ELECTRICAL BIOIMPEDANCE FOR CARDIAC OUTPUT MEASUREMENT

Policy Number: 2017T0346N

Effective Date: August 1, 2017

Table of Contents

INSTRUCTIONS FOR USE .......................................................... 1
BENEFIT CONSIDERATIONS .................................................... 1
COVERAGE RATIONALE ............................................................. 1
APPLICABLE CODES ............................................................... 2
DESCRIPTION OF SERVICES .................................................... 2
CLINICAL EVIDENCE ............................................................... 2
U.S. FOOD AND DRUG ADMINISTRATION ............................... 4
CENTERS FOR MEDICARE AND MEDICAID SERVICES ............. 5
REFERENCES ................................................................. 5
POLICY HISTORY/REVISION INFORMATION ............................ 6

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines 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.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Electrical bioimpedance is unproven and not medical necessary for measuring cardiac output.

Definitive patient selection criteria for the use of electrical bioimpedance have not been established for measurement of cardiac output, primarily due to inadequate evidence regarding the impact of cardiac output monitoring on patient management or clinical outcomes. Further research is needed to confirm whether electrical bioimpedance can offer comparable clinical utility regarding cardiac function as thermodilution catheterization (TDC).
Electrical bioimpedance for cardiac output measurement

In a nonrandomized controlled trial, 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 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.

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 nonrandomized controlled trial, 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 who were 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 using 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 value were mostly poor. No individual variable alone or in combination 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.

**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 two times more likely to achieve a goal blood pressure reading than if the technology was not used. More than 65% of patients across all 5 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 the emergency physician opinion.
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 (Jordan, 2002).

**Professional Societies**

**American College of Cardiology (ACC)/American Heart Association (AHA)**
A guideline on the management of heart failure in adults does not include electrical bioimpedance in the recommendations for non-invasive cardiac monitoring (Yancy et al., 2013).

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

**Heart Failure Society of America (HFSA)**
The HFSA practice guideline on heart failure does not specifically address electrical bioimpedance as a technique for diagnosing heart failure (Lindenfeld et al., 2010).

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**
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/pmncfr](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmncfr). (Accessed May 15, 2017)
Additional Product Information
BioZ (CardioDynamics), Cheetah Reliant (Cheetah Medical), AESCULON and ICON (Osypka Medical), LIFEGARD (Analogic), TECBO (Hemo Sapiens, Inc.)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare covers thoracic electrical bioimpedance (TEB) when criteria are met. Refer to the National Coverage Determination (NCD) for Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB) (20.16). Local Coverage Determinations (LCDs) do not exist at this time. (Accessed April 26, 2017)

REFERENCES


**POLICY HISTORY/REVISION INFORMATION**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/01/2017</td>
<td>• Updated supporting information to reflect the most current clinical evidence and references; no change to coverage rationale or list of applicable codes&lt;br&gt;• Archived previous version 2016T0346M</td>
</tr>
</tbody>
</table>