

Medical Coverage Policy | Cardiac Hemodynamic Monitoring



EFFECTIVE DATE: 09|04|2003

POLICY LAST UPDATED: 10|15|2013

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

Prior Authorization is required for BlueCHiP for Medicare only

POLICY STATEMENT

BlueCHiP for Medicare:

Thoracic electrical bioimpedance

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.

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. 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

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

**BlueCHiP for Medicare and Commercial:
Inert gas rebreathing**

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 members:

Thoracic electrical bioimpedance is covered for **BlueCHiP for Medicare ONLY** for the following uses:¹

- 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 evidence is not sufficient to determine that hemodynamic monitoring of patients with heart failure improves outcomes. Evidence from randomized controlled trials for invasive pulmonary artery pressure monitoring has demonstrated a correlation between increased pressure readings and increased heart failure event risk. However, the optimal filling pressures and threshold readings for event avoidance have not been established. One report from the CHAMPION RCT noted that pressure readings may be used to reduce

heart failure-related hospitalizations. However, this trial was single-blinded, and the decision to hospitalize patients may have been influenced by knowledge of group assignment. The REDUCEhf study was also single-blinded but reported no differences in heart failure event rates, including hospitalizations, emergency department visits, and urgent clinic visits, despite the inclusion of pressure monitoring readings in treatment planning. Also, the surgical risks of pressure monitoring devices must be balanced with improvements in net health outcomes and compared longer-term with outcomes of traditional management. Finally, FDA-approval for invasive pulmonary artery pressure monitoring devices has been denied.

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, subscriber agreement, or benefit booklet for services not medically necessary and diagnostic services.

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

None

PUBLISHED

Provider Update	Jan 2014
Provider Update	Dec 2010
Provider Update	July 2009
Policy Update	July 2008
Policy Update	May 2007
Policy Update	April 2006

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