Noninvasive Measurement of Cardiac Bioimpedance in the Outpatient Setting

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This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and be updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

DESCRIPTION

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 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.

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 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 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. One method is reviewed here: thoracic bioimpedance. Use of thoracic bioimpedance is not widespread because of several limitations making it difficult to confirm validity and lack of large randomized controlled trials to evaluate treatment decisions guided by this hemodynamic monitor.

Bioimpedance is defined as the electrical resistance of tissue to the flow of current. Cardiac bioimpedance, also referred to as thoracic electrical bioimpedance (TEB) or impedance cardiography (ICG), uses change in impedance by an alternating current applied across the thorax to determine various hemodynamic parameters, including stroke volume, cardiac output, and thoracic fluid content. The technology utilizes voltage changes in the flow of thoracic electrical impulses to estimate changes in the blood volume in the aorta and changes in fluid volume in the thorax. The current is introduced by electrodes placed on both sides of the neck and both sides of the lower thorax. 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 the bioimpedance, resulting from the pulsatile changes in volume and velocity of blood in the aorta, are inversely proportional to the stroke volume (cardiac output equals the stroke volume times the heart rate).

The noninvasive nature of cardiac bioimpedance has prompted interest in the use of this technology in a variety of outpatient applications. It has been proposed as a technique to determine cardiac versus non-cardiac causes of dyspnea; promote optimization of drug therapy in patients with heart failure or hypertension. Prognostic values have been

studied in relationship to heart failure in profiling survivors versus non-survivors and in association with the need of hospitalization.

Clinical Context and 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.

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

Interventions
The test being considered is thoracic bioimpedance.

Bioimpedance is defined as the electrical resistance of current flow through tissue. For example, when small electrical signals are transmitted through the thorax, the current travels along the blood-filled aorta, which is the most conductive area. Changes in bioimpedance, measured during each beat of the heart, are inversely related to pulsatile changes in volume and velocity of blood in the aorta. Cardiac output is the product of stroke volume by heart rate 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.

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 (QOL).

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

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).

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.

A number of early studies evaluated the accuracy of thoracic bioimpedance compared with other methods of cardiac output measurements, in both the outpatient and inpatient settings. In 2002, the Agency for Health Care Research and Quality (AHRQ) published a technology assessment on thoracic electrical bioimpedance (TEB) to evaluate data on the clinical effectiveness for several cardiovascular applications: patients with suspected or known cardiovascular disease; acute dyspnea; pacemakers; inotropic therapy; post-heart transplant evaluation; cardiac patients with a need for fluid management; and hypertension. A systematic review and meta-analysis of the TEB literature was conducted. The authors concluded that limitations in the available studies did not allow meaningful conclusions concerning the accuracy of thoracic electrical bioimpedance (TEB) compared with other hemodynamic parameters. There is also little conclusive evidence regarding TEB's usefulness in the specific clinical areas addressed. This was largely due to the lack of focus on clinical outcomes by researchers in this area. The clinical reports on the use of TEB for a variety of clinical indications in reports published from 1991 onwards suggested that this non-invasive method is of interest and may potentially support some of these indications, but there is little evidence that directly addressed how this monitoring technique can affect patient outcomes.

Several small case series have reported variable results regarding the relation between measurements of cardiac output determined by thoracic bioelectrical impedance and thermodilution techniques.

Numerous studies have assessed the association between thoracic bioimpedance measurements and heart failure-related outcomes:

(2019) Sato et al reported on a prospective single-center study on bioelectrical impedance analysis (BIA) in the management of heart failure (HF) in adult patients with congenital heart disease to clarify the correlation between BIA and HF severity as well as the prognostic value of BIA in adult patients with CHD. This prospective single-center study included 170 patients with CHD admitted between 2013 and 2015. We evaluated BIA parameters (intra- and extracellular water, protein, and mineral levels, edema index [EI, extracellular water-to-total body water ratio]), laboratory values, and HF-related admission prevalence. Patients with New York Heart Association (NYHA) functional classes III-IV had a higher EI than those with NYHA classes I-II (mean ± SD, 0.398 ± 0.011 vs 0.384 ± 0.017, $P < .001$). EI was significantly correlated with brain natriuretic peptide level ($r = 0.51$, $P < .001$). During the mean follow-up period of 7.1 months, Kaplan-Meier analysis showed that a discharge EI > 0.386, the median value in the present study, was significantly associated with a future increased risk of HF-related admission (HR = 4.15, 95% CI = 1.70－11.58, $P < .001$). A body weight reduction during hospitalization was also related to EI reduction. The authors concluded, EI determined using BIA could be a useful marker for HF severity that could predict future HF related admissions in adult patients with CHD.

(2017) Amir et al tested whether remote dielectric sensing (ReDS) directored fluid management reduces readmissions in patients recently hospitalized for heart failure (HF). Pulmonary congestion is the most common cause of worsening HF leading to hospitalization. Accurate remote monitoring of lung fluid volume may guide optimal treatment and prevent re-hospitalization. ReDS technology is a quantitative non-invasive method for measuring absolute lung fluid volume. Patients hospitalized for acute decompensated HF were enrolled during their index admission and followed at home for 90 days post-discharge. Daily ReDS readings were obtained using a wearable vest and were used as a guide to optimizing HF therapy, with a goal of maintaining normal lung fluid content. Comparisons of the number of HF hospitalizations during ReDS-guided HF therapy were made, both to the 90 days prior to enrollment and to the 90days following discontinuation of ReDS monitoring. Fifty patients were enrolled, discharged, and followed at home for 76.9 ± 26.2days. Patients were 73.8 ± 10.3years old, 40% had LVEF above 40%, and 38% were women. Compared to the pre- and post-ReDS periods, there were 87% and 79% reductions in the rate of HF hospitalizations, respectively, during ReDS-guided HF therapy. The hazard ratio between the ReDS and the pre-ReDS period was 0.07 (95% CI [0.01-0.54] p=0.01), and between the ReDS and the post-ReDS period was 0.11 (95% CI [0.014-0.88] p=0.037). The authors concluded; these findings suggest that ReDS-guided management has the potential to reduce HF readmissions in acute decompensated HF patients recently discharged from the hospital.

(2017) Lyons et al reported on noninvasive bioelectrical impedance for predicting clinical outcomes in outpatients with heart failure. Noninvasive bioelectrical impedance analysis (BIA) has shown promise in acute heart failure (HF) management. To our knowledge, its use in predicting outcomes in outpatients with chronic HF patients has not been well described. BIA assessment of edema index was performed in 359 outpatients with HF using the InBody 520 scale. Edema index was calculated by dividing extracellular by total body water. Patients were stratified into those with low (≤0.39) and high (>0.39) edema indices. The outcome of interest was death, urgent transplant, or ventricular assist device over 2-year follow up. Patients with a high edema index were older, had higher B-type natriuretic peptide values and New York Heart Association Class. Patients with a high edema index had poorer outcomes (unadjusted hazard ratio 1.90, 95% confidence intervals 1.05-3.56). However, in multivariate analyses, a high edema index was not an independent predictor of outcomes (adjusted hazard ratio 1.21, 95% confidence interval 0.51-2.90). The authors concluded, a high edema index using a bioimpedance scale in a HF clinic correlated with patient outcomes in unadjusted analyses but was not a predictor of outcomes once other measures of HF severity are accounted for. As a noninvasive measure of volume status, use of BIA in a HF clinic may be beneficial in determining patient prognosis and treatment when other outcome predictors are not immediately available.

(2012) Anand et al reported results on the Multi-Sensor Monitoring in Congestive Heart Failure (MUSIC) Study, a non-randomized prospective study designed to develop and validate an algorithm for the prediction of acute heart failure decompensation using a

clinical prototype of the MUSE system, multisensory system that includes intrathoracic bioimpedance measurements, along with electrocardiographic and accelerometry data. This study enrolled 543 heart failure patients (206 in the development phase, 337 in the validation phase) with an ejection fraction $\leq$ 40% and a recent heart failure admission. Patients were remotely monitored for 90 days using multisensory device. There was a high rate of study dropout: 229 (42% of the total) primarily due to withdrawal of consent or failure of the prototype device to function. 314 patients (114 in the development phase, 200 in the validation phase) were included in the analysis. Subjects were assessed for the development of an acute heart failure decompensation event (ADHF), which was defined as any of the following: (1) any heart failure related hospitalization, emergency department or urgent care visit that required administration of IV diuretics, inotropes, or ultrafiltration for fluid removal; (2) a change in diuretic directed by the health care provider that included 1 or more of the following: a change in the prescribed diuretic type; an increase in dose of an existing diuretic; or the addition of another diuretic; (3) an ADHF event for which death was the outcome. Development patient data were used to develop a multi-parameter heart failure detection algorithm. Algorithm performance in the development cohort had 65% sensitivity, 90% specificity, and a false positive rate of 0.7 per patient-year for detection of HF events. In the validation cohort, algorithm performance met the prespecified end points with 63% sensitivity, 92% specificity, and a false positive rate of 0.9 per patient-year. The overall rate of significant adverse skin response was 0.4%. The authors concluded using an external multisensory monitoring system, an HF decompensation prediction algorithm was developed that met the prespecified performance end point. Further studies are required to determine whether the use of this system will improve patient outcomes.

(2009) In a sub-analysis of 170 subjects from the ESCAPE study, a multicenter randomized trial to assess pulmonary artery catheter guided therapy in patients with advanced heart failure, Kamath et. al. compared cardiac output estimated with the BioZ thoracic impedance plethysmography device with subsequent heart failure or hospitalization and to directly measured hemodynamics from right heart catheterization in a subset of patients (n=82). The results showed there was modest correlation between ICG (impedance cardiography) and invasively measured cardiac output (r=0.4 to 0.6 on serial measurement). Thoracic fluid content (TFC) measured by ICG was not a reliable measure of pulmonary capillary wedge pressure (PCWP). There was poor agreement between ICG and invasively measured hemodynamic profiles (kappa < 0.1). No ICG variable alone or in combination was associated with outcome. The authors concluded in hospitalized patients with advanced heart failure, ICG provides some information about cardiac output but no left-sided filling pressures. ICG did not have prognostic utility in this patient population.

(2006) Packer et al reported on the use of the potential utility of impedance cardiography (ICG) in predicting clinical decompensation in ambulatory patients with heart failure (HF). This study prospectively evaluated 212 stable patients with HF and a recent episode of clinical decompensation who underwent serial clinical evaluation and blinded ICG testing every 2 weeks for 26 weeks and were followed up for the occurrence of death or

worsening HF requiring hospitalization or emergent care. During the study 59 patients experienced 104 episodes of decompensated HF (16 deaths, 78 hospitalizations, and 10 emergency visits). Multivariate analysis identified 6 clinical and ICG variable that independently predicted an event within 14 days of assessment. These included three clinical variables (visual analog score, New York Heart Association functional class, and systolic blood pressure) and three ICG parameters (velocity index, thoracic fluid content index, and left ventricular ejection time). The composite score of 3 ICG parameters was a predictor of an event during the next 14 days (p=0.0002). Patients noted to have a high-risk composite score at a visit had a 2.5 times greater likelihood of a near-term event, and those with a low-risk score had a 70% lower likelihood of a near-term event compared with patients at intermediate risk. The authors concluded that these results suggested that when performed at regular intervals in stable patients with HF with a recent episode of clinical decompensation, ICG can identify patients at increased near-term risk of recurrent decompensation.

Summary of Evidence

The evidence on cardiac bioimpedance (thoracic electrical bioimpedance (TEB) or impedance cardiography (ICG)) devices consists of nonrandomized studies that correlate measurements with other measures of cardiac function and studies that use bioimpedance measurement as part of an algorithm for predicting future heart failure events. No studies were identified that determined how cardiac bioimpedance measurements are associated with changes in patient management or patient outcomes. Additional randomized clinical trials are needed that evaluate whether prediction of heart failure decompensation through cardiac bioimpedance allows earlier intervention or other management changes are needed to demonstrate that outcomes are improved.

For individuals who have heart failure in the outpatient setting who receive hemodynamic monitoring by cardiac bioimpedance (thoracic electrical bioimpedance [TEB] or impedance cardiography [ICG]), there is lack of randomized clinical trial (RCT) evidence that evaluates whether the use of this technology improves health outcomes over standard active management of heart failure patient. The studies performed report 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 on net health outcomes.

Practice Guidelines and Position Statements

American College of Cardiology Foundation (ACCF), American Heart Association (AHA) and Heart Failure Society of America (HFSA)

(2017) The American College of Cardiology Foundation (ACCF), the American Heart Association (AHA) and the Heart Failure Society of America (HFSA) issued a joint guideline that updates the 2013 ACCF/AHA guideline for the management of heart failure which offers no recommendations for use of ambulatory monitoring devices.

National Institute for Health and Care Excellence (NICE)
(2018) The National Institute for Health and Care Excellence (NICE) updated their guidelines on chronic heart failure management and did not include outpatient hemodynamic monitoring as a recommendation. (*Accessed January 2022*)

Regulatory Status
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) through the 510(k) process. The FDA determined that the device was substantially equivalent to existing devices for use of peripheral blood flow monitoring. The list below includes noninvasive thoracic impedance devices, this is not meant to be a comprehensive list.

Device	Manufacturer	Year of FDA Clearance
BioZ Thoracic Impedance Plethysmograph	SonoSite	1997
Cheetah NICOM System	Cheetah Medical	2008
PhysioFlow Signal Morphology-based Impedance Cardiography (SM-ICG)	Vasocom, now NeuMeDx	2008
ReDS Wearable System	Sensible Medical Innovations	2015
Sorba Steorra® Non-Invasive Impedance Cardiography	Sorba Medical Systems	2001
Zoe Fluid Status Monitor	Noninvasive Medical Technologies	2004

PRIOR APPROVAL

Not applicable.

POLICY

Cardiac bioimpedance (thoracic electrical bioimpedance [TEB] or impedance cardiography [ICG]) in the outpatient setting is considered **investigational** when utilized for cardiac hemodynamic monitoring for the management of heart failure.

For individuals who have heart failure in the outpatient setting who receive hemodynamic monitoring with cardiac bioimpedance (thoracic electrical bioimpedance [TEB] or impedance cardiography [ICG]), there is lack of randomized clinical trial (RCT) evidence that evaluates whether the use of this technology improves health outcomes over standard active management of heart failure patient. The studies performed report 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 net health outcomes.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 93701 Bioimpedance-derived physiologic cardiovascular analysis

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- PhysioFlow Signal Morphology Based Impedance Cardiography (SM-ICG). Also available at https://www.physioflow.com
- ReDS Wearable System. Sensible Medical. Also available at http://www.sensible-medical.com
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POLICY HISTORY

Date	Reason	Action
January 2022	Annual Review	Policy Renewed
January 2021	Annual Review	Policy Renewed
January 2020	Annual Review	Policy Renewed
January 2019	Annual Review	Policy Renewed
January 2018	Annual Review	Policy Renewed
January 2017		New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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