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

Introduction

Hemodynamic monitoring measures blood pressure inside the heart, veins, and arteries. It’s often done in a hospital for patients with acute heart failure. Implantable hemodynamic monitoring devices have been developed for outpatient use. The device measures the pressure of the pulmonary artery (which transports blood from the heart to the lungs) and the heart rate. The data is transmitted through a computerized system to the patient’s doctor. The goal of the device is to try to see the early signs of acute heart failure and prevent hospitalizations. In the studies published so far, there is limited data about safety and no demonstration that the devices save more lives. There are also unanswered questions about whether these devices reduce hospitalization. For these reasons, implantable hemodynamic monitoring devices are considered investigational (unproven).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
### Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac hemodynamic monitoring</td>
<td><strong>In the ambulatory care and outpatient setting, cardiac hemodynamic monitoring for the management of heart failure using any of the following devices is considered investigational:</strong></td>
</tr>
<tr>
<td></td>
<td>• Arterial pressure during the Valsalva maneuver</td>
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<tr>
<td></td>
<td>• Implantable direct pressure monitoring of the pulmonary artery (this includes the implantation of the device, eg, CardioMEMS device)</td>
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<tr>
<td></td>
<td>• Inert gas rebreathing</td>
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<td></td>
<td>• Thoracic bioimpedance</td>
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</table>

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
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</tr>
<tr>
<td>33289</td>
<td>Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed (new code effective 1/1/19)</td>
</tr>
<tr>
<td>93264</td>
<td>Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional (new code effective 1/1/19)</td>
</tr>
<tr>
<td>93701</td>
<td>Bioimpedance-derived physiologic cardiovascular analysis</td>
</tr>
<tr>
<td>93799</td>
<td>Unlisted cardiovascular service or procedure</td>
</tr>
</tbody>
</table>

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Related Information

This policy refers only to the use of stand-alone cardiac output measurement devices designed for use in ambulatory care and outpatient settings. The use of cardiac hemodynamic monitors or intrathoracic fluid monitors that are integrated into other implantable cardiac devices, including implantable cardioverter defibrillators, cardiac resynchronization therapy devices, and cardiac pacing devices are not addressed in this policy.

Evidence Review

Description

A variety of outpatient cardiac hemodynamic monitoring devices are intended to improve quality of life and reduce morbidity for patients with heart failure by decreasing episodes of acute decompensation. Monitors can identify physiologic changes that precede clinical symptoms and thus allow preventive intervention. These devices operate through various mechanisms, including implantable pressure sensors, thoracic bioimpedance measurement, inert gas rebreathing, and estimation of left ventricular end-diastolic pressure by arterial pressure during the Valsalva maneuver.

Background

Chronic Heart Failure

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
Management

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 health care provider, education, and medication adjustments as appropriate. These encounters may occur face-to-face in the office or at home, or via cellular or computed technology.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, and Doppler ultrasound are noninvasive methods for monitoring cardiac output on an intermittent basis for the more stable patient but are not addressed herein. A variety of biomarkers and radiologic techniques may be used for dyspnea when the diagnosis of acute decompensated heart failure is uncertain.

The criterion standard for hemodynamic monitoring is pulmonary artery catheters and central venous pressure catheters. However, they are invasive, inaccurate, and inconsistent in predicting fluid responsiveness. Several studies have demonstrated that catheters fail to improve outcomes in critically ill patients and may be associated with harm. To overcome these limitations, multiple techniques and devices have been developed that use complex imaging technology and computer algorithms to estimate fluid responsiveness, volume status, cardiac output and tissue perfusion. Many are intended for use in outpatient settings but can be used in the emergency department, intensive care unit, and operating room. Four methods are reviewed here: implantable pressure monitoring devices, thoracic bioimpedance, inert gas rebreathing, and arterial waveform during the Valsalva maneuver. Use of the last three is not widespread because of several limitations including use of proprietary technology making it difficult to confirm their validity and lack of large randomized controlled trials to evaluate treatment decisions guided by these hemodynamic monitors.

Left Ventricular End-Diastolic Pressure Estimation

**Pulmonary Artery Pressure Measurement to Estimate Left Ventricular End-Diastolic Pressure**

Left ventricular end-diastolic pressure (LVEDP) can 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 U.S. Food and Drug Administration (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.

**Thoracic Bioimpedance**

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

**Inert Gas Rebreathing**

Inert gas rebreathing is based on the observation that the absorption and disappearance of a blood-soluble gas are proportional to cardiac blood flow. The patient is asked to breathe and rebreathe from a bag filled with oxygen mixed with a fixed proportion of 2 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 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 Maneuver to Estimate LVEDP**

Left ventricular end-diastolic pressure (LVEDP) is elevated with 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.
Summary of Evidence

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring with an implantable pulmonary artery pressure sensor device, the evidence includes RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. One implantable pressure monitor, the CardioMEMS device, has U.S. Food and Drug Administration approval. The pivotal CHAMPION RCT reported a statistically significant decrease in heart failure-related hospitalizations in patients implanted with CardioMEMS device compared with usual care. However, trial results were potentially biased in favor of the treatment group due to use of additional nurse communication to enhance protocol compliance with the device. The manufacturer conducted multiple analyses to address potential bias from the nurse interventions. Results were reviewed favorably by the Food and Drug Administration. While these analyses demonstrated the consistency of benefit from the CardioMEMS device, all such analyses have methodologic limitations. Early safety data have been suggestive of a higher rate of procedural complications, particularly related to pulmonary artery injury. Given that the intervention is invasive and intended to be used for a highly prevalent condition, in the light of limited safety data, lack of demonstrable mortality benefit, and pending questions related to its benefit in reducing hospitalizations, the net benefit remains uncertain. Many of these concerns may be clarified by an ongoing postmarketing study that proposes to enroll 1200 patients (at least 35% women) is reported. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring by thoracic impedance, with inert gas rebreathing, or of arterial pressure during the Valsalva maneuver, the evidence includes uncontrolled prospective studies and case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. There is a lack of RCT evidence evaluating whether the use of these technologies improves health outcomes over standard active management of heart failure patient. The case series have reported physiologic measurement-related outcomes and/or associations between monitoring information and heart failure exacerbations, but do not provide definitive evidence on device efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.
Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT01121107</td>
<td>Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy Study</td>
<td>486</td>
<td>Apr 2015 (completed)</td>
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<tr>
<td>NCT00409916</td>
<td>Prevention of Heart Failure Events With Impedance Cardiography Testing (PREVENT-HF): Device BioZ Dx</td>
<td>500</td>
<td>Dec 2012 (unknown)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

**American College of Cardiology et al**

The 2017 joint guidelines from the American College of Cardiology, American Heart Association, and Heart Failure Society of America on the management of heart failure offered no recommendations for the use of ambulatory monitoring devices.22

**European Society of Cardiology**

The European Society of Cardiology guidelines on the diagnosis and treatment of acute and chronic heart failure stated the following: “Monitoring of pulmonary artery pressures using a wireless implantable hemodynamic monitoring system (CardioMEMS) may be considered in symptomatic patients with heart failure with previous heart failure hospitalization in order to reduce the risk of recurrent heart failure hospitalization (Class IIb Level B recommendation).”23
National Institute for Health and Care Excellence

The updated 2010 guidance from the National Institute for Health and Care Excellence on chronic heart failure management did not include outpatient hemodynamic monitoring as a recommendation. This guidance is under review and update and is expected in August 2018.

In 2013, the Institute issued guidance on the insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure. The recommendations concluded that “Current evidence on the safety and efficacy of the insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure is limited in both quality and quantity.”

Medicare National Coverage

In 2014, the Centers for Medicare & Medicaid Services updated its 2006 decision memorandum on thoracic electrical bioimpedance. Medicare’s national coverage determination found thoracic bioimpedance to be reasonable and necessary for the following indications:

1. Differentiation of cardiogenic from pulmonary causes of acute dyspnea;
2. Optimization of atroventricular interval for patients with atroventricular sequential cardiac pacemakers;
3. Monitoring of continuous inotropic therapy for patients with terminal heart failure;
4. Evaluation for rejection in patients with a heart transplant as a predetermined alternative to myocardial biopsy; and

While Medicare permits coverage of thoracic bioimpedance in these conditions, it has acknowledged that there is a “...general absence of studies evaluating the impact of using thoracic bioimpedance for managing patients with cardiac disease....” Medicare does not cover the use of thoracic bioimpedance in the management of hypertension due to inadequate evidence.

Medicare has also specified that thoracic bioimpedance is not covered for “the management of all forms of hypertension (with the exception of drug-resistant hypertension...).” Further, Medicare specified that:

[Contractors] have discretion to determine whether the use of TEB [thoracic bioimpedance] 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.

There is no Medicare national coverage determination on implantable direct pressure monitoring, inert gas rebreathing, and arterial pressure with Valsalva.

Effective April 7, 2016, Novitas Solutions issued a noncoverage local coverage determination (ID L36419) for outpatient wireless pulmonary artery pressure monitoring for heart failure (CardioMEMS).

Regulatory Status

**Noninvasive LVEDP Measurement Devices**

In 2004, the VeriCor® (CVP Diagnostics), a noninvasive LVEDP measurement device, was cleared for marketing by FDA through the 510(k) process. 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.

FDA product code: DXN

**Thoracic Bioimpedance Devices**

Multiple thoracic impedance measurement devices that do not require invasive placement have been cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices used for peripheral blood flow monitoring. Table 2 presents an inexhaustive list of representative devices

FDA product code: DSB
Table 2. Noninvasive Thoracic Impedance Plethysmography Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Clearance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioZ® Thoracic Impedance Plethysmograph</td>
<td>SonoSite</td>
<td>2009</td>
</tr>
<tr>
<td>Zoe® Fluid Status Monitor</td>
<td>Noninvasive Medical Technologies</td>
<td>2004</td>
</tr>
<tr>
<td>Cheetah Starling SV</td>
<td>Cheetah Medical</td>
<td>2008</td>
</tr>
<tr>
<td>PhysioFlow® Signal Morphology-based Impedance Cardiography (SM-ICG™)</td>
<td>Vasocom, now NeuMeDx</td>
<td>2008</td>
</tr>
<tr>
<td>ReDS™ Wearable System</td>
<td>Sensible Medical Innovations</td>
<td>2015</td>
</tr>
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</table>

Also, several manufacturers market thoracic impedance measurement devices integrated into implantable cardiac pacemakers, cardioverter defibrillator devices, and cardiac resynchronization therapy devices.

**Inert Gas Rebreathing Devices**

In 2006, the Innocor® (Innovision), an inert gas rebreathing device, was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent to existing inert gas rebreathing devices for use in computing blood flow. FDA product code: BZG.

**Implantable Pulmonary Artery Pressure Sensor Devices**

In 2014, the CardioMEMS™ Champion Heart Failure Monitoring System (CardioMEMS, now St. Jude Medical) was cleared for marketing by FDA through the premarket approval process. This device consists of an implantable pulmonary artery (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.³ The device originally underwent FDA review in 2011, at which point FDA found no reasonable assurance that the monitoring system would be effective, particularly in certain subpopulations, although FDA agreed this monitoring system was safe for use in the indicated patient population.⁴

Several other devices that monitor cardiac output by measuring pressure changes in the PA or right ventricular outflow tract have been investigated in the research setting but have not received FDA approval. They include the Chronicle® implantable continuous hemodynamic...
monitoring device (Medtronic), which includes a sensor implanted in the right ventricular outflow tract, and the ImPressure® device (Remon Medical Technologies), which includes a sensor implanted in the PA.

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

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td>08/01/18</td>
<td>New policy, approved July 10, 2018, effective November 2, 2018. Add to Cardiology section. This policy was previously archived but it is now being reinstated. Literature review through March 2018. Policy statement: cardiac hemodynamic monitoring for the management of heart failure in the outpatient setting using any of the stated devices is considered investigational.</td>
</tr>
<tr>
<td>01/01/19</td>
<td>Interim Review, approved December 19, 2018. Clarified that implantable direct pressure monitoring of the pulmonary artery includes the implantation of the device as well. Added CPT code 33289 and 93264.</td>
</tr>
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</table>

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Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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