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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>   |

|                                    |                 |
|------------------------------------|-----------------|
| Original Issue Date (Created):     | 7/1/2002        |
| Most Recent Review Date (Revised): | 6/2/2020        |
| <b>Effective Date:</b>             | <b>7/1/2020</b> |

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**I. POLICY**

In the ambulatory care and outpatient setting, cardiac hemodynamic monitoring for the management of heart failure using implantable direct pressure monitoring of the pulmonary artery, thoracic bioimpedance, inert gas rebreathing, and arterial pressure during the Valsalva maneuver 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**

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This policy is only applicable to certain programs and products administered by Capital BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

**FEP PPO** - Refer to FEP Benefit Brochure for information on Lab, X-ray and Other Diagnostic Tests: <https://www.fepblue.org/benefit-plans/benefit-plans-brochures-and-forms>

*Note\** - The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services.

**III. DESCRIPTION/BACKGROUND**

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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

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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.

**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.

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 validity and lack of large randomized controlled trials to evaluate treatment decisions guided by these hemodynamic monitors.

**Regulatory Status**

**Noninvasive Left Ventricular End-Diastolic Pressure Measurement Devices**

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In 2004, the VeriCor® (CVP Diagnostics), a noninvasive left ventricular end-diastolic pressure measurement device, was cleared for marketing by U.S. Food and Drug Administration (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."

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**

| <b>Device</b>   | <b>Manufacturer</b>                | <b>Clearance Date</b> |
|---|------------------------------------|-----------------------|
| ▪ <b>BioZ® Thoracic Impedance Plethysmograph</b>                              | ▪ SonoSite                         | ▪ 2009                |
| ▪ <b>Zoe® Fluid Status Monitor</b>  | ▪ Noninvasive Medical Technologies | ▪ 2004                |
| ▪ <b>Cheetah Starling SV</b>  | ▪ Cheetah Medical                  | ▪ 2008                |
| ▪ <b>PhysioFlow® Signal Morphology-based Impedance Cardiography (SM-ICG™)</b> | ▪ Vasocom, now NeuMeDx             | ▪ 2008                |
| ▪ <b>ReDSTM Wearable System</b>   | ▪ 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 the FDA through the 510(k) process. The FDA determined that this device was substantially

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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 Abbott) was cleared for marketing by the 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 the 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 the 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**

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**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. The pivotal CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA III Heart Failure Patients randomized controlled trial 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

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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

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring by thoracic bioimpedance, 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 randomized controlled trial evidence evaluating whether the use of these technologies improves health outcomes over standard active management of heart failure patients. 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.

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring with inert gas rebreathing, no studies have been identified on clinical validity or clinical utility. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. 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 of arterial pressure during the Valsalva maneuver, a single study was identified. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. The study assessed the use of LVEDP monitoring and reported an 85% sensitivity and an 80% specificity to detect LVEDP greater than 15 mm Hg. The evidence is insufficient to determine the effects of the technology on health outcomes.

**V. DEFINITIONS**

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**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.

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**VI. BENEFIT VARIATIONS**

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

**VII. DISCLAIMER**

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*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. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

**VIII. CODING INFORMATION**

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**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:**

| <b>CPT Codes®</b> |       |       |       |       |       |  |  |
|-------------------|-------|-------|-------|-------|-------|--|--|
| 0607T             | 0608T | 33289 | 93050 | 93264 | 93701 |  |  |

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| <b>HCPCS Code</b> | <b>Description</b>   |
|-------------------|--|
| C2624             | Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components  |
| C9758             | Blinded procedure for nyha class iii/iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study |

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

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| CPT Codes® |  |  |  |  |  |  |  |
|------------|--|--|--|--|--|--|--|
| 93799      |  |  |  |  |  |  |  |

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**IX. REFERENCES**

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*From the Heart Failure Society of America Scientific Statements Committee. J. Card. Fail., 2018 Oct 12;24(10). PMID 30308242*

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**X. POLICY HISTORY**

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| <b>MP 2.051</b> | <b>CAC 8/30/05</b>  |
|                 | <b>CAC 6/27/06</b>  |
|                 | <b>CAC 6/26/07</b>  |
|                 | <b>CAC 5/27/08</b>  |
|                 | <b>CAC 5/26/09</b>  |
|                 | <b>CAC 5/25/10 Consensus</b>  |
|                 | <b>CAC 7/26/11 Adopt BCBSA.</b> 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. |
|                 | <b>CAC 10/30/12 Consensus Review.</b> No change to policy statements. References updated. FEP variation revised to refer to the FEP medical policy manual. Codes reviewed 10/23/12  |
|                 | <b>CAC 11/26/13 Consensus.</b> No change to policy statements. Changed Medicare variation to reference Novitas Solutions Local Coverage Determination (LCD) L32684 Cardiac Output Monitoring by Bioimpedance. Rationale added.  |
|                 | <b>CAC 11/25/14 Consensus review.</b> 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.   |
|                 | <b>03/26/2015-Administrative code review.</b> No changes to policy stance.  |

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|  | <b>9/24/15 Administrative Change.</b> Added 4 <sup>th</sup> Quarter New Code.   |
|  | <b>CAC 11/24/15 Consensus review.</b> No changes to the policy statements. References and rationale updated. Coding updated including 2016 updates.                                 |
|  | <b>4/7/16 Administrative change.</b> Added Medicare variation to reference L36419.  |
|  | <b>5/10/2016 Administrative Change:</b> Typographical error corrected; code is 93701, not 92701 (invalid code).   |
|  | <b>CAC 11/29/16 Consensus review.</b> No change to policy statements. References and rationale updated. Variation reformatting. Coding Reviewed                                     |
|  | <b>Admin Update 1/1/18:</b> Removed end dated codes 0293T and 0294T; effective 1/1/18. Medicare variations removed from Commercial Policies.  |
|  | <b>9/21/2017 Consensus review.</b> Verbiage clarification to policy statement, intent unchanged. Description/Background, Rationale and Reference sections updated. Coding Reviewed. |
|  | <b>6/5/18 Consensus.</b> No change to policy statements. References updated. Rationale condensed.   |
|  | <b>1/1/19 Admin Update:</b> Added new codes effective 1/1/19 and removed deleted HCPCS code.  |
|  | <b>6/10/19 Consensus review.</b> No change to policy statements. References updated.  |
|  | <b>01/01/20 Admin code update.</b> New code added, C9728.   |
|  | <b>5/20/2020 Admin code update.</b> New codes 0607T and 0608T added.  |
|  | <b>6/3/2020 Consensus Review.</b> No change to policy statement. Rationale and references updated.  |

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