INSTRUCTIONS FOR USE

This Medical Policy 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 Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee’s specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit 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

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 (such as maternity benefits), 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 guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage.
Electrical Bioimpedance for Cardiac Output Measurement: Medical Policy (Effective 10/01/2014)

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**COVERAGE RATIONALE**

Electrical bioimpedance is unproven and not medical necessary for the measurement of 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).

**APPLICABLE CODES**

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Description</th>
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<tr>
<td>93701</td>
<td>Bioimpedance-derived physiologic cardiovascular analysis</td>
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**DESCRIPTION OF SERVICES**

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.

**CLINICAL EVIDENCE**

A review was conducted of the available health technology assessments (HTAs), systematic reviews, meta-analyses, and the primary medical literature, all of which evaluated the use of electrical bioimpedance cardiography for measuring cardiac output in patients with serious health conditions.

**Electrical Bioimpedance in 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.
groups using a reference standard. Additional limitations included lack of blinded outcome assessments and lack of information regarding how patients were randomized.

**Electrical Bioimpedance in 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. 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 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 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). 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.

A prospective study involving 53 patients found that the latest impedance cardiography technology for determining cardiac output was less variable and more reproducible in an intrapatient sense than thermodilution. Impedance cardiography was equivalent to the average accepted thermodilution cardiac output in post-coronary artery bypass graft patients. It was in agreement with thermodilution cardiac output compared to measurements made using previous generation impedance cardiography cardiac output equations (Van De Water et al., 2003).
Electrical Bioimpedance in 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.

Electrical Bioimpedance in 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 impedance cardiography compared with the emergency physician opinion 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.

Health Technology Assessments (HTAs)

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 (CMS, 2002).

Summary

Electrical bioimpedance is a noninvasive measurement tool designed to measure cardiac output and may offer advantages compared with conventional invasive measurements. However, there is insufficient evidence in the peer-reviewed medical literature that electrical bioimpedance offers
comparable and clinically-relevant data compared with conventional measurements. Limitations of the evidence include use of surrogate outcome measures, lack of direct comparisons between the technology and an appropriate reference standard to determine diagnostic and prognostic accuracy, and heterogeneity across study outcomes and devices. Many of the assessed studies did not assess the impact of electrical bioimpedance on disease management or the ability to predict important health outcomes, such as cardiovascular events or survival. Adequate patient selection criteria have not yet been established for this technology. Additional well-designed RCTs evaluating clinically relevant health outcomes are necessary to establish the role of this technology in disease management.

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).

The clinical evidence was reviewed in June 2014 with no additional information identified that would change the conclusion.

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. Accessed June 25, 2014

Additional Product Information
BioZ (CardioDynamics), Cheetah Reliant (Cheetah Medical), AESCULON and ICON (Osypka Medical), LIFEGARD (Analogic), TEBCO (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) exist. Refer to the LCDs for Cardiac Output Measurement Thoracic Electrical Bioimpedance, Cardiac Output Monitoring by Electrical Bioimpedance and Cardiac Output Monitoring By Thoracic Electrical Bioimpedance. (Accessed July 10, 2014)
REFERENCES


Smith RD, Levy P, Ferrario CM; Consideration of Noninvasive Hemodynamic Monitoring to Electrical Bioimpedance for Cardiac Output Measurement: Medical Policy (Effective 10/01/2014)


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<thead>
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<th>Date</th>
<th>Action/Description</th>
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<tr>
<td>10/01/2014</td>
<td>• Reorganized policy content</td>
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<tr>
<td></td>
<td>• Added benefit considerations language for Essential Health Benefits for Individual and Small Group plans to indicate:</td>
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<tr>
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<td>• Updated coverage rationale; added language to indicate the unproven service is “not medically necessary”</td>
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