BlueCross BlueShield of Alabama

Name of Policy:

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

Policy #: 441
Category: Medicine

Latest Review Date: May 2018
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

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

Chronic Heart Failure

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

Management

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

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 (TEE), 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 radiological techniques may be used for dyspnea when the diagnosis of acute decompensated heart failure is uncertain.

The criterion standard for hemodynamic monitoring is pulmonary artery catheters and central venous pressure catheters. However, they are invasive, inaccurate and inconsistent in predicting fluid responsiveness. Several studies have demonstrated that it fails to improve outcome 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 of these are intended to be used in outpatient setting but can potentially be also 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. The use of last 3 is not widespread because of several limitations including use proprietary technology making it difficult to confirm their validity and no large randomized controlled trials have been conducted to evaluate treatment decisions guided by these hemodynamic monitors.

LVEDP Estimation Methods

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 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 Food and Drug Administration 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 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.

Inert Gas Rebreathing

Inert gas rebreathing 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 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 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.

Arterial Pressure during Valsalva Maneuver to Estimate LVEDP

Left ventricular end diastolic pressure (LVEDP) is elevated in the setting of acute decompensated heart failure. While direct catheter measurement of LVEDP is possible for patients undergoing cardiac catheterization for diagnostic or therapeutic reasons, its invasive nature precludes its outpatient use. Noninvasive measures 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 correlated to the LVEDP.

This policy refers only to the use of stand-alone cardiac output measurement devices designed for use in ambulatory care and outpatient settings. The use of cardiac hemodynamic monitors or intrathoracic fluid monitors that are integrated into other implantable cardiac devices, including implantable cardioverter defibrillators, cardiac resynchronization therapy devices, and cardiac pacing devices, is addressed in medical policy *# 055 – Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure.*

Policy:

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 does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature review was updated through March 5, 2018.

For the first indication, because we have direct evidence from a large randomized controlled trial (RCT), we will 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 are 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 Direct Pulmonary Artery Pressure Measurement Methods

CardioMEMS Device

Abraham et al (2011, 2016) 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 CardioMEMS group, in which daily uploaded pulmonary artery pressures were used to guide medical therapy, or to the control group, in which daily uploaded pressures were not made available to investigators and they continued to receive standard of care management, which included drug changes in response to patients' clinical signs and symptoms. An independent clinical endpoints committee, blinded to the treatment groups, reviewed abstracted clinical data and determined if a 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 by an open access phase during which investigators had access to pulmonary artery 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(s) in response to an abnormal PA pressure elevation, a remote CardioMEMS nurse could send communications to investigator related to clinical management. No such activity occurred in the nonrandomized phase. Trial characteristics and results are summarized in Tables 1 and 2. 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, the members of the FDA advisory committee in 2011 were unable to distinguish the effect of the device from the effect of nurse communications and as such FDA denied the approval of CardioMEMS and requested additional clarification from the manufacturer. Subsequently, the FDA held a second Advisory committee meeting in 2013 and reviewed additional data (including open-access phase) to address the previous concerns related to impact of nurse communication on the CHMAPION trial were discussed.

The 2 major limitations in the early data were related to 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 that included (1) an independent audit of all nurse communication to estimate quantitatively the number of hospitalization that could have potentially be influenced by nurse communication, (2) using a propensity-based score matching approach to match patients in the CardioMEMS group that did not receive nurse communications and match them to control based, (3) compare if the new knowledge of pulmonary arterial pressure in the former control during the open-access phase led to reduction in heart failure related hospitalizations, (4)

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

According to FDA documents, the apparent lack of reduction in heart failure-related hospitalization in women was a result of greater number of deaths early in the trial among women in the control group and this early mortality resulted in a competing risk for future heart failure hospitalizations. While both FDA and sponsor conducted multiple analyses to understand device effectiveness in women but FDA statisticians concluded that such analyses did not provide clarity in delineating limited treatment effect in women. The effectiveness of CardioMEMS in women may be clarified from the results of a postmarketing study that is currently ongoing and proposes to enroll at least 35% (n=420) women of the enrollment (n=1200).

Other subgroup analysis of CHAMPION trial in patients with reduced ejection fraction, preserved ejection fraction, Medicare-eligible patients, and patients with chronic obstructive pulmonary disease (COPD)12 are not discussed in this evidence review.

Table 1. 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 2. Summary of Key RCT Results

Study	HFH,n (events per patient per 6mo)	HFH, n (events per patient per 12 mo)	Device- or System Related Complications at 6 Months, n (%)	Device- or System Related Complications at 12 Months, n (%)	Pressure-Sensor Failures at 6 or 12 Months
Abraham et al (2011, 2016); CHAMPION	550	550	550	550	550
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

CI: confidence interval; HFH: heart failure hospitalization; HR: hazard ratio; NNT: number needed to treat.

Table 3. 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). CI: confidence interval; HFH: heart failure hospitalization; HR: hazard ratio

Table 4. Relevance Gaps

Study; Trial	Population	Intervention	Comparator	Outcomes	Follow-up
Abraham et al (2011, 2016); CHAMPION	1.None	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.	1.None	1.None	1.None

PA: pulmonary artery

Table 5. Study Design and Conduct Gaps

Study	Allocation	Blinding	Selective Reporting	Follow-Up	Power
Abraham (2011, 2016)5,6; CHAMPION	1.None	1.Physicians not blinded to treatment assignment but outcome assessment was independent and blinded	1.None	1.None	1.None

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 prior to, 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 6 and 7. The cumulative incidence of heart failure−related hospitalizations was significantly lower in the postimplantation period compared with preimplantation period at both 6- and 12-month follow-ups. Limitations of this pre-post retrospective study include lack of data regarding medical history, ejection fraction, indication for implantation and possible confounding due to amplified touchpoints with the healthcare system necessitated by the device's implantation.

Heywood et al (2017) reported pulmonary artery pressure data of first 2000 consecutive patients with at least 6 months of follow-up that were implanted with CardioMEMS. No clinical data was reported except for PA measurement. Study characteristics and results are summarized in Tables 8 and 9. 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.

Vaduganathan (2017) reported on an analysis of 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 about 2.8%. There were 28 reports of pulmonary artery injury/hemoptysis (0.5%) that included 14 intensive care unit stays, 7 intubations, and 6 deaths. Sensor failure, malfunction, or migration occurred in 46 cases, of which 35 required recalibrations. Compared with a 2.8% event rate reported in this analysis, the serious adverse event rate in CHAMPION trial was 2.6% with 575 implant attempts, including 1 case of pulmonary artery injury and 2 deaths. Limitation of the current analysis primarily included lack of adjudication and limited clinical data.

Table 6. 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 CPT codes consistent with use of procedure	CardioMEMS implant	2 cohorts: • 6-mo preimplant and postimplant data (n=1114) • 12-mo preimplant and postimplant data (n=480)
Vaduganathan (2017)	Postmarketing surveillance study	U.S./FDA and Abbott	2014-2017	Individuals reporting CardioMEMS-related adverse event	CardioMEMS implant	Not applicable

FDA: Food and Drug Administration.

Table 7. Summary of Key Nonrandomized Study Results

Study	HFH at 6 months	HFH at 12 months	Safety
Desal 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)			5500 estimated individuals who received CardioMEMS
AE cohort identified from MAUDE database	-	-	155 (2.8%) AEs; 28 pulmonary artery injury or hemoptysis (0.5%), and 22 deaths (0.4%)

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

Table 8. Summary of Key Case Series Characteristics

Author	Country/institution	Participants	Treatment Delivery	Follow-Up (SD)
Heywood et al (2010)	U.S./ Abbott	First 2000 individuals who received CardioMEMS with followup data for a minimum of 6 mo	CardioMEMS	333 (125) d

Table 9. Summary of Key Case Series Results

Author	Treatment	AUC (mm Hg day)	Adherence
Heywood et al (2010)	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: CardioMEMS Device

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, the results were potentially biased in favor of the treatment group due to use of additional nurse communication to enhance protocol compliance with the device. However, the intention of the trial was to assess the physician's ability to use pulmonary artery pressure information and not the capabilities of the sponsor's nursing staff to monitor and correct physician directed therapy. The manufacture conducted multiple analyses to address the issue of potential bias from the nurse interventions. These were reviewed favorably by the FDA. While these analyses demonstrated 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 as compared with the CHAMPION trial. Early safety data are suggestive of a higher rate of procedural complications, particularly related to pulmonary artery injury. Given that the intervention is invasive, 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 of these issues may be clarified from the results of an ongoing postmarketing study that is currently ongoing and proposes to enroll 1200 patients with at least 35% women.

Noninvasive Thoracic Bioimpedance/Impedance Cardiography (ICG)

Clinical Context and Test Purpose

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

Interventions
The test being considered is thoracic bioimpedance/impedance cardiography.

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

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

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

Setting
Outpatient setting

Simplifying Test Terms
There are 3 core characteristics for assessing a medical test. Whether imaging, laboratory, or other, all medical tests must be:

- Technically reliable
- Clinically valid
- Clinically useful.

Because different specialties may use different terms for the same concept, we are highlighting the core characteristics. The core characteristics also apply to different uses of tests, such as diagnosis, prognosis, and monitoring treatment.

Diagnostic tests detect presence or absence of a condition. Surveillance and treatment monitoring are essentially diagnostic tests over a time frame. Surveillance to see whether a condition develops or progresses is a type of detection. Treatment monitoring is also a type of detection because the purpose is to see if treatment is associated with the disappearance, regression, or progression of the condition.

Prognostic tests predict the risk of developing a condition in the future. Tests to predict response to therapy are also prognostic. Response to therapy is a type of condition and can be either a beneficial response or adverse response. The term predictive test is often used to refer to

response to therapy. To simplify terms, we use prognostic to refer both to predicting a future condition or to predicting a response to therapy.

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/impedance cardiography test because they did not include information needed to assess clinically validity.

Packer et al (2006) reported on use of impedance cardiography (ICG) measured by BioZ ICG 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 ICG testing every 2 weeks for 26 weeks and were followed 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, including 16 deaths, 78 hospitalizations, and 10 emergency department visits. Results are summarized in Table 10. A composite score of 3 ICG parameters was a predictor of an event during the next 14 days ($p<0.001$).

Table 10. Clinical Validity of 3-Level Risk Score for BioZ ICG 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; ER: emergency department; HF: heart failure.

Section Summary: Clinically Valid

Clinical validity of using thoracic bioimpedance/impedance cardiography for patients with chronic heart failure who are at risk of developing acute decompensated heart failure has not been established. Association studies are insufficient evidence to determine whether thoracic bioimpedance/impedance cardiography can improve outcomes patients with chronic heart failure who are at risk of developing acute decompensated heart failure. There are no studies reporting the clinical validity in terms of sensitivity, specificity, or predictive value; therefore it is not

possible to construct an indirect chain of evidence to determine the impact of thoracic bioimpedance/impedance cardiography on predictive decision making.

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 randomized controlled trials.

Table 11. 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)

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

Table 12. Summary of Key Nonrandomized Study Results

Study	HFH (events/patient/3 mo)	Deaths
Amir et al (2017)20	50	50
Pre-90-day period (control)	0.04	NA
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); 0.01a • 0.11 (0.014 to 0.88); 0.037b	

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 clinical validity of using thoracic bioimpedance/impedance cardiography has not been proven, a chain of evidence to build a case for clinical utility cannot be made.

Section Summary: Clinical Utility
Clinical utility of using thoracic bioimpedance/impedance cardiography for patients with chronic heart failure who are at risk of developing acute decompensated heart failure has not been established. One prospective longitudinal study reported ReDS-guided management reduced heart failure readmissions in acute decompensated heart failure patients recently discharged from the hospital. However, interpretation of results is uncertain due to the lack of concurrent control and randomization, short-term follow-up, large confidence intervals, and lack of clarity about

lost-to-follow-up during the post-ReDS period. An RCT comparing ReDS monitoring with standard of care was initiated but terminated prior to 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 to (1) guide volume management, (2) identify physiologic changes that precede clinical symptoms and thus allow preventive interventions, and (3) 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 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 acute decompensated heart failure.

Interventions

The test being considered is inert gas breathing.

Comparators

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

Outcomes

The general outcomes of interest are 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

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 for clinically validity were identified that determined how use of inert gas rebreathing measurements are helpful in detecting the likelihood of decompensation.

Section Summary: Clinically Valid
Clinical validity of using inert gas breathing for patients with chronic heart failure who are at risk of developing acute decompensated heart failure has not been established as no studies were identified.

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 randomized controlled trials. No studies were identified that determined how use of inert gas rebreathing measurements is associated with changes in patient management or evaluated 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 clinical validity of using inert gas breathing has not been proven, an indirect chain of evidence to build a case for clinical utility cannot be made.

Section Summary: Clinically Valid
No studies of clinical utility were identified that determined how use of inert gas breathing measurements in managing heart failure affects patient outcomes. We did not construct chain of evidence on the clinical utility of inert gas breathing measurement devices because it is unclear how these devices will improve patient outcomes.

Noninvasive left ventricular End Diastolic Pressure Estimation Methods
Clinical Context and Test Purpose
The purpose of noninvasive left ventricular end diastolic pressure estimation methods in patients who have heart failure in an outpatient setting is to (1) guide volume management, (2) identify physiologic changes that precede clinical symptoms and thus allow preventive interventions, and (3) prevent hospitalizations.

The question addressed in this evidence review is does use of noninvasive left ventricular end diastolic pressure estimation methods improve health outcomes in individuals with heart failure in 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 acute decompensated heart failure.

Interventions
The test being considered is noninvasive left ventricular end diastolic pressure estimation methods.

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

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

Timing
Trials of using noninvasive left ventricular end diastolic pressure estimation methods in this population were not found. Generally, demonstration of outcomes over a 1-year period is meaningful for interventions.

Setting
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.21 Left ventricular end-diastolic pressure (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 Valsalva maneuver was 85% sensitive (95% confidence interval [CI], 54% to 97%) and 80% specific (95% CI, 56% to 93%).

Section Summary: Clinically Valid
One study reported 85% sensitivity and 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 randomized controlled trials. No studies were identified that determined how use of noninvasive left ventricular end diastolic pressure estimation methods is associated with changes in patient management or evaluated 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 clinical validity of using noninvasive left ventricular end diastolic pressure estimation methods has only been demonstrated in a small single study, an indirect chain of evidence to build a case for clinical utility cannot be made.

Section Summary: Clinically Valid
No studies of clinical utility were identified that determined how use of noninvasive left ventricular end diastolic pressure estimation methods in managing heart failure affects patient outcomes. We did not construct chain of evidence on the clinical utility of noninvasive left ventricular end diastolic pressure estimation methods because it is unclear how these devices will improve patient outcomes.

Summary of Evidence
For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring with an implantable pulmonary artery pressure sensor device, the evidence includes randomized controlled trials (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. Food and Drug Administration 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, the 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 manufacture conducted multiple analyses to address the issue of potential bias from the nurse interventions. These were reviewed favorably by FDA. While these analyses demonstrated consistency of benefit from the CardioMEMS device, all such analyses have methodologic limitations. Early safety data is suggestive of a higher rate of procedural complications, particularly related to pulmonary artery injury. Given that the intervention is invasive, 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 of these issues may be clarified from the results of an ongoing postmarketing study that is currently ongoing and proposes to enroll

1200 patients with at least 35% women. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have heart failure in outpatient setting 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 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.

Practice Guidelines and Positions Statements

American College of Cardiology et al

The 2017 joint guidelines by the American College of Cardiology, American Heart Association, and Heart Failure Society of America on the management of heart failure offered no recommendations for use of ambulatory monitoring devices.

European Society of Cardiology

The European Society of Cardiology guidelines on the diagnosis and treatment of acute and chronic heart failure state the following: "Monitoring of pulmonary artery pressures using a wireless implantable hemodynamic monitoring system (CardioMEMS) may be considered in symptomatic patients with heart failure with previous heart failure hospitalization in order to reduce the risk of recurrent heart failure hospitalization (Class IIb Level B recommendation)."

National Institute for Health and Clinical Excellence

The updated 2010 guidance from the National Institute for Health and Care Excellence (NICE) on chronic heart failure management did not include outpatient hemodynamic monitoring as a recommendation. This guidance is under review and update and is expected in August 2018.

In 2013, NICE issued guidance on the insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure. The recommendations concluded that "Current evidence on the safety and efficacy of the insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure is limited in both quality and quantity"

U.S. Preventive Services Task Force Recommendations

Not applicable

Key Words:

Thoracic electrical bioimpedance, TEB, impedance cardiography, ICD, cardiac output, CO, thermodilution, inert gas rebreathing, BioZ®, Innocor, VeriCor®, Endosure®, Implantable Direct Pulmonary Artery Pressure, Left Ventricular End Diastolic Pressure, LVEDP,

Noninvasive Measurement, CardioMEMS, thoracic bioimpedance, TEBCO®, IQ™, Zoe®, Cheetah NICOM®, PhysioFlow®, Cardiography

Approved by Governing Bodies:

Noninvasive Left Ventricular End Diastolic Pressure Measurement Devices

In June 2004, the VeriCor® (CVP Diagnostics, Boston, MA), a noninvasive left ventricular end diastolic pressure measurement device, was cleared for marketing by the U.S. Food and Drug Administration (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."

Thoracic Bioimpedance Devices

Multiple thoracic impedance measurement devices that do not require invasive placement have been cleared for marketing by the U.S. Food and Drug Administration (FDA) 510(k) process. FDA determined that this device was substantially equivalent to existing devices for use 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
BioZ ® Thoracic Impedance Plethysmograph	SonoSite (Bothell, WA)	2009
Zoe® Fluid Status Monitor	Noninvasive Medical Technologies LLC (Las Vegas, NV)	2004
Cheetah Starling SV	Cheetah Medical Inc.	2008
Physioflow® Signal Morphology-based Impedance Cardiography (SM-ICG™)	Vasocom Inc., now Neumedx Inc. (Bristol, PA)	2008
ReDS™ Wearable System	Sensible Medical Innovations (Philadelphia, PA)	2015

FDA: U.S. Food and Drug Administration.

In 2007, the NEXFIN HD™ Continuous Noninvasive Hemodynamic Monitor (BYMEYE, now Edwards Lifesciences, Irvine, CA), which uses an inflatable finger cuff with a built-in photoelectric plethysmograph that calculates estimated cardiac output from continuous blood pressure monitoring, was cleared for marketing by FDA through the 510(k) process. Other noninvasive monitors that derive cardiac output estimates from measured parameters exist, but not all are designed for use 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.

Inert Gas Rebreathing Devices

In March 2006, the Innocor® (Innovision, Denmark), 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 May 2014, the CardioMEMS™ Champion Heart Failure Monitoring System (CardioMEMS, now St. Jude Medical, St. Paul, MN) was cleared for marketing by FDA through the premarket approval process. This device consists of an implantable pulmonary artery (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 decided that there was no reasonable assurance that the discussed monitoring system would be effective, particularly in certain subpopulations, although it was agreed that 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, Minneapolis, MN), which includes a sensor implanted in the right ventricular outflow tract, and the ImPressure® device (Remon Medical Technologies, Caesara, Israel), which includes a sensor implanted in the PA.

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

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT Codes:

There is a specific CPT code for bioimpedance:

93701 Bioimpedance-derived physiologic cardiovascular analysis

Inert gas rebreathing measurement and LVEDP should be reported using the unlisted code 93799.

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

93799 Unlisted cardiovascular service or procedure

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Policy History:

Medical Policy Group, July 2010 **(1)**
Medical Policy Administration Committee, July 2010
Available for comment July 23-September 6, 2010
Medical Policy Group, July 2011 **(1):** Update to Key Points, Approved by Governing Bodies and References
Medical Policy Group, August 2011 **(1):** Merge policy #363 onto this policy related to non-invasive measurement of LVEDP in outpatient setting and archive policy #363
Medical Policy Administration Committee, August 2011
Medical Policy Group, July 2012 **(1):** Update to Key Points and References related to MPP update; no change to policy statement
Medical Policy Group, July 2013 **(4):** 2013 Update to Description, Key Points and References

Medical Policy Panel, July 2014
Medical Policy Group, July 2014 **(4):** 2014 Update to Description, Approved Governing Bodies, Key Points, Key Words, & References; no change in policy statement
Medical Policy Group, September 2014 **(3):** October Quarterly Coding Update – added to current coding section code C9741 & description with effective date 10/1/14
Medical Policy Group, November 2014: Annual Coding update. Added HCPC code C2624 to current coding, effective date01/01/15; also updated C9741 with the removal of "includes provision of patient home electronics unit".
Medical Policy Panel, July 2015
Medical Policy Group, July 2015**(4):** Updates to Description, Key Points, Key Words and References. No change to policy statement.
Medical Policy Panel, May 2016
Medical Policy Group, May 2016 (**4**): Updates to Description, Key Points and References. No change to policy statement.
Medical Policy Panel, May 2017
Medical Policy Group, June 2017 **(4)**: Updates to Description, Key Points, Approved by Governing Bodies, Coding and References. No change to policy statement. Removed Previous CPT coding 0104T and 0105T that were deleted 1/1/11 and removed HCPCs codes C2624 and C9741.
Medical Policy Panel, May 2018
Medical Policy Group, May 2018 **(4):** Updates to Description, Key Points, Approved by Governing Bodies, and References. No change to policy statement.
