**Medical Coverage Policy |** Cardiac Hemodynamic Monitoring

**EFFECTIVE DATE:** 10|01|2019
**|POLICY LAST UPDATED:** 07|16|2020

## OVERVIEW

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.

## MEDICAL CRITERIA

Not applicable

## PRIOR AUTHORIZATION

Not applicable

## POLICY STATEMENT

**Thoracic Electrical Bioimpedance (TEB)**

**BlueCHiP for Medicare**

Cardiac hemodynamic monitoring for the management of heart failure using thoracic electrical bioimpedance is covered.

**Note:** Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all BlueCHiP for Medicare policies. Therefore, BlueCHiP for Medicare policies may differ from Commercial products. In some instances, benefits for BlueCHiP for Medicare may be greater than what is allowed by the CMS.

**Commercial Products**

Cardiac hemodynamic monitoring for the management of heart failure using thoracic electrical bioimpedance (TEB) is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

**Implantable Direct Pressure Monitoring, Inert Gas Rebreathing and Arterial Pressure during Valsalva Maneuver**

**BlueCHiP for Medicare**

Cardiac hemodynamic monitoring for the management of heart failure using implantable direct pressure monitoring of the pulmonary artery, inert gas rebreathing, and arterial pressure during the Valsalva maneuver is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

**Commercial Products**

Cardiac hemodynamic monitoring for the management of heart failure using implantable direct pressure monitoring of the pulmonary artery, inert gas rebreathing, and arterial pressure during the Valsalva maneuver is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

## COVERAGE

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

## 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.

#### 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 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 cellular or computed technology.

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 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.

#### Left Ventricular End-Diastolic Pressure Estimation

<u>Pulmonary Artery Pressure Measurement to Estimate Left Ventricular End-Diastolic Pressure</u>

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.

<u>Thoracic Bioimpedance</u>

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 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 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.

REGULATORY STATUS

Noninvasive Left Ventricular End-Diastolic Pressue Measurement Devices (LVEDP)

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."

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.

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.

Implantable Pulmonary Artery Pressure Sensor Devices

In 2014, the CardioMEMS™ Champion Heart Failure Monitoring System (CardioMEMS, ~~now St. Jude Medical~~ now Abbott) 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. 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.

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.

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring with an implantable pulmonary artery pressure sensor device, 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 is insufficient to determine the effects of the technology on health outcomes.

## CODING

The following code is covered for BlueCHiP for Medicare and is considered not medically necessary for Commercial Products.

**93701** Bioimpedance-derived physiologic cardiovascular analysis

The following CPT codes for implantation and monitoring of a wireless pulmonary artery pressure sensor are new codes effective 1/1/2019. They are not covered for BlueCHiP for Medicare and not medically necessary for Commercial products. Effective 1/1/2019, the Unlisted CPT code below should no longer be used for these services.

**33289** 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 1/1/2019)

**93264** 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 1/1/2019)

**BlueCHiP for Medicare and Commercial Products**

There is no specific code for inert gas rebreathing measurement or left ventricular end diastolic pressure and should be reported using the unlisted code:

**93799** Unlisted cardiovascular service or procedure

## RELATED POLICIES

Not applicable

## PUBLISHED

Provider Update, September 2020
Provider Update, December 2019
Provider Update, November 2018
Provider Update, August 2018
Provider Update, December 2017
Provider Update, October 2016

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