Medical Policy
Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting

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Policy Number: 287
BCBSA Reference Number: 2.02.24
NCD/LCD: National Coverage Determination (NCD) for Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB) (20.16)

Related Policies
- Biventricular Pacemakers for the Treatment of Heart Failure, #101
- Wireless Pressure Sensors in Endovascular Aneurysm Repair, #306

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Cardiac hemodynamic monitoring for the management of heart failure utilizing thoracic bioimpedance, inert gas rebreathing, arterial pressure/Valsalva, and implantable direct pressure monitoring of the pulmonary artery in the ambulatory care and outpatient setting is INVESTIGATIONAL.

This policy only addresses use of these techniques in ambulatory care and outpatient settings.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

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.

D. Other
Medicare Administrative Contractors have discretion to determine whether the use of TEB for the management of drug-resistant hypertension is reasonable and necessary. 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. Effective November 24, 2006, after reconsideration of Medicare policy, CMS will continue current Medicare policy for TEB.

National Coverage Determination (NCD) for Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB) (20.16)

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
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<tr>
<th>Outpatient</th>
<th>Commercial Managed Care (HMO and POS)</th>
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<td>Commercial PPO and Indemnity</td>
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CPT Codes / HCPCS Codes / ICD Codes
Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following CPT and HCPCS codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO and Indemnity:
CPT Codes

<table>
<thead>
<tr>
<th>CPT codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>93701</td>
<td>Bioimpedance-derived physiologic cardiovascular analysis.</td>
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HCPCS Codes

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<tr>
<th>HCPCS codes</th>
<th>Code Description</th>
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<tr>
<td>C2624</td>
<td>Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components.</td>
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<tr>
<td>C9741</td>
<td>Right heart catheterization with implantation of wireless pressure sensor in the pulmonary artery, including any type of measurement, angiography, imaging supervision, interpretation, and report, includes provision of patient home electronics unit.</td>
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Description

Patients with chronic heart failure are at elevated risk of developing acute decompensated heart failure, often requiring hospital admission. Patients with a history of acute decompensation have additional risk of future episodes of decompensation, and death. 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.

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 new outpatient devices include bioimpedance, inert gas rebreathing, and estimating left-ventricular end-diastolic pressure by arterial pressure during Valsalva or use of an implantable pressure sensor.

Thoracic Bioimpedance

Bioimpedance is defined as the electrical resistance of tissue to the flow of current. 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.

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. 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. 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 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.
Examples of cardiac hemodynamic monitoring devices for management of heart failure in the outpatient setting include the "BioZ®" from SonoSite, the "Innocor®" from Innovision, and the “VeriCor®” from CVP Diagnostics. All cardiac hemodynamic monitoring devices for management of heart failure in outpatient settings are considered investigational regardless of the commercial name, the manufacturer or FDA approval status except when used for the medically necessary indications that are consistent with the policy statement.

Summary
The quality of the evidence for most categories of hemodynamic monitoring remains limited. 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 re-breathing, and arterial pressure/Valsalva techniques.

Evidence from randomized controlled trials is emerging for invasive pulmonary artery pressure monitoring. One report from the CHAMPION RCT reports 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. 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 is lacking for these devices at the present time. While this preliminary evidence suggests that intensive outpatient monitoring and follow-up for patients with heart failure may benefit patients with heart failure, convincing evidence that the use of these technologies improves outcomes cannot be supported at the present time. Therefore the technology remains investigational.

Policy History

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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References