

EFFECTIVE DATE: 12|01|2014
POLICY LAST UPDATED: 02|17|2015

OVERVIEW

A variety of outpatient cardiac hemodynamic monitoring devices have been proposed to decrease episodes of acute decompensation in patients with heart failure and thus improve quality of life and reduce morbidity. These devices include bioimpedance, inert gas rebreathing, and estimation of left ventricular end diastolic pressure by arterial pressure during Valsalva or use of an implantable pressure sensor.

PRIOR AUTHORIZATION

BlueCHiP for Medicare

Prior authorization **is required for BlueCHiP for Medicare** only and is obtained via the online tool for participating providers. See the Related Policies section.

Commercial

Not applicable.

POLICY STATEMENT

Thoracic Electrical Bioimpedance (TEB)

BlueCHiP for Medicare

Thoracic electrical bioimpedance is considered medically necessary when the medical criteria in this policy has been met.

Thoracic Electrical Bioimpedance (TEB) is not medically necessary when treatment is used for patients for any of the following indications:

- I. With proven or suspected disease involving severe regurgitation of the aorta;
- II. With minute ventilation (MV) sensor function pacemakers, since the device may adversely affect the functioning of that type of pacemaker;
- III. During cardiac bypass surgery; or,
- IV. In the management of all forms of hypertension (with the exception of drug-resistant hypertension as outlined below).
 - o 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.

All other uses of TEB not otherwise specified remain not medically necessary.

NOTE: Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from CMS (Centers for Medicare and Medicaid Services), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services as Medicare offers.

Commercial

Thoracic electrical bioimpedance is considered **not medically necessary** as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

Inert Gas Rebreathing

BlueCHiP for Medicare and Commercial

Inert gas rebreathing is considered **not medically necessary** as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

MEDICAL CRITERIA

BlueCHiP for Medicare

Thoracic electrical bioimpedance is medically necessary when used for any one of the indications below:

- I. 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.
- II. 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.
- III. 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.
- IV. 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.
- V. 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.

BACKGROUND

Patients with chronic heart failure are at risk of developing acute decompensated heart failure, often requiring hospital admission. Patients with a history of acute decompensation have the additional risk of future episodes of decompensation, and death. Reasons for the transition from a stable, chronic state to an acute, decompensated state include disease progression, as well as acute events such as coronary ischemia and dysrhythmias. While precipitating factors are frequently not identified, the most common preventable cause is noncompliance with medication and dietary regimens. (1) Strategies for reducing decompensation, and thus the need for hospitalization, are aimed at early identification of patients at risk for imminent decompensation. Programs for early identification of heart failure are characterized by frequent contact with patients to review signs and symptoms with a healthcare provider and with education or adjustment of medications as appropriate. These encounters may occur face-to-face in the office or at home, or via transmission telephonically or electronically of symptoms and conventional vital signs, including weight. (2)

Precise measurement of cardiac hemodynamics is often employed in the intensive care setting to carefully manage fluid status in acutely decompensated heart failure. Transthoracic echocardiography, transesophageal echocardiography (TEE), and Doppler ultrasound are noninvasive methods for monitoring cardiac output on an intermittent basis for the more stable patient but are not addressed in this policy. A variety of biomarkers and radiologic techniques may be utilized in the setting of dyspnea when the diagnosis of acute decompensated heart failure is uncertain.

A number of novel approaches have been investigated as techniques to measure cardiac hemodynamics in the outpatient setting. It is postulated that real-time values of cardiac output or left ventricular end diastolic pressure (LVEDP) will supplement the characteristic signs and symptoms and improve the clinician's ability to intervene early to prevent acute decompensation. Four methods are reviewed here: thoracic bioimpedance, inert gas rebreathing, arterial waveform during Valsalva, and implantable pressure monitoring devices.

Thoracic Bioimpedance

Bioimpedance is defined as the electrical resistance of tissue to the flow of current. For example, 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, measured during each beat of the heart, are inversely related to pulsatile changes in volume and velocity of blood in the aorta. Cardiac output is the product of stroke volume by heart rate and, thus can be calculated from bioimpedance. Cardiac output is generally reduced in patients with systolic heart failure. Acute decompensation is characterized by worsening of cardiac output from the patient's baseline status. The technique is alternatively known as impedance +++ and impedance cardiography (ICG).

Inert Gas Rebreathing

This technique is based on the observation that the absorption and disappearance of a blood-soluble gas is proportional to cardiac blood flow. The patient is asked to breathe and rebreathe from a rebreathing bag filled with oxygen mixed with a fixed proportion of two inert gases; typically nitrous oxide and sulfur hexafluoride. The nitrous oxide is soluble in blood and is therefore absorbed during the blood's passage through the lungs at a rate that is proportional to the blood flow. The sulfur hexafluoride is insoluble in blood and therefore stays in the gas phase and is used to determine the lung volume from which the soluble gas is removed. These gases and carbon dioxide are measured continuously and simultaneously at the mouthpiece.

Arterial Pressure during Valsalva to Estimate LVEDP

Left ventricular end diastolic pressure (LVEDP) is elevated in the setting of acute decompensated heart failure. While direct catheter measurement of LVEDP is possible for patients undergoing cardiac catheterization for diagnostic or therapeutic reasons, its invasive nature precludes outpatient use. Noninvasive measurements of LVEDP have been developed based on the observation that arterial pressure during the strain phase of the Valsalva maneuver may directly reflect the LVEDP. Arterial pressure responses during repeated Valsalva maneuvers can be recorded and analyzed to produce values that correlate to the LVEDP.

Pulmonary Artery Pressure Measurement to Estimate LVEDP

LVEDP can also be approximated by direct pressure measurement of an implantable sensor in the pulmonary artery wall. The sensor is implanted via right heart catheterization and transmits pressure readings wirelessly to external monitors.

Different outpatient cardiac hemodynamic monitoring devices have been proposed to decrease episodes of acute decompensation in patients with heart failure and thus improve quality of life and reduce morbidity. These include bioimpedance, inert gas rebreathing, and estimation of left ventricular end diastolic pressure by arterial pressure during Valsalva or use of an implantable pressure sensor.

The largest body of evidence is for direct pulmonary pressure monitors, such as the CardioMEMS device that has FDA-approval. Evidence from randomized controlled trials (RCTs) for various pulmonary artery pressure monitors has demonstrated a correlation between increased pressure readings and increased heart failure event risk. One RCT (the CHAMPION trial) noted that the use of pulmonary artery pressure readings may reduce heart failure-related hospitalizations, but this study was subject to a number of potential biases. Therefore, the evidence is insufficient to form conclusions that the CardioMEMS device is associated with improvements in health outcomes. Studies of other implantable direct pulmonary artery pressure measurement devices have not demonstrated significantly improved outcomes.

For other types of hemodynamic monitoring, there is limited available evidence on efficacy. Randomized controlled trials, as well as studies that specifically address use of ambulatory cardiac hemodynamic monitoring compared with current care are lacking for thoracic bioimpedance, inert gas rebreathing, and arterial pressure/Valsalva techniques. While some evidence suggests that intensive outpatient pulmonary artery pressure monitoring may reduce hospitalizations for patients with heart failure, convincing evidence that the use of these technologies improves health outcomes over standard, active heart failure patient

management is not available. Therefore, these technologies are considered not medically necessary as there is no proven efficacy.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for limitations of benefits/coverage for diagnostic services and when services are not medically necessary.

CODING

BlueCHiP for Medicare and Commercial

The following code **requires Prior Authorization for BlueCHiP for Medicare** and is considered **not medically necessary for Commercial**.

93701

There is no specific code for Inert gas rebreathing measurement and should be reported using the unlisted code:

93799

RELATED POLICIES

Preauthorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, April 2015

Provider Update, January 2015

Provider Update, January 2014

Provider Update, December 2010

Provider Update, July 2009

Policy Update, July 2008

Policy Update, May 2007

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB) (20.16)
2. Opasich C, Rapezzi C, Lucci D et al. Precipitating factors and decision-making processes of short-term worsening heart failure despite "optimal" treatment (from the IN-CHF Registry). *The American journal of cardiology* 2001; 88(4):382-7.
3. McAlister FA, Stewart S, Ferrua S et al. Multidisciplinary strategies for the management of heart failure patients at high risk for admission: a systematic review of randomized trials. *Journal of the American College of Cardiology* 2004; 44(4):810-9.
4. FDA. Summary of Safety and Effectiveness Data (SSED) -- CardioMEMS HF System. 2014. Available online at: http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100045b.pdf. Last accessed June 12, 2014.
5. Loh JP, Barbash IM, Waksman R. Overview of the 2011 Food and Drug Administration Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting on the CardioMEMS Champion Heart Failure Monitoring System. *Journal of the American College of Cardiology* 2013; 61(15):1571-6.
6. Belardinelli R, Ciampani N, Costantini C et al. Comparison of impedance cardiography with thermodilution and direct Fick methods for noninvasive measurement of stroke volume and cardiac output during incremental exercise in patients with ischemic cardiomyopathy. *The American journal of cardiology* 1996; 77(15):1293-301.
7. Shoemaker WC, Wo CC, Bishop MH et al. Multicenter trial of a new thoracic electrical bioimpedance device for cardiac output estimation. *Critical care medicine* 1994; 22(12):1907-12.

8. Sageman WS, Amundson DE. Thoracic electrical bioimpedance measurement of cardiac output in post-aortocoronary bypass patients. *Critical care medicine* 1993; 21(8):1139-42.
9. Doering L, Lum E, Dracup K et al. Predictors of between-method differences in cardiac output measurement using thoracic electrical bioimpedance and thermodilution. *Critical care medicine* 1995; 23(10):1667-73.
10. Raisinghani A, Diaco DN, Sageman SW et al. Raisinghani A DN, Sageman SW et al. The COST study: a multicenter trial comparing measurement of cardiac output by thoracic bioimpedance and thermodilution. *American College of Cardiology 47th Annual Scientific Sessions*. 1998.
11. Kamath SA, Drazner MH, Tasissa G et al. Correlation of impedance cardiography with invasive hemodynamic measurements in patients with advanced heart failure: the BioImpedance CardioGraphy (BIG) substudy of the Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE) Trial. *American heart journal* 2009; 158(2):217-23.
12. Packer M, Abraham WT, Mehra MR et al. Utility of impedance cardiography for the identification of short-term risk of clinical decompensation in stable patients with chronic heart failure. *Journal of the American College of Cardiology* 2006; 47(11):2245-52.

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