

# Healthcare Operations Utilization Management Protocol

## Electrical Bioimpedance for Cardiac Output Measurement

HEALTH PLAN OF NEVADA, INC.™ SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC.®

Number  
CAR022

For Sierra Health-Care Options products, please review plan documents prior to issuing a determination.

<b>Description</b>	After evaluating relevant benefit document language (exclusions or limitations), refer to Coverage sections of this document to determine coverage.
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This policy describes the use of electrical bioimpedance, a noninvasive method of determining how much blood the heart pumps during the cardiac cycle. Measurement of cardiac output, by detecting changes in electrical impedance as blood is pumped into the aorta, is performed in patients with a variety of conditions, including cardiovascular disease, severe trauma, hypothermia, multiple organ system failure, or in patients undergoing high-risk surgery.

<b>Coverage</b>	All reviewers must first identify member eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this policy.
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### Commercial Coverage Rationale:

- Electrical bioimpedance is **not medically necessary** for the measurement of cardiac output due to inadequate clinical evidence of safety and/or efficacy in published, peer reviewed medical literature.

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 supply similar information regarding cardiac function, as does thermodilution catheterization (TDC). In the future, depending on the results of research, electrical bioimpedance may be a suitable alternative in patients for whom there is a clear clinical indication for measurement of cardiac output and when TDC is contraindicated, not feasible, or not available.

See the medical policy titled, Plethysmography, for information regarding assessment of body composition, detection of deep vein thrombosis, and measurement of blood flow in extremities or genitalia.

### Medicare & Medicaid Coverage Rationale:

Medicare **National Coverage Determination (NCD)** for thoracic electrical bioimpedance (TEB):

## 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, TEB is **covered** for 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

1. TEB is **non-covered** when used for 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).

2. All other uses of TEB not otherwise specified remain non-covered.

Local Carrier Determination (LCD) policies exist and compliance with these policies are required where applicable: Cardiac Output Measurement Thoracic Electrical Biomepedance (L27564).

### **Indications and Limitations of Coverage and/or Medical Necessity**

#### **1. Abstract:**

Cardiac output determined by thoracic electrical bioimpedance is based upon the resistive changes in the thorax to an applied current. A special device measures electrical impedance during the cardiac cycle after the introduction of a high frequency low amplitude current, by way of surface electrodes placed at the root of the neck and the lower chest. Since impedance changes are related to the flow of blood, stroke volume and cardiac output can be determined. Related hemodynamic parameters such as cardiac index, index of contractility, acceleration index, thoracic fluid content and systemic vascular resistance can also be derived.

For the purposes of this policy, the term cardiac output monitoring determination implies not only cardiac output per se, but all related parameters.

#### **2. Indications:**

Thoracic Electrical Bioimpedance (TEB) **is covered** for 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 is 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. NOTE: Services provided to patients who have elected Hospice are included in the Hospice payment and are not separately billable.

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 is necessary for appropriate management of the patient.

### 3. Limitations:

A) Thoracic Electrical Bioimpedance is **non-covered** per the National Coverage Determination:

1. Thoracic electrical bioimpedance (TEB) is **non-covered** for any of the following specific applications:

- a. Patients with proven or suspected disease involving severe regurgitation of the aorta;
- b. Patients 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. For the management of all forms of hypertension, (with the exception of drug-resistant hypertension [coverage for drug-resistant hypertension is left to contractor discretion and will be denied as not medically necessary based on local coverage determination.]) 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.

2. All other uses of thoracic electrical bioimpedance (TEB) not otherwise specified remain **non-covered**.

B) Additional limitations:

1. The test can be administered by a hospital nurse or technician and does not require performance by a physician. The equipment used to perform this test automatically performs the calculations and prints out a written report with the results. Review of the test results and report for the purpose of patient management is part of the medical decision-making component of E&M services, and is not part of the professional component of this test.
2. The professional component of the service is not covered/reimbursable in the hospital or facility setting, as it does not require performance by a physician.
3. Thoracic electrical bioimpedance for management of drug-resistant hypertension will be denied as not medically necessary.
4. Repeat measurements to monitor or evaluate acute interventions (e.g., for pacemaker evaluation or

adjustment of pacing parameters) will be considered a single service, and be reimbursed only once per day.

5. Tests not ordered by the treating physician will be denied as not medically necessary.

6. Tests not needed or not used in the actual management of the patient will be considered not medically necessary and denied.

7. Tests performed during the course of anesthesia monitoring are part of the anesthesia service and are excluded from reimbursement per the NCD. They will be denied as not medically necessary.

8. Tests performed incident to other diagnostic tests or therapeutic procedures (except for patients treated with inotropic support at home per indication #3) for monitoring are not covered, and are excluded from reimbursement. They will be denied as bundled services when billed with anesthesia services 00100-01999.

9. When monitoring patients who are at home, on continuous inotropic therapy for treatment of terminal congestive heart failure (see indication #3), the testing must be personally performed by the billing physician or under his/her direct supervision.

10. Repeat tests on different days will be considered medically necessary only when indicated by changes in the patient's signs or symptoms, or medical status.

11. This modality will be considered as not medically necessary when performed on patients with stable congestive heart failure (CHF) or cardiomyopathy, or on patients who have not decompensated. Decompensation is defined as a deterioration in the status of a patient's heart failure, wherein the body's endogenous mechanisms and standard of care have failed to optimize the patient's condition, as evidenced by new or worsening signs and symptoms. A patient with stable signs and symptoms is considered to be optimally treated and to not require repeated cardiac output determinations.

- This modality will be considered not medically necessary when performed on patients for the management of hypertension.

12. If the use of bioimpedance is not supported by documented changes in the clinical examination and provide for a level of clinical decision-making beyond the findings of the history and physical examination, then the service will be denied as not medically necessary.

**For Medicare and Medicaid Service 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>

**Regulatory Requirements**

**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:

\* These protocols are to be used as guidelines in the decision-making process and do not represent standards of care of any individual patient. They are proprietary documents and may not be copied or distributed without express permission.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm> . (Accessed October 29, 2008). Use product codes DSB (plethysmograph, impedance) or DXG (computer, diagnostic, pre-programmed, single-function). Not all of the devices under these product codes are indicated for cardiac output monitoring and not all of the devices in product code DXG are indicated for use with impedance cardiography devices. For information on a specific device or manufacturer, search the above Web site by product or manufacturer name and then check for the appropriate indication in the Summary section of the results.

### Research Evidence

Measurement of cardiac output is used as a way 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 or 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.

There is no single universal standard method for measurement of cardiac output; all the available techniques are associated with limitations and significant degrees of error. Currently, the most widely accepted methods for the determination of cardiac output are Fick oximetry, thermodilution catheterization (TDC), and indicator dilution using dye or a radioisotope. All of these techniques depend on the principle of measuring concentration of a known volume of indicator (such as dye, oxygen, or cold liquid) and generally estimate cardiac output over a period of time rather than on a beat-by-beat basis. The potential problem with these techniques is that they are invasive procedures requiring the placement of a catheter.

Transthoracic electric bioimpedance (TEB), also called plethysmography or impedance cardiography (ICG), has been investigated as a noninvasive method for the measurement of cardiac output. Bioimpedance is performed by applying a small electrical current to the chest, and through electrodes placed on the neck and sides. The pulsatile flow of blood causes fluctuations in the current, and the device calculates cardiac output from the impedance waveform. Changes in the impedance of the transthoracic electric current are measured electronically, processed by a computer to calculate blood flow, and displayed in real time. The computer software typically displays cardiac data collected over the preceding seconds or minutes, which allows continuous monitoring of alterations in heart rate, cardiac output, and other cardiovascular functions.

The principal advantages of electrical bioimpedance for measurement of cardiac output are that it allows continuous monitoring and is noninvasive, without the small but definite risk associated with catheterization during TDC. Compared with bioimpedance cardiography, catheterization takes longer to initiate and it requires more highly skilled personnel. Cardiac output measurements are often important in critical situations, such as in hospital emergency rooms and intensive care units, where the difference in time to start bioimpedance monitoring offers a significant advantage over TDC.

A large study by Shoemaker et al. suggests that the continuous monitoring provided by electrical bioimpedance devices might provide information that would allow early recognition of deteriorating hemodynamic status, and thus facilitate timely intervention. (Shoemaker et al., 1998) This hypothesis

was supported by Weiss et al., reporting on a study that compared thermodilution catheterization (TDC) with bioimpedance in the intensive care unit (ICU). They concluded that bioimpedance has a limited ability to measure absolute values of cardiac output, but that it may have a role in monitoring relative changes in cardiac parameters and thereby detecting changes in clinical status. (Weiss et al., 1995)

A multicenter prospective cohort study by Connors et al. failed to document a benefit for cardiac output measurement in critically ill patients receiving care in an ICU. In this study, invasive measurement of cardiac function did not improve outcomes; rather, it was associated with increased mortality and increased utilization of resources. (Connors et al., 1996)

Findings of a study by Velmahos et al. indicate that while hemodynamic status can predict clinical outcomes in critically injured patients, there is no evidence that early interventions to improve hemodynamic values lead to better outcomes. (Velmahos et al., 2000)

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

Kaukinen, et al. reported on the compared values obtained by continuous cardiac output monitoring with whole-body impedance cardiography after coronary artery bypass grafting with values measured using the bolus and continuous thermodilution methods. This prospective study included 20 patients in a university hospital ICU. The authors found that agreement between whole-body impedance cardiography and bolus thermodilution is slightly inferior to that between the bolus and continuous thermodilution methods. (Kaukinen et al., 2003)

Cotter et al. 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. (Cotter et al., 2004)

Raajmakers et al. performed a meta-analysis of 154 studies published prior to May 1997 comparing impedance cardiography with other tests for measuring cardiac output. The authors noted that differences between impedance cardiography and other methods cannot be assumed to represent errors in the impedance measurement because the applied reference method and patient characteristics demonstrated a significant influence on the correlation coefficient. The authors indicated that great care should be used when impedance cardiography is applied to cardiac patients. (Raajmakers et al., 1999)

A randomized controlled trial (RCT) was done to compare impedance cardiography with thermodilution. Length of stay was shorter in the impedance cardiography group and change in treatment occurred in 49% of patients in the impedance cardiography group as compared to 29% of patients in the thermodilution or control group. The investigators concluded that impedance cardiography enhances clinical assessment of cardiac output and improves care of hemodynamically compromised patients. (Stout et al., 2006)

In another RCT, 164 patients with uncontrolled hypertension were randomized to a standard group (n=95) or impedance cardiography group (n=69). Systolic blood pressure and diastolic blood pressure reductions were greater in the impedance cardiography group from baseline. The impedance cardiography group achieved goal blood pressure more frequently and a more aggressive blood pressure level more frequently. The investigators concluded that antihypertensive therapy guided by impedance cardiography is more effective than standard measurements. (Smith et al., 2006)

Peacock et al. evaluated the impact of impedance cardiography in 89 dyspneic patients. Physicians documented diagnosis and treatment plans before and after seeing impedance cardiography data. Impedance cardiography data changed the working diagnosis in 12 (13%) patients and medications administered in 35 (39%) patients. The investigators concluded that impedance cardiography data result in significant changes in diagnosis and therapeutic planning during the evaluation of dyspneic patients. (Peacock et al., 2006)

Two studies compared physician assessment of hemodynamic data to values obtained using impedance cardiography and concluded that impedance cardiography has potential benefit for the assessment of cardiac output. (Van De Water et al., 2005; Neath et al., 2005)

Leslie et al. 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. (Leslie et al., 2004)

#### **Technology Assessments:**

Several other recent controlled trials or comparative studies concluded that impedance cardiography cardiac output closely correlates with standard invasive cardiac output techniques. (Brown et al., 2005; Albert et al., 2004; Suttner et al., 2006; Shoemaker et al., 2006; Karakitsos et al., 2006) Many of the studies evaluating impedance cardiography compare impedance cardiography results with thermodilution results and do not include follow-up or patient health after the tests. (ECRI, 2007)

The available studies provide a moderate level of evidence that, in properly selected patients, electrical bioimpedance devices can provide information about changes in cardiac output similar to that provided by invasive techniques, without the risks associated with arterial or cardiac catheterization. However, a number of factors can interfere with the accuracy of electrical bioimpedance measurements, and

absolute values of cardiac output may not be accurate. Moreover, patient selection criteria have not been clearly defined for measurement of cardiac output using any method, invasive or noninvasive, and unanswered questions remain regarding the appropriate role for cardiac output measurement in patient management and its impact on clinical outcomes. (Hayes, 2003)

### Professional Societies

Agency for Healthcare Research and Quality (AHRQ): AHRQ has published a technology assessment on thoracic electrical bioimpedance. This technology assessment was commissioned by the Centers for Medicare & 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)

## References and Resources

### Resources

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### History/Update Approval

11/13/2008	Medical Technology Assessment Committee
04/24/2009	Corporate Medical Affairs Committee

### Coding

The Current Procedural Terminology (CPT) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service 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.

**CPT Codes**

93701	Bioimpedance, thoracic, electrical
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