nurse communication to estimate quantitatively the number of hospitalization that could have been influenced by nurse communication, (2) using a propensity-based score to match patients in the CardioMEMS group who did not receive nurse communications with those in the control base, (3) comparing whether the new knowledge of pulmonary arterial pressure in the former control during the open-access phase led to reductions in heart failure–related hospitalizations, (4) comparing whether the ongoing access to PA pressures in the treatment group during the open-access phase was accompanied by continued reduced rates of heart failure hospitalizations, and (5) comparing whether if similar access to PA pressures in the former control group and treatment group during the open-access phase was associated with similar rates

of heart failure–related hospitalizations. FDA concluded that all such analyses had methodologic limitations. Propensity matching cannot balance unmeasured characteristics and confounders, and therefore conclusions drawn from propensity analysis were not definitive. While FDA concluded that the third-party audit of nurse communication was valid, it was difficult to estimate accurately how many heart failure–related hospitalizations were avoided by the nurse communications. FDA stated that the longitudinal analyses (see points 3 to 5 above) were the most useful regarding supporting device effectiveness. Therefore, only data from analyses 3 to 5 are summarized in Table 4 and discussed next. It is important to acknowledge that all such analyses were post hoc and were conducted with the intent to test the robustness of potentially biased RCT results and therefore results from these analyses should be evaluated to assess consistency and not as an independent source of evidence to support efficacy. As indicated in Table 4, the longitudinal analyses of individual patient data showed that the device appears to be associated with reducing heart failure–related hospitalization rate. However, there are important trial limitations, notably, subject dropouts were not random, and patient risk profiles could have changed from the randomized phase to the open-access phase. In the open-access phase, 93 (34%) of 270 subjects in the treatment group and 110 (39%) of 280 subjects in control group remained in the analysis.

According to the FDA documents, the apparent lack of reduction in heart failure–related hospitalization in women resulted from a greater number of deaths among women in the control group early in the trial and this early mortality resulted in a competing risk for future heart failure hospitalizations. While both the FDA and sponsor conducted multiple analyses to understand device effectiveness in women, FDA statisticians concluded that such analyses did clearly delineate the limited treatment effect in women. The effectiveness of CardioMEMS in women may be clarified when results of a postmarketing study, currently ongoing and proposed to enroll at least 35% (n=420) women of the enrollment (n=1200), are published.

Other subgroup analysis of CHAMPION trial in patients with reduced ejection fraction, preserved ejection fraction, Medicare-eligible patients, and chronic obstructive pulmonary disease are out of scope and not discussed in this evidence review.

Table 2. Summary of Key RCT Characteristics

Author; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Abraham et al (2011, 2016); CHAMPION	U.S.	64	2007-2009	• At least 1 previous HFH in the past 12 mo and NYHA class III HF for at least 3 mo • 40% patients from academic setting and 60% from community setting	Disease management by daily measurement of pulmonary artery pressures (via CardioMEMS) plus standard of care (n=270)	Disease management by standard of care alone (n=280)

HF: heart failure; HFH: heart failure hospitalization; NYHA: New York Heart Association.

Table 3. Summary of Key RCT Results

Study	HFH, n (events per patient)		Device- or System-Related Complications, n (%)		Pressure-Sensor Failures at 6 or 12 Months
	At 6 Months	At 12 Months	At 6 Months	At 12 Months	
Abraham et al	550	550	550	550	550

(2011, 2016); CHAMPION					
CardioMEMS	84 (0.32)	182 (0.46)	3 (1)	0	0
Control	120 (0.44)	279 (0.68)	3 (1)	0	0
HR (95% CI)	0.72 (0.60 to 0.85)	0.67 (0.55 to 0.80)	NA	NA	NA
NNT (95% CI)	8 (not reported)	4 (not reported)	NA	NA	NA

CI: confidence interval; HFH: heart failure hospitalization; HR: hazard ratio; NA: not applicable; NNT: number needed to treat.

Table 4. Summary of Additional Analyses of the CHAMPION RCT

Trial Period	Randomized Group	CardioMEMS Data Available	Nurse Communications	Comparison	HR for HFH (95% CI)
Randomized access	Treatment	Yes	Yes	Former control to control	0.52 (0.40 to 0.69)
	Control	No	No	Former treatment to treatment	0.93 (0.70 to 1.22)
Open access	Former control	Yes	No	Former control to former treatment	0.80 (0.56 to 1.14)
	Former treatment	Yes	No	-	-

Adapted from Abraham et al (2016) and FDA (2013).[7,8]
CI: confidence interval; HFH: heart failure hospitalization; HR: hazard ratio.

The purpose of the gaps tables (see Tables 5 and 6) is to display notable gaps identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement.

Table 5. Relevance Gaps

Study; Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Abraham et al (2011, 2016); CHAMPION		1. Delivery not similar intensity as comparator. Treatment group received additional nurse communication for enhanced protocol compliance. Trial intention was to assess physician's ability to use PA pressure information and not capabilities of sponsor's nursing staff to monitor and correct physician-directed therapy.			

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

Table 6. Study Design and Conduct Gaps

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Abraham (2011, 2016); CHAMPION		1. Physicians not blinded to treatment assignment but outcome assessment was independent and blinded				

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

Nonrandomized Studies

Desai et al (2017) published a retrospective cohort study of Medicare administrative claims data for individuals who received the CardioMEMS device following FDA approval. Of 1935 Medicare enrollees who underwent implantation of the device, 1114 were continuously enrolled and had evaluable data for at least 6 months before, and following, implantation. A subset of 480 enrollees had complete data for 12 months before and after implantation. Study characteristics and results are summarized in Tables 7 and 8. The cumulative incidence of heart failure–related hospitalizations were significantly lower in the postimplantation period than in the preimplantation period at both 6- and 12-month follow-ups. Limitations of this pre-post retrospective study include lack of data on medical history, ejection fraction, indication for implantation and possible confounding due to amplified touchpoints with the health care system necessitated by the device's implantation.

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

Table 7. Summary of Key Nonrandomized Study Characteristics

Author	Study Type	Country/Institution	Dates	Participants	Treatment	Follow-Up
Desai et al (2017)	Retrospective cohort	U.S./Medicare	2014-2015	Individuals with inpatient	CardioMEMS implant	2 cohorts: • 6-mo preimplant

				CPT codes consistent with use of procedure		and postimplant data (n=1114) • 12-mo preimplant and postimplant data (n=480)
Vaduganathan et al (2017)	Postmarketing surveillance study	U.S./FDA and Abbott	2014-2017	Individuals reporting Cardio-MEMS-related adverse event	CardioMEMS implant	Not applicable

FDA: Food and Drug Administration.

Table 8. Summary of Key Nonrandomized Study Results

Study	HFH at 6 Months	HFH at 12 Months	Safety
Desai et al (2017)	1114	480	-
Preimplant, n	1020	696	-
Postimplant, n	381	300	-
HR (95% CI); p	0.55 (0.49 to 0.61); <0.001	0.66 (0.57 to 0.76); <0.001	-
Vaduganathan et al (2017)			Estimated 5500 received CardioMEMS
AE cohort identified from MAUDE database	-	-	155 (2.8%) AEs; 28 pulmonary artery injury or hemoptysis (0.5%), and 2 (0.4%) deaths

AE: adverse event; CI: confidence interval; HFH: heart failure hospitalization; HR: hazard ratio.

Case Series

Heywood et al (2017) reported PA pressure data for the first 2000 consecutive patients with at least 6 months of follow-up who were implanted with CardioMEMS. No clinical data were reported except for PA measurement. Study characteristics and results are summarized in Tables 9 and 10. The mean age of the cohort enrolled was 70 years and the mean follow-up period was 333 days. There was a median of 1.2 days between remote pressure transmissions and greater than 98% weekly use of the system, demonstrating a high level of adherence.

Table 9. Summary of Key Case Series Characteristics

Author	Country/institution	Participants	Treatment Delivery	Follow-Up (SD)
Heywood et al (2017)	U.S./Abbott	First 2000 individuals who received CardioMEMS with follow-up data for a minimum of 6 mo	CardioMEMS	333 (125) d

Table 10. Summary of Key Case Series Results

Author	Treatment	AUC (mm Hg day)	Adherence
Heywood et al (2017)	CardioMEMS device	• -32.8 mm Hg/d (1 mo) • -156.2 mm Hg/d (3 mo) • -434.0 mm Hg/d (6 mo)	• Median days between transmissions: 1.07 d (first 30 d) and 1.27 days (after 6 mo) • Use of the system: 98.6% (IQR, 82.9%-100.0%)

AUC: area under the curve; IQR: interquartile range.

Section Summary: Implantable Pulmonary Artery Pressure Monitoring
The pivotal CHAMPION RCT reported a statistically significant decrease in heart failure–related hospitalizations in patients implanted with CardioMEMS device compared with usual care. However, trial results were potentially biased in favor of the treatment group due to use of additional nurse communication to enhance protocol compliance with the device. The trial intended to assess the physician's ability to use PA pressure information and not the capabilities of the sponsor's nursing staff to monitor and correct physician-directed therapy. The manufacturer conducted multiple analyses to address the potential bias from the nurse interventions. These analyses were reviewed favorably by FDA. While these analyses demonstrated the consistency of benefit from the CardioMEMS device, all such analyses have methodologic limitations. With greater adoption of this technology, it is likely to be used by a broader group of clinicians with variable training in the actual procedure and used in patients at a higher risk compared with those in the CHAMPION trial. Early safety data have been suggestive of a higher rate of procedural complications, particularly related to PA injury. Given that the intervention is invasive and intended to be used for a highly prevalent condition, in the light of limited safety data, lack of demonstrable mortality benefit, and pending questions related to its benefit for reduction in hospitalization, the net benefit remains uncertain. Many concerns may be clarified by an ongoing postmarketing study that proposes to enroll 1200 patients (at least 35% women) is reported.

NONINVASIVE THORACIC BIOIMPEDANCE/IMPEDANCE CARDIOGRAPHY

Clinical Context and Test Purpose

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

The question addressed in this evidence review is: Does use of thoracic bioimpedance/impedance cardiography improve health outcomes in individuals with heart failure in the outpatient setting?

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

Patients

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

Interventions

The test being considered is thoracic bioimpedance.

Comparators

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

Outcomes

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

Timing
Trials of using thoracic bioimpedance in this population were not found. Generally, demonstration of outcomes over a 1-year period is meaningful for interventions.

Setting
Patients will receive treatment in the outpatient setting.

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review, and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

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

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

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

Table 11. Clinical Validity of 3-Level Risk Score for BioZ Impedance Cardiography Monitor

Author	Initial N	Final N	Excluded Samples	Prevalence of Condition	Clinical Validity: Mean Probability of Outcome (95% CI), %		
					Low Risk	Medium Risk	High Risk
Packer et al (2006)	212	212	None	59 patients had 104 episodes of decompensated HF including 16 deaths, 78 hospitalizations, 10 ED visits	1.0 (0.5 to 1.9)	3.5 (2.4 to 4.8)	8.4 (5.8 to 11.6)

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

Section Summary: Clinically Valid
The clinical validity of using thoracic bioimpedance for patients with chronic heart failure who are at risk of developing ADHF has not been established. Association studies are insufficient evidence to determine whether thoracic bioimpedance can improve outcomes patients with chronic heart failure who are at risk of

developing ADHF. There are no studies reporting the clinical validity regarding sensitivity, specificity, or predictive value.

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

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

Amir et al (2017) reported on results of a prospective study in which 59 patients recently hospitalized for heart failure were selected for ReDS-guided treatment for 90 days. The number of heart failure hospitalizations during 90-day ReDS-guided therapy were compared with hospitalizations in the preceding 90 days before enrollment and the 90 days following discontinuation of ReDS monitoring. During treatment, patients were equipped with the ReDS wearable vest, which was worn once a day at home to measure lung fluid content. Study characteristics and results are summarized in Tables 12 and 13. The rate of heart failure hospitalizations was lower during the ReDS-guided follow-up compared with pre and posttreatment periods. Interpretation of results is uncertain due to the lack of concurrent control and randomization, short-term follow-up, large CIs, and lack of clarity about lost-to-follow-up during the post-ReDS period. An RCT comparing ReDS monitoring with standard of care (SMILE; NCT02448342) was initiated but terminated before its completion.

Table 12. Summary of Key Nonrandomized Study Characteristics

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

FU: follow-up; LVEF: left ventricular ejection fraction; SD: standard deviation.

Table 13. Summary of Key Nonrandomized Study Results

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

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

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

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

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

The question addressed in this evidence review is: Does use of inert gas breathing improve health outcomes in individuals with heart failure in the outpatient setting?

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

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

Interventions
The test being considered is inert gas breathing.

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

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

Timing
Trials of using inert gas breathing in this population were not found. Generally, demonstration of outcomes over a 1-year period is meaningful for interventions.

Setting
Patients will receive treatment in the outpatient setting.

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review, and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

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

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

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

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

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

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

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

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

NONINVASIVE LEFT VENTRICULAR END-DIASTOLIC PRESSURE ESTIMATION
Clinical Context and Test Purpose
The purpose of noninvasive LVEDP estimation in patients who have heart failure in an outpatient setting is (1) to guide volume management, (2) to identify physiologic changes that precede clinical symptoms and thus allow preventive interventions, and (3) to prevent hospitalizations.

The question addressed in this evidence review is: Does use of noninvasive LVEDP estimation improve health outcomes in individuals with heart failure in the outpatient setting?

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

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

Interventions
The test being considered is noninvasive LVEDP estimation.

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

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

Timing
Trials of using noninvasive LVEDP estimation in this population were not found. Generally, demonstration of outcomes over a 1-year period is meaningful for interventions.

Setting
Patients will receive treatment in the outpatient setting.

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review, and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

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

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

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

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

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

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

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

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

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

Policy # 00287
Original Effective Date: 01/31/2005
Current Effective Date: 07/11/2018

SUMMARY OF EVIDENCE

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring with an implantable PA pressure sensor device, the evidence includes RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. One implantable pressure monitor, the CardioMEMS device, has U.S. FDA approval. The pivotal CHAMPION RCT reported a statistically significant decrease in heart failure–related hospitalizations in patients implanted with CardioMEMS device compared with usual care. However, trial results were potentially biased in favor of the treatment group due to use of additional nurse communication to enhance protocol compliance with the device. The manufacturer conducted multiple analyses to address potential bias from the nurse interventions. Results were reviewed favorably by the FDA. While these analyses demonstrated the consistency of benefit from the CardioMEMS device, all such analyses have methodologic limitations. Early safety data have been suggestive of a higher rate of procedural complications, particularly related to PA injury. Given that the intervention is invasive and intended to be used for a highly prevalent condition, in the light of limited safety data, lack of demonstrable mortality benefit, and pending questions related to its benefit in reducing hospitalizations, the net benefit remains uncertain. Many of these concerns may be clarified by an ongoing postmarketing study that proposes to enroll 1200 patients (at least 35% women) is reported. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring by thoracic impedance, with inert gas rebreathing, or of arterial pressure during the Valsalva maneuver, the evidence includes uncontrolled prospective studies and case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. There is a lack of RCT evidence evaluating whether the use of these technologies improves health outcomes over standard active management of heart failure patient. The case series have reported physiologic measurement–related outcomes and/or associations between monitoring information and heart failure exacerbations, but do not provide definitive evidence on device efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

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Policy History

Original Effective Date: 01/31/2005
Current Effective Date: 07/11/2018

12/07/2004	Medical Director review
12/14/2004	Medical Policy Committee review
01/31/2005	Managed Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged
02/07/2007	Medical Director review
02/21/2007	Medical Policy Committee approval. Coverage eligibility unchanged. Rationale/Source and reference updated.
02/04/2009	Medical Director review
02/19/2009	Medical Policy Committee approval. No change to coverage eligibility.
02/04/2010	Medical Policy Committee approval
02/17/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/03/2011	Medical Policy Committee review
03/16/2011	Medical Policy Implementation Committee approval. This policy replaces medical policies 00116 and 00151 to create a single policy addressing cardiac hemodynamic monitoring for the management of heart failure in the outpatient setting.
03/01/2012	Medical Policy Committee review
03/21/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/16/2012	Policy Retired
06/02/2016	Medical Policy Committee review
06/20/2016	Medical Policy Implementation Committee approval. Policy returned to active status.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Changed “arterial pressure/Valsalva” to “arterial pressure during the Valsalva maneuver”. Coverage eligibility unchanged.

Next Scheduled Review Date: 07/2019

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	93701, 93799
HCPCS	C9741
ICD-10 Diagnosis	I20.1, I20.8, I20.9, I21.01, I21.02, I21.09, I21.11, I21.19, I21.21, I21.29, I21.3, I21.4, I21.20, I21.21, I21.22, I22.8, I22.9, I25.10, I25.110, I25.111, I25.118, I25.119, I25.5, I25.6, I25.700, I25.701. I25.708, I25.709, I25.710, I25.711, I25.718, I25.719, I25.720 I25.721, I25.728, I25.729, I25.730, I25.731, I25.738, I25.739, I25.750, I25.751, I25.758, I25.759, I25.760, I25.761, I25.768, I25.769, I25.790, I25.791, I25.798, I25.799, I25.810, I25.811, I25.812, I25.82, I25.89, I25.9, I27.0, I27.2, I27.81, I27.89, I27.9, I48.0, I48.1 I48.2, I48.3, I48.4, I48.91, I48.92, I50.1, I50.20, I50.21, I50.22, I50.23, I50.30, I50.31, I50.32, I50.33, I50.40, I50.41, I50.42, I50.43, I50.9, Z13.6

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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