

MEDICAL POLICY

**SUBJECT: NONINVASIVE MEASUREMENT OF
CARDIAC BIOIMPEDANCE**

EFFECTIVE DATE: 04/17/02
**REVISED DATE: 02/20/03, 12/18/03, 12/16/04, 12/15/05,
10/19/06, 08/16/07, 07/17/08**

ARCHIVED DATE: 12/18/08

**EDITED DATE: 11/19/09, 11/18/10, 11/17/11, 11/15/12,
11/21/13, 11/20/14, 11/19/15, 10/20/16,
10/19/17, 10/18/18**

POLICY NUMBER: 6.01.26

CATEGORY: Technology Assessment

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- *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*
- *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.*
- *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT:

Based upon our criteria and review of the peer-reviewed literature, cardiac/thoracic electrical bioimpedance has not been medically proven to be effective and is considered **investigational** in the outpatient setting.

Refer to Corporate Medical Policy # 7.01.91 regarding Implantable Cardiac Hemodynamic Monitoring for Heart Failure.

Refer to Corporate Medical Policy # 11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

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 of 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. 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 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 a variety of outpatient applications. It has been proposed as a technique to: determine cardiac versus noncardiac causes of dyspnea, promote optimization of drug therapy in patients with heart failure or hypertension, provide early detection of rejection in heart transplant recipients, monitor patients with pulmonary hypertension, or optimize the programming of pacemakers. Prognostic values have been studied in relationship to heart failure in profiling survivors versus non-survivors and in association with the need for hospitalization.

RATIONALE:

The BioZ™ (Cardiodynamics, Inc.) and TEBCO® (Thoracic Electrical Bioimpedance Cardiac Output, Hemo Sapiens, Inc) are devices approved by the U.S. Food and Drug Administration (FDA) to measure thoracic bioimpedance.

Most of the studies that evaluated the utility of impedance cardiography reported that the data is reproducible and is correlated with measurements from other techniques such as radionuclide ventriculography and thermodilution. However, the majority of the studies have been on acutely ill patients hospitalized for the management of a medical emergency who were undergoing hemodynamic assessments as part of their care. Studies that have shown significant correlation between thoracic electrical impedance measurements and invasive means of measuring cardiac output/index (thermodilution, Fick method) have had small patient numbers. As a result of small patient numbers, and the use of only high-risk/acutely ill study patients, these studies have not demonstrated whether evaluation of the status of central circulation by impedance

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cardiography can predict clinical events and thus be used to alter treatment and improve outcomes in the outpatient setting.

In 2002, the Agency for Healthcare Research and Quality (AHRQ) published a technology assessment on thoracic electrical bioimpedance (TEB), which concluded that limitations in available studies did not allow the agency to draw meaningful conclusions to determine whether the accuracy of TEB compared to other hemodynamic parameters. The Agency also found a lack of studies focusing on clinical outcomes and little evidence to draw conclusions on patient outcomes for the following clinical areas:

- I. Monitoring in patients with suspected or known cardiovascular disease;
- II. Acute dyspnea;
- III. Pacemakers;
- IV. Inotropic therapy;
- V. Post heart transplant evaluation;
- VI. Cardiac patients with need for fluid management; and
- VII. Hypertension.

The 2009 ACCF/AHA Guidelines for the Diagnosis and Management of Heart Failure in Adults state “There has been no established role for periodic invasive or noninvasive hemodynamic measurements in the management of heart failure. Most drugs used for the treatment of HF [heart failure] are prescribed on the basis of their ability to improve symptoms or survival rather than their effect on hemodynamic variables. Moreover, the initial and target doses of these drugs are selected on the basis of experience in controlled trials and are not based on the changes they may produce in cardiac output or pulmonary wedge pressure.” For patients at high risk for developing heart failure (Stage A) the guidelines recommend “Healthcare providers should perform a noninvasive evaluation of LV function (i.e., LVEF) in patients with a strong family history of cardiomyopathy or in those receiving cardiotoxic interventions. (Level of Evidence: C)”. (Hunt, et al).

The 2013 ACCF/AHA Guideline for the Management of Heart Failure offers no recommendations for use of ambulatory monitoring devices (Yancy, et al).

The evidence on cardiac bioimpedance 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. These monitors have also been part of clinical trials in combination with ICD and/or CRT devices. The evidence does not demonstrate that these devices improve clinical outcomes.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT: 93701 (E/I) Bioimpedance-derived physiologic cardiovascular analysis

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HCPCS: No specific code(s)

ICD10: Investigational for all diagnoses

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* key article

KEY WORDS:

Impedance cardiography, ICG, Thoracic electrical bioimpedance, TEB.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB). Please refer to the following NCD website for Medicare Members:

<https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=267&ncdver=3&bc=AgAAgAAAAAA&>