

ELECTRICAL BIOIMPEDANCE FOR CARDIAC OUTPUT MEASUREMENT

Policy Number: CARDIOLOGY 021.18 T2

Effective Date: December 1, 2018

[Instructions for Use](#) ⓘ

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Related Policies

None

APPLICABLE LINES OF BUSINESS/PRODUCTS

This policy applies to Oxford Commercial plan membership.

NON-COVERAGE RATIONALE

Electrical bioimpedance is unproven and not medically necessary for measuring cardiac output due to insufficient evidence of efficacy.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

CPT Code	Description
93701	Bioimpedance-derived physiologic cardiovascular analysis <i>CPT® is a registered trademark of the American Medical Association</i>

DESCRIPTION OF SERVICES

Electrical bioimpedance is a noninvasive measurement tool proposed as a method to measure cardiac output. Measurement of cardiac output is used to evaluate global cardiac function, based on the theory that cardiac output is directly related to cardiac workload. Changes in cardiac output may be used to identify a change in the hemodynamic status of an individual; to confirm the need for or the efficacy of treatment; and may be routinely monitored in critically ill individuals or perioperatively in high-risk individuals.

The principle method for measuring cardiac output is thermodilution catheterization. However, this is an invasive technique that requires placement of a catheter in the pulmonary artery, and as a result, may pose a risk to the individual.

Transthoracic electric bioimpedance (TEB), also called impedance plethysmography or impedance cardiography (ICG), is a noninvasive method that is being evaluated in the measurement of cardiac output. This method involves applying a small electrical current through electrodes placed on the neck and sides of the chest. The pulsatile flow of blood causes fluctuations in the current, and the device calculates cardiac output from the impedance waveform. TEB has

been used as an alternative to invasive methods in the management of several heart-related conditions, including congestive heart failure (CHF), pacemaker calibration and heart transplant.

CLINICAL EVIDENCE

End Stage Renal Disease

In a randomized controlled trial (RCT), Onofriescu et al. (2011) compared results obtained with bioelectrical impedance with conventional clinical assessments for guiding ultrafiltration in patients with end stage renal disease who were undergoing hemodialysis (n=135). The follow-up period was 12 months. Outcomes included various cardiovascular disease risk factors and markers, such as effects on patient blood pressure, state of hydration, and arterial stiffness. Based on the final study results, the overall clinical utility of bioelectrical impedance for guiding ultrafiltration was not clear since some variables were significantly correlated with one another and others were not. Most importantly, there were no direct comparisons between the two study groups using a reference standard. Additional limitations included lack of blinded outcome assessments and lack of information regarding how patients were randomized.

Shin et al. (2017) conducted a retrospective review to evaluate whether phase angle (PA), known as a nutritional marker, can predict various clinical outcomes in 142 patients with end-stage renal disease (ESRD) who were receiving hemodialysis. Using bioelectrical impedance analysis (BIA), PA was obtained every 6 months, and patients were divided into two groups according to baseline PA: group A included patients with PA $\geq 4.5^\circ$, and group B included patients with PA $< 4.5^\circ$. We followed 142 patients for a median of 29 months (12-42 months). The authors identified that a decrease in PA was associated with an increased risk for death that persisted after adjusting for age, sex, and comorbidities (hazard ratio [HR], 0.56; 95% confidence interval [CI], 0.33-0.97). Cardiovascular events were not associated with PA (P = 0.685). In addition, their findings predicted the occurrence of infection, independent of age, sex, and comorbidities (HR, 0.65; 95% CI, 0.45-0.94). In longitudinal analyses, the authors did not find increases in PA over time in patients who had a mean dialysis adequacy ≥ 1.4 , daily protein catabolic rate ≥ 1.2 g/kg, or total carbon dioxide level ≥ 22 mmol/L. They concluded that PA assessed in a simple manner using BIA provides practical information to predict clinical outcomes in ESRD patients on maintenance hemodialysis. Randomized controlled trials with longer term outcomes are needed to validate the use of bioelectrical impedance in this patient population.

Zouridakis et al. (2016) evaluated the impact of bioelectrical bioimpedance analysis (BIA) to correlate the PhA with parameters of oxidative stress in chronic kidney disease. Measurements were recorded from 30 patients (16 men and 14 women) aged 64 ± 14 years before, during, and after dialysis, and in 15 healthy volunteers aged 56 ± 12 years. The phase angle (PhA) was obtained by BIA. The plasma TAC increased significantly (41%, $p < 0.05$). Intracellular total antioxidant capacity (TAC) noted a non-significant increase. Total antioxidant capacity of the patients before and after hemodialysis was significantly lower from the healthy volunteers ($p < 0.05$) showing that ESRD patients are at the state of increased oxidative stress. The PhA increased in significantly positive correlation with plasma TAC at the end of hemodialysis. The process of hemodialysis with biocompatible synthetic membranes and bicarbonate dialysate improved plasma TAC. The positive correlation of PhA with extracellular TAC could evolve to a method of oxidative stress estimation by BIA but further research is needed.

Heart Disease or Heart Failure

In a prospective cohort study, Taylor et al. (2011) compared measures of cardiac output using either continuous electrical bioimpedance cardiography (Physioflow, Neumedx) or direct Fick measurement in children with congenital heart disease undergoing diagnostic cardiac catheterization (n=65). Results generally showed poor to very poor correlation between the two measurements. Study authors concluded that electrical bioimpedance cardiography was unreliable in children with congenital heart disease.

Kamath et al. (2009) conducted a blinded RCT evaluating a subgroup of patients with advanced heart failure (n=170) derived from the Evaluation Study of congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE) trial. Of 170 patients, 82 underwent right heart catheterization. Impedance cardiography was compared with invasively measured hemodynamics by simple correlation analysis and overall impedance cardiography hemodynamic profiles. The study authors also determined whether impedance cardiography measurements were associated with subsequent death or hospitalization within six months of the end of the study. Study results demonstrated that there was modest correlation between impedance cardiography and invasively measured cardiac output. However, thoracic fluid content measured by impedance cardiography was not a reliable measure of pulmonary capillary wedge pressure. There was also poor agreement between impedance cardiography and invasively measured hemodynamic profiles. Results of sensitivity, specificity, positive predictive value, and negative predictive were mostly poor. No individual variable alone or in combination associated with impedance cardiography was associated with outcome. Study authors concluded that impedance cardiography did not have prognostic utility in hospitalized patients with advanced heart failure.

Cotter et al. (2004) published a prospective double-blind comparison of a noninvasive, continuous whole-body bioimpedance system (NICO system) and thermodilution cardiac output determinations in 122 cardiac patients in three different groups: during cardiac catheterization (n = 40); before, during, and after coronary bypass surgery (n = 51); and while being treated for acute congestive heart failure (CHF) exacerbation (n = 31). CO was measured at one time point in patients undergoing coronary catheterization; before, during, and after bypass surgery in patients undergoing coronary bypass surgery; and before and during vasodilator treatment in patients treated for acute heart failure. The overall correlation between the whole-body bioimpedance system cardiac index and the thermodilution cardiac index was $r=0.886$. The authors concluded that whole-body bioimpedance measurements with the NICO system are accurate in rapid, noninvasive measurement and the follow-up of CO in a wide range of cardiac clinical situations.

In a prospective longitudinal cohort trial, Andreas et al. (2016) evaluated the use of bioimpedance cardiography in patients with pregnancy-associated cardiovascular pathologies to determine if it would provide additional outcome-relevant information and serve as a predictive instrument for pregnancy-associated diseases. Cardiac output and concomitant hemodynamic data were recorded bioimpedance cardiography in 242 pregnant women from the 11th–13th week of gestation every 5th week as well as at two occasions post-partum. Cardiovascular adaptation during pregnancy is characterized by distinct patterns which may be altered in women at risk for preeclampsia or reduced birthweight. In the authors' opinion, the assessment of cardiac parameters by bioimpedance cardiography is an option to measure cardiac output in pregnant women without additional risks. Additional studies are needed in this patient population to confirm the applicable use of bioimpedance cardiography.

Leslie et al. (2004) compared thoracic bioimpedance with thermodilution in patients with stable chronic heart failure. A total of 282 paired measurements of cardiac output from 11 patients were evaluated. The study showed a correlation between thoracic bioimpedance and thermodilution but also demonstrated a poor level of agreement. Thoracic bioimpedance underestimated cardiac output compared with thermodilution, and this was greater with higher cardiac outputs. The investigators indicated that the study did not support the use of thoracic bioimpedance in its current form as an alternative to thermodilution in patients with stable chronic heart failure.

Following coronary artery bypass grafting, Kaukinen, et al. (2003) prospectively compared the values obtained by continuous cardiac output monitoring with whole-body impedance cardiography with values measured using the bolus and continuous thermodilution methods (n=20) after coronary artery bypass grafting. The authors found that agreement between whole-body impedance cardiography and bolus thermodilution was slightly inferior to that between the bolus and continuous thermodilution methods.

Nguyen and Squara (2017) reviewed non-invasive monitoring devices for cardiac output in critical care medicine, including electrical bioimpedance. As several physical and anatomical hypotheses are required for bioimpedance, in the authors' opinion, this limits its effectiveness, most notably when there is no association between aortic systolic deformation and the SV (i.e., aortic dissection, aortic prosthesis), when hematocrit is very low, when pulmonary arterial pressure is elevated (for which, correction factors exist) or because of physical abnormalities such as obesity and dehydration. In their review of the literature, the authors found that at least a third of the publications failed to assess bioimpedance as a reliable mean to assess CO. Most studies with positive outcomes took place outside from an ICU setting most often in situations where the absolute value of CO has less importance than relative changes. They concluded that further developments may be required to improve bioimpedance and bioreactance performance focusing on better understanding of the signal composition and better extraction of the aortic expansion signal.

In a systematic review and meta-analysis, Joosten et al. (2017) evaluated the accuracy and precision of non-invasive cardiac output monitoring devices in perioperative medicine including non-invasive pulse contour analysis, thoracic electrical bioimpedance/bioreactance, and CO₂ rebreathing. A total of 37 studies (1543 patients) were included. Mean CO of both methods was 4.78 litres min⁻¹. Bias was presented as the reference method minus the tested methods in 15 studies. Only six studies assessed the random error (repeatability) of the tested device. The overall random-effects pooled bias (limits of agreement) and the percentage error were -0.13 [-2.38 , 2.12] litres min⁻¹ and 47%, respectively. Inter-study sensitivity heterogeneity was high ($I^2=83%$, $P<0.001$). The colleagues concluded that with a wide percentage error, completely non-invasive CO devices are not interchangeable with bolus thermodilution. Additional studies are warranted to demonstrate the role of non-invasive cardiac output monitoring devices in improving the quality of care.

The European Society of Cardiology (ESC) guidelines for the diagnosis and treatment of acute and chronic heart failure do not specifically address electrical bioimpedance as a technique for diagnosing heart failure. The guideline states that imaging and other studies should only be performed when they have a meaningful clinical consequence. (Ponikowski et al., 2016)

Hypertension

Ferrario et al. (2010) conducted a meta-analysis of five studies (n=759), including two RCTs (n=268) and three nonrandomized controlled trials (n=491) evaluating impedance cardiography to guide treatment decisions in hypertensive patients. The combined odds ratio (OR) for the two RCTs was 2.41 (95% CI, 1.44-4.05; P=0.0008) favoring treatment monitoring with impedance cardiography. An OR of 2.41 indicates that impedance cardiography was twice as likely to achieve a goal blood pressure reading than if the technology was not used. More than 65% of patients across all five studies achieved a blood pressure reading of <140/90 mmHg. Study authors concluded that there is clinical utility in using impedance cardiography as an adjunct to treatment decisions for hypertensive patients.

Dyspnea

In a blinded, nonrandomized controlled trial (n=52), Lo et al. (2007) evaluated the diagnostic accuracy of impedance cardiography in differentiating between cardiac and noncardiac causes of dyspnea. Hemodynamic parameters were derived from impedance cardiography and emergency physician opinions. A final diagnosis established by a blinded physician was used as a reference standard. Results showed that impedance cardiography was superior to emergency physician opinion because it was able to distinguish cardiac from noncardiac causes of dyspnea with greater accuracy. Diagnostic accuracy was higher for higher for impedance cardiography compared with emergency physician option for sensitivity (75% vs. 60%), specificity (88% vs. 66%), positive predictive value (79% vs. 52%), and negative predictive value (85% vs. 72%).

In a nonrandomized controlled trial, Peacock et al. (2006) evaluated the impact of impedance cardiography in 89 patients with dyspnea. Physicians documented diagnosis and treatment plans before and after viewing impedance cardiography data. Impedance cardiography data changed the working diagnosis in 12 (13%) patients and medications administered in 35 (39%) patients. For diagnoses categorized as cardiac or noncardiac, the diagnosis obtained with impedance cardiography was identical to the diagnosis obtained using the usual means in 67% of patients. The investigators concluded that impedance cardiography data probably resulted in changes in diagnosis and therapeutic planning during the evaluation of dyspneic patients. However, the accuracy of a diagnosis led by impedance cardiography diagnosis needs to be substantiated by a standardized diagnostic approach.

Génot et al. (2015) conducted a prospective analysis (n=77) of bioimpedance vector analysis (BIVA) for the diagnosis of acute heart failure (AHF) in patients presenting with acute dyspnea to the emergency department (ED). Four parameters were assessed: resistance (R), reactance (Ra), total body water (TBW), and extracellular body water (EBW). Brain natriuretic peptide (BNP) measures and cardiac ultrasound studies were performed in all patients at admission. Patients were classified into AHF and non-AHF groups retrospectively by cardiologists. Of the 4 BIVA parameters, Ra was significantly lower in the AHF compared to non-AHF group (32.7±14.3 vs 45.4±19.7; P<.001). Brain natriuretic peptide levels were significantly higher in the AHF group (1050.3±989 vs 148.7±181.1ng/L; P<.001). Reactance levels were significantly correlated to BNP levels (r=-0.5; P<.001). Patients with different mitral valve Doppler profiles (E/e'≤8, E/e' ≥9 and <15, and E/e'≥15) had significant differences in Ra values (47.9±19.9, 34.7±19.4, and 31.2±11.7, respectively; P=.003). Overall, the sensitivity of BIVA for AHF diagnosis with a Ra cutoff at 39Ω was 67% with a specificity of 76% and an area under the curve at 0.76. However, Ra did not significantly improve the area under the curve of BNP for the diagnosis of AHF (P=not significant). The authors concluded that in this patient population, BIVA was significantly related to the AHF status but did not improve the diagnostic performance for AHF in addition to BNP alone.

The Agency for Healthcare Research and Quality (AHRQ) published a technology assessment on thoracic electrical bioimpedance. The technology assessment was commissioned by the Centers for Medicare and Medicaid Services (CMS) for use in coverage policy revisions. The assessment concluded that there was insufficient evidence for meaningful conclusions on the accuracy or clinical usefulness of electrical bioimpedance. The data provided in the available studies suggested that electrical bioimpedance measurements generally correlated similarly with measurements obtained by other testing modalities. Limitations were noted in most reported studies with a scarcity of articles reporting patient outcomes. CMS issued a decision memorandum announcing their intent to refine their national coverage policy regarding TEB for cardiac-related indications. Based on the review of evidence as a whole, CMS decided to continue coverage for all previously covered indications with only minor wording modifications except for general coverage in persons with suspected or known cardiovascular disease due to the paucity of studies evaluating the impact of TEB in these persons. CMS found no clinical evidence to make any changes in the previous non-coverage indications. (Jordon, 2002)

Professional Societies

American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Failure Society of American (HFSA)

The updated ACC/AHA and HFSA guideline on the management of heart failure in adults does not address electrical bioimpedance. (Yancy et al., 2017)

A number of devices for bioimpedance measurement of cardiac output have been approved for marketing by the FDA as Class II devices. See the following web site for more information (use product code DSB). Available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed April 11, 2018)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2018T0346Q]

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
12/01/2018	<ul style="list-style-type: none">Simplified non-coverage rationale (no change to guidelines)Archived previous policy version CARDIOLOGY 021.17 T2

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.