

<b>POLICY TITLE</b>	<b>CARDIAC HEMODYNAMIC MONITORING FOR THE MANAGEMENT OF HEART FAILURE IN THE OUTPATIENT SETTING</b>
<b>POLICY NUMBER</b>	<b>MP-2.051</b>

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[POLICY RATIONALE](#)  
[DISCLAIMER](#)  
[POLICY HISTORY](#)

[PRODUCT VARIATIONS](#)  
[DEFINITIONS](#)  
[CODING INFORMATION](#)

[DESCRIPTION/BACKGROUND](#)  
[BENEFIT VARIATIONS](#)  
[REFERENCES](#)

**I. POLICY**

In the ambulatory care and outpatient setting, cardiac hemodynamic monitoring for the management of heart failure utilizing thoracic bioimpedance, inert gas rebreathing, arterial pressure during the Valsalva maneuver, and implantable direct pressure monitoring of the pulmonary artery is considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

**Policy Guidelines**

This policy refers only to the use of stand-alone cardiac output measurement devices that are designed to be used 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, is addressed in MP-2.007.

*Cross-reference:*

**MP-2.007** Cardiac Resynchronization Therapy for the Treatment of Heart Failure

**II. PRODUCT VARIATIONS**

[Top](#)

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

**FEP PPO** - Refer to FEP Medical Policy Manual MP-2.02.24, Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting. The FEP Medical Policy Manual can be found at:

<https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>.

POLICY TITLE	CARDIAC HEMODYNAMIC MONITORING FOR THE MANAGEMENT OF HEART FAILURE IN THE OUTPATIENT SETTING
POLICY NUMBER	MP-2.051

**III. DESCRIPTION/BACKGROUND**

[Top](#)

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.

**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.<sup>1</sup>

**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.<sup>2</sup>

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 last three is not widespread because of several limitations including use proprietary technology making it difficult to confirm their

<b>POLICY TITLE</b>	<b>CARDIAC HEMODYNAMIC MONITORING FOR THE MANAGEMENT OF HEART FAILURE IN THE OUTPATIENT SETTING</b>
<b>POLICY NUMBER</b>	<b>MP-2.051</b>

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*

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.

<b>POLICY TITLE</b>	<b>CARDIAC HEMODYNAMIC MONITORING FOR THE MANAGEMENT OF HEART FAILURE IN THE OUTPATIENT SETTING</b>
<b>POLICY NUMBER</b>	<b>MP-2.051</b>

**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 1 presents an inexhaustive list of representative devices (FDA product code: DSB).

**Table 1. Noninvasive Thoracic Impedance Plethysmography Devices**

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

Also, several manufacturers market thoracic impedance measurement devices integrated into implantable cardiac pacemakers, cardioverter defibrillator devices, and cardiac resynchronization therapy devices. Thoracic bioimpedance devices integrated into implantable cardiac devices are addressed in evidence review 2.02.10.

**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

<b>POLICY TITLE</b>	<b>CARDIAC HEMODYNAMIC MONITORING FOR THE MANAGEMENT OF HEART FAILURE IN THE OUTPATIENT SETTING</b>
<b>POLICY NUMBER</b>	<b>MP-2.051</b>

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.<sup>3</sup> 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.<sup>4</sup>

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 evidence review only addresses the use of these technologies in ambulatory care and outpatient settings.

**IV. RATIONALE**

[Top](#)

**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 randomized controlled trials (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. Using the CardioMEMS device, the CHAMPION RCT reported that use of pulmonary artery pressure readings reduced heart failure–related hospitalizations, but this trial was subject to several potential biases. It was single-blinded, with treating clinicians aware of group assignment. 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 outpatient setting 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 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

<b>POLICY TITLE</b>	<b>CARDIAC HEMODYNAMIC MONITORING FOR THE MANAGEMENT OF HEART FAILURE IN THE OUTPATIENT SETTING</b>
<b>POLICY NUMBER</b>	<b>MP-2.051</b>

exacerbations, but do not provide definitive evidence on device efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

**V. DEFINITIONS**

[Top](#)

**CARDIAC OUTPUT** is the volume of blood expelled by the ventricles of the heart, equal to the amount of blood ejected at each beat (the stroke output) multiplied by the heart rate per minute/number of beats in the period of time used in the computation. A normal heart in a resting adult ejects from four (4) to eight (8) liters of blood per minute.

**HEMODYNAMIC** refers to the study of the forces involved in circulating blood through the body.

**THORAX** is the cage of bone and cartilage containing the principal organs of respiration and circulation and covering part of the abdominal organs.

**VALSALVA’S MANEUVER** is an attempt to forcibly exhale with the glottis, nose and mouth closed. This maneuver causes increased intrathoracic pressure, slowing of the pulse, decreased return of blood to the heart, and increased venous pressure. If the Eustachian tubes are not obstructed, the pressure on the tympanic membranes also will be increased. When this maneuver is done with just the glottis closed, only intrathoracic pressure will increase.

**VI. BENEFIT VARIATIONS**

[Top](#)

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital BlueCross for benefit information.

**VII. DISCLAIMER**

[Top](#)

*Capital BlueCross’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

<b>POLICY TITLE</b>	<b>CARDIAC HEMODYNAMIC MONITORING FOR THE MANAGEMENT OF HEART FAILURE IN THE OUTPATIENT SETTING</b>
<b>POLICY NUMBER</b>	<b>MP-2.051</b>

**VIII. CODING INFORMATION**

[Top](#)

**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

**Investigational; therefore, not covered:**

CPT Codes®							
33289	93050	93264	93701				

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HCPCS Code	Description
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components

**The following code is investigational when used for ambulatory care and outpatient setting Inert Gas Rebreathing as outlined in the policy section:**

CPT Codes®							
93799							

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**IX. REFERENCES**

[Top](#)

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<b>POLICY TITLE</b>	<b>CARDIAC HEMODYNAMIC MONITORING FOR THE MANAGEMENT OF HEART FAILURE IN THE OUTPATIENT SETTING</b>
<b>POLICY NUMBER</b>	<b>MP-2.051</b>

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<b>POLICY TITLE</b>	<b>CARDIAC HEMODYNAMIC MONITORING FOR THE MANAGEMENT OF HEART FAILURE IN THE OUTPATIENT SETTING</b>
<b>POLICY NUMBER</b>	<b>MP-2.051</b>

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POLICY TITLE	CARDIAC HEMODYNAMIC MONITORING FOR THE MANAGEMENT OF HEART FAILURE IN THE OUTPATIENT SETTING
POLICY NUMBER	MP-2.051

X. POLICY HISTORY

[Top](#)

MP 2.051	CAC 8/30/05
	CAC 6/27/06
	CAC 6/26/07
	CAC 5/27/08
	CAC 5/26/09
	CAC 5/25/10 Consensus
	CAC 7/26/11 Adopt BCBSA. CBC policy addressed thoracic bioimpedance and inert gas rebreathing only. By adopting BCBSA - arterial pressure Vasalva and implantable direct pressure monitoring of the pulmonary artery is also listed as investigational. CBC was silent on these prior to this revision. Other policy statements unchanged.
	CAC 10/30/12 Consensus Review. No change to policy statements. References updated. FEP variation revised to refer to the FEP medical policy manual. Codes reviewed 10/23/12
	CAC 11/26/13 Consensus. No change to policy statements. Changed Medicare variation to reference Novitas Solutions Local Coverage Determination (LCD) L32684 Cardiac Output Monitoring by Bioimpedance. Rationale added.
	CAC 11/25/14 Consensus review. No changes to the policy statements. References and rationale updated. Medicare variation revised to reflect NCD 20.16 Cardiac Output Monitoring by Thoracic Electrical Bioimpedance as LCD L32684 has been retired. Coding reviewed, no changes.
	03/26/2015-Administrative code review. No changes to policy stance.
	9/24/15 Administrative Change. Added 4 <sup>th</sup> Quarter New Code.
	CAC 11/24/15 Consensus review. No changes to the policy statements. References and rationale updated. Coding updated including 2016 updates.
	4/7/16 Administrative change. Added Medicare variation to reference L36419.
	5/10/2016 Administrative Change: Typographical error corrected; code is 93701, not 92701 (invalid code).
	CAC 11/29/16 Consensus review. No change to policy statements. References and rationale updated. Variation reformatting. Coding Reviewed
	Admin Update 1/1/18: Removed end dated codes 0293T and 0294T; effective 1/1/18. Medicare variations removed from Commercial Policies.
	9/21/2017 Consensus review. Verbiage clarification to policy statement, intent unchanged. Description/Background, Rationale and Reference sections updated. Coding Reviewed.
	6/5/18 Consensus. No change to policy statements. References updated. Rationale condensed.
1/1/19 Admin Update: Added new codes effective 1/1/19 and removed deleted HCPCS code.	

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