ELECTRICAL BIOIMPEDANCE FOR CARDIAC OUTPUT MEASUREMENT

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INSTRUCTIONS FOR USE

This protocol provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Evidence of Coverage (EOC)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this protocol. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Protocol. Other Protocols, Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Protocols, Policies and Guidelines as necessary. This protocol is provided for informational purposes. It does not constitute medical advice. This policy does not govern Medicare Group Retiree members.

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.

COMMERCIAL & MEDICAID COVERAGE RATIONALE

Electrical bioimpedance is not medically 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).
MEDICARE COVERAGE RATIONALE

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 (20.16) (accessed August 2016). Local Coverage Determinations (LCDs) for Nevada do not exist at this time.

General
Thoracic electrical bioimpedance (TEB) devices, a form of plethysmography, monitor cardiac output by non-invasively measuring hemodynamic parameters, including: stroke volume, systemic vascular resistance, and thoracic fluid status. Under a previous coverage determination, effective for services performed on and after July 1, 1999, use of TEB was covered for the "noninvasive diagnosis or monitoring of hemodynamics in patients with suspected or known cardiovascular disease." In reconsidering this policy, the Centers for Medicare & Medicaid Services (CMS) concluded that this use was neither sufficiently defined nor supported by available clinical literature to offer the guidance necessary for practitioners to determine when TEB would be covered for patient management. Therefore, CMS revised its coverage policy language in response to a request for reconsideration to offer more explicit guidance and clarity for coverage of TEB based on a complete and updated literature review.

Indications and Limitations of Coverage
Nationally Covered Indications
Effective for services performed on and after January 23, 2004, Thoracic Electrical Bioimpedance (TEB) is covered for all of the following uses:

1. Differentiation of cardiogenic from pulmonary causes of acute dyspnea when medical history, physical examination, and standard assessment tools provide insufficient information and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.
2. Optimization of atrioventricular (A/V) interval for patients with A/V sequential cardiac pacemakers when medical history, physical examination, and standard assessment tools provide insufficient information and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.
3. Monitoring of continuous inotropic therapy for patients with terminal congestive heart failure, when those patients have chosen to die with comfort at home, or for patients waiting at home for a heart transplant.
4. Evaluation for rejection in patients with a heart transplant as a predetermined alternative to a myocardial biopsy. Medical necessity must be documented should a biopsy be performed after TEB.
5. Optimization of fluid management in patients with congestive heart failure when medical history, physical examination, and standard assessment tools provide insufficient information and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.

Nationally Non-Covered Indications
Thoracic Electrical Bioimpedance (TEB) is non-covered when used for the patients:
a. With proven or suspected disease involving severe regurgitation of the aorta;

b. With minute ventilation (MV) sensor function pacemakers, since the device may adversely affect the functioning of that type of pacemaker;

c. During cardiac bypass surgery; or,

d. In the management of all forms of hypertension (with the exception of drug-resistant hypertension as outlined below).

All other uses of Thoracic Electrical Bioimpedance (TEB) not otherwise specified remain **non-covered**.

**Other**

Medicare Administrative Contractors have discretion to determine whether the use of TEB for the management of drug-resistant hypertension is **reasonable and necessary**. Drug resistant hypertension is defined as failure to achieve goal blood pressure in patients who are adhering to full doses of an appropriate 3-drug regimen that includes a diuretic. Effective November 24, 2006, after reconsideration of Medicare policy, CMS will continue current Medicare policy for TEB.

There is no Local Coverage Determination for Nevada for Cardiac Output Measurement Thoracic Electrical Bioimpedance (Accessed August 2015).

**For Medicare and Medicaid Determinations Related to States Outside of Nevada:**

Please review Local Coverage Determinations that apply to other states outside of Nevada. [http://www.cms.hhs.gov/mcd/search](http://www.cms.hhs.gov/mcd/search)

**Important Note:** Please also review local carrier Web sites in addition to the Medicare Coverage database on the Centers for Medicare and Medicaid Services’ Website. (Accessed October, 2010)

**DESCRIPTION OF SERVICES**

Electrical bioimpedance is a noninvasive measurement tool designed to measure cardiac output. Measurement of cardiac output is used to evaluate global cardiac function, based on the assumption 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 a patient; to confirm the need for or the efficacy of treatment; and may be routinely monitored in critically ill patients or perioperatively in high-risk patients.

The gold standard for measuring cardiac output is thermodilution catheterization (TDC). 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 patient. Transthoracic electric bioimpedance (TEB), also called impedance plethysmography or impedance cardiography (ICG), is a noninvasive method for measuring 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 is used in the management of several heart-related conditions, including congestive heart failure (CHF), pacemaker calibration, and heart transplant.
**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.

**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 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 = 50); 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.

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.

Patients with 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 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 (Jordan, 2002).

Professional Societies

**American College of Cardiology (ACC)/American Heart Association (AHA)**
A guideline on diagnosing and managing heart failure in adults states that there is no established role for periodic invasive or noninvasive hemodynamic measurements in the management of patients with heart failure (Hunt, 2009).

**European Society of Cardiology (ESC)**
The 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. However, the guidelines do state that management adapted in response to monitoring thoracic impedance with an implantable device has not been shown to improve outcomes. The optimum approach to noninvasive
remote monitoring is uncertain, and randomized controlled trials performed to date have given inconsistent results and do not yet support a guideline recommendation (ESC, 2012).

**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 (HFSA, 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/pmncfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmncfm) (Accessed August 2016)

**Additional product information**

BioZ (CardioDynamics), Cheetah Reliant (Cheetah Medical), AESCULON and ICON (Osypka Medical), LIFEGARD (Analogic), TEBCO (Hemo Sapiens, Inc.)

**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 and Coverage Determination Guidelines may apply.

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<tr>
<th>CPT® Code</th>
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<tr>
<td>93701</td>
<td>Bioimpedance-derived physiologic cardiovascular analysis</td>
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**REFERENCES**


The foregoing Health Plan of Nevada/Sierra Health & Life Health Operations protocol has been adopted from an existing UnitedHealthcare coverage determination guideline that was researched, developed and approved by the UnitedHealthcare Coverage Determination Committee.