Cardiac Hemodynamic Monitoring in the Outpatient Setting

**Description of Procedure or Service**

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. Monitors can identify physiologic changes that precede clinical symptoms and thus allow early intervention to prevent decompensation. These devices operate through a variety of mechanisms, including implantable pressure sensors, thoracic bioimpedance measurement, inert gas rebreathing, and estimation of left-ventricular end-diastolic pressure by arterial pressure during Valsalva maneuver.

**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 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 coronary ischemic events and dysrhythmias. While precipitating factors are frequently not identified, the most common preventable cause is noncompliance with medication and dietary regimens. 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 office or in home, or via transmission of symptoms and conventional vital signs, including weight, telephonically or electronically.

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 radiological 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. Five methods will be reviewed here: thoracic bioimpedance, inert gas rebreathing, arterial waveform during Valsalva, and implantable left atrial and implantable pressure monitoring devices.

**Thoracic Bioimpedance**
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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 at 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 plethysmography 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.

**Left Ventricular End Diastolic Pressure Estimation Methods**

**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 left ventricular end diastolic pressure is possible for patients undergoing cardiac catheterization for diagnostic or therapeutic reasons, its invasive nature precludes its 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 or right ventricular outflow tract. The sensor is implanted via right heart catheterization, and transmits pressure readings wirelessly to external monitors. One device, the CardioMEMS Champion Heart Failure Monitoring System has approval from the FDA for the ambulatory management of heart failure patient. The CardioMEMS device is implanted using a heart catheter system fed through the femoral vein and generally requires patients have an overnight hospital admission for observation after implantation.

**Left Atrial Hemodynamic Monitor**

This is an implantable device capable of detecting increases in LAP (left atrial pressure) before clinical deterioration. Direct monitoring of LAP may allow for earlier identification of incipient decompensation prior to clinical symptoms and could make it possible to guide the adjustment of vasodilator and diuretic dosing at an earlier stage.

**Regulatory Status**

The following devices have received specific FDA clearance or approval.

- **Non-invasive thoracic impedance plethysmography devices.** Multiple thoracic impedance measurement devices that do not require invasive placement have been approved through the FDA 510(k) process, based on substantial equivalence to predicate devices that are used for peripheral blood flow monitoring.
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Table 1 includes a representative list of devices, but is not meant to be comprehensive.

<table>
<thead>
<tr>
<th>Table 1: Non-Invasive Thoracic Impedance Plethysmography Devices</th>
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<tbody>
<tr>
<td>Device</td>
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<tr>
<td>------------------------------------------------</td>
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<tr>
<td>TEBCO® (Thoracic Electrical Bioimpedance Cardiac Output)</td>
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<tr>
<td>BioZ ® Thoracic Impedance Plethysmograph</td>
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<tr>
<td>IQ™ System Cardiac Output Monitor</td>
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<td>Sorba Steorra® Non-Invasive Impedance Cardiography</td>
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<td>Zoe® Fluid Status Monitor</td>
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<td>Cheetah NICOM® system</td>
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<tr>
<td>Physioflow® Signal Morphology- based Impedance Cardiography (SM-ICG™)</td>
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<td>ReDS™ Wearable System</td>
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The NEXTFIN HD™ Continuous Noninvasive Hemodynamic Monitor (BYMEYE, now Edwards Lifesciences, Irvine, CA) uses an inflatable finger cuff with a built-in photoelectric plethysmograph, which calculates estimated cardiac output from continuous blood pressure monitoring; it was cleared by FDA through the 510(k) process in 2007. Other noninvasive monitors that derive cardiac output estimates from measured parameters exist, but not all are designed to be used in the outpatient setting.

In addition, several manufacturers market thoracic impedance measurement devices that are integrated into implantable cardiac pacemakers, cardioverter-defibrillator (ICD) devices, and cardiac resynchronization therapy (CRT) devices. With the integrated devices, the electrical resistance of tissue to flow of current is measured using a vector from the right ventricular coil on the lead in the right side of the heart to the implanted cardiac devices; changes in bioimpedance reflect intrathoracic fluid status and are evaluated based on a computer algorithm. These include the CorVue® Thoracic Impedance Monitoring feature (St. Jude Medical, St. Paul, MN) which is integrated in St. Jude Medical’s Unify, Fortify, and Quadra family of cardiac rhythm devices, and the OptiVol® Fluid Status Monitor (Medtronic, Inc., Minneapolis, MN), which is integrated into multiple Medtronic cardiac rhythm devices. The CorVue device was approved by FDA in 2012 as a premarket approval (PMA) supplement, and the OptiVol Fluid Status Monitor’s integration into other devices has been approved through multiple PMA supplements since the device’s pivotal trial results in 2008.

- **Inert gas rebreathing devices.** In March 2006, the Innocor® (Innovision, Denmark) inert gas rebreathing device was cleared for marketing by the FDA through the 510(k) process. Several other inert gas rebreathing devices have been approved through the same process. The FDA determined that this device was substantially equivalent to existing devices for use in computing blood flow.

- **Noninvasive LVEDP measurement devices.** In June 2004, the VeriCor® (CVP Diagnostics, Boston) noninvasive LVEDP measurement device was cleared for marketing.
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by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for the following indication: “The VeriCor is indicated for use in estimating non-invasively, left ventricular end-diastolic pressure (LVEDP). This estimate, when used along with clinical signs and symptoms and other patient test results, including weights on a daily basis, can aid the clinician in the selection of further diagnostic tests in the process of reaching a diagnosis and formulating a therapeutic plan when abnormalities of intravascular volume are suspected. The device has been clinically validated in males only. Use of the device in females has not been investigated.”

- **Implantable pulmonary artery pressure measurement devices.** In May 2014, FDA approved the CardioMEMS™ Champion Heart Failure Monitoring System (CardioMEMS, now St. Jude Medical, St. Paul, MN) through the premarket approval (PMA) process. This device consists of an implantable PA sensor, which is implanted in the distal PA, a transvenous delivery system, and an electronic sensor that processes signals from the implantable PA sensor and transmits PA pressure measurements to a secure database. The device originally underwent FDA review in 2011, at which point the Circulatory System Device Panel decided that there was not reasonable assurance that the discussed monitoring system is effective, particularly in certain subpopulations, although the majority of panel members agreed that the discussed monitoring system is safe for use in the indicated patient population.

Several additional devices that monitor cardiac output through measurements of pressure changes in the PA or right ventricular outflow tract have been investigated in the research setting, but have not received FDA approval. These include the Chronicle® implantable continuous hemodynamic monitoring device (Medtronic, Inc., Minneapolis, MN), which includes a sensor implanted in the right ventricular outflow tract and, and the ImPressure® device (Remon Medical Technologies, Caesara, Israel), which includes a sensor implanted in the PA.

- **Left Atrial Hemodynamic Monitor.** The HeartPOD™ System (Savacor, Inc.) is a medical device that allows the patient to directly monitor left atrial pressure, the intracardiac electrogram, and core body temperature. The implant’s readings are communicated with a hand-held computer called a Patient Advisory Module, or PAM. This information is used to adjust medications on a dose-by-dose basis according to the patient’s prescriptive instructions. This permits real-time adjustment and dosing of medications similar to the way diabetics adjust insulin doses in response to home glucose monitoring. The HeartPOD™ System is not FDA approved at this time.

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

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

**Policy**

Cardiac hemodynamic monitoring in the outpatient setting is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

**Benefits Application**
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This medical policy relates only to the services or supplies described herein. Please refer to the Member’s Benefit Booklet for availability of benefits. Member’s benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Cardiac Hemodynamic Monitoring in the Outpatient Setting is covered

Not applicable.

When Cardiac Hemodynamic Monitoring in the Outpatient Setting is not covered

In the ambulatory care and outpatient setting, cardiac hemodynamic monitoring for the management of heart failure utilizing thoracic bioimpedance, inert gas rebreathing, arterial pressure/Valsalva, implantable direct pressure monitoring of the pulmonary artery, and left atrial hemodynamic monitoring is considered investigational.

Policy Guidelines

For individuals who have heart failure in the outpatient setting and receive hemodynamic monitoring with an implantable pulmonary artery pressure sensor device, the evidence consists of RCTs. Relevant outcomes include overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. One implantable pressure monitor, the CardioMEMS device has FDA-approval. An RCT (the CHAMPION trial) using the CardioMEMS device noted that the use of pulmonary artery pressure readings may reduce heart failure-related hospitalizations, but this trial was subject to a number of potential biases. The trial was single-blinded, with treating clinicians aware of group assignment. The treating clinicians also made decisions on whether to hospitalize patients, which may have been influenced by knowledge of group assignment. Also, patients in the monitoring group received detailed care recommendations from a study nurse, while patients in the control group did not. Further high-quality RCTs are needed to corroborate whether hospitalizations are reduced by use of an implantable pulmonary artery pressure monitor. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have heart failure in the outpatient setting who receive hemodynamic monitoring with thoracic impedance, inert gas rebreathing or arterial pressure during Valsalva, the evidence includes case series. Relevant outcomes include overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. There is a lack of RCT evidence to evaluate whether the use of these technologies improves health outcomes over standard active management of the heart failure patient. The case series report physiologic measurement-related outcomes and the association between monitoring information and heart failure exacerbations, but do not provide definitive evidence on the efficacy of these devices. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.
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Applicable codes: 93701, 93799, 0293T, 0294T, C2624, C9741

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources


Senior Medical Director – 9/2010


Specialty Matched Consultant Advisory Panel review 10/2011

Medical Director review 12/2011


Specialty Matched Consultant Advisory Panel review 10/2012


Specialty Matched Consultant Advisory Panel review 10/2013


Loh JP, Barbash IM, Waksman R. Overview of the 2011 Food and Drug Administration Circulatory
Cardiac Hemodynamic Monitoring in the Outpatient Setting


Medical Director review 8/2014
Senior Medical Director review 11/2014

Specialty Matched Consultant Advisory Panel review 10/2015
Medical Director review 10/2015
Medical Director review 5/2016

Medical Director review 10/2016

Medical Director review 5/2017

Policy Implementation/Update Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>9/28/10</td>
<td>New policy implemented as a combination of policies titled, “Non-Invasive Left Ventricular End Diastolic Pressure” and “Non-Invasive Measurements of Cardiac Hemodynamics in the Outpatient Setting”. Cardiac hemodynamic monitoring in the outpatient setting is considered investigational. Reviewed by Senior Medical Director 9/2010. Notice given 9/28/10 Effective date 1/4/11.</td>
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<tr>
<td>1/4/11</td>
<td>Removed codes 0104T and 0105T. (mco)</td>
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<tr>
<td>8/30/11</td>
<td>Removed information regarding the Endosure® (CardioMEMS, Atlanta) wireless abdominal aortic aneurysm (AAA) pressure measurement device as this device is addressed in the policies titled, “Endovascular Stent Grafts for Abdominal Aortic Aneurism” and “Endovascular Stent Grafts for Thoracic Aortic Aneurism.” Policy Guidelines updated. References updated. No changes to policy statements. (mco)</td>
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12/30/11 Added new codes to “Billing/Coding” section: 0293T and 0294T. Effective date 1/1/2012. Added information on Left Atrial Hemodynamic Monitor, HeartPOD™ System, to “Description” section. Added “left atrial hemodynamic monitoring” to the “When not Covered” section. Medical Director review 12/2011. (mco)


10/30/12 Specialty Matched Consultant Advisory Panel review 10/2012. No changes to Policy Statements. (mco)

8/27/13 Policy Guidelines updated. References updated. No changes to Policy Statements. (mco)

11/12/13 Specialty Matched Consultant Advisory Panel review 10/2013. No changes to Policy Statements. (mco)

8/26/14 Description section extensively revised to include new hemodynamic monitoring devices. References updated. Policy Guidelines updated. Medical Director review 8/2014. No changes to Policy Statement. Added C9741 (effective October 1, 2014) to Billing/Coding section. (mco)

12/30/14 References updated. Specialty Matched Consultant Advisory Panel review 11/2014. Senior Medical Director review. Added C2624 to the Billing/Coding section effective 1/1/15. No change to Policy statement. (td)


7/1/16 Minor updates to the Description section. Policy Guidelines updated. References updated. Medical Director review 5/2016. (jd)


6/30/17 Description and Table 1 updated. References updated. Medical Director review 5/2017. (jd)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.