Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

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

Policy #: 441
Latest Review Date: June 2023
Category: Medicine
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service May 1, 2022 and after:

Blue Advantage will treat **cardiac hemodynamic monitoring for the management of heart failure** utilizing noninvasive pulmonary fluid monitoring, inert gas rebreathing, arterial pressure/Valsalva, and noninvasive left ventricular end diastolic pressure monitoring as a **non-covered benefit** and as **investigational** in the ambulatory care and outpatient setting.

For coverage criteria for cardiac hemodynamic monitoring for the management of heart failure using thoracic bioimpedance, refer to the NCD for Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB) (20.16).

For coverage criteria for cardiac hemodynamic monitoring for the management of heart failure using implantable direct pressure monitoring of the pulmonary artery, refer to Medicare Program Integrity Manual, 3.6.2.2.

Effective for dates of service prior to May1, 2022:

Blue Advantage will treat **cardiac hemodynamic monitoring for the management of heart failure** utilizing inert gas rebreathing, arterial pressure/Valsalva, and implantable direct pressure monitoring of the pulmonary artery as a **non-covered benefit** and as **investigational** in the ambulatory care and outpatient setting.

For coverage criteria for cardiac hemodynamic monitoring for the management of heart failure using thoracic bioimpedance, refer to the NCD for Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB) (20.16).

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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 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 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 healthcare provider, education and 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 radiological 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 (PA) 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 outcome 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 to be used in outpatient setting but can be used in the emergency department, intensive care unit, and operating room. Five methods are reviewed here: non-invasive pulmonary fluid monitoring, implantable pressure monitoring devices, thoracic bioimpedance, inert gas rebreathing, and arterial waveform during the Valsalva maneuver. The use of last 3 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.

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, is addressed in medical policy # 055 – Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure.

KEY POINTS:

The most recent literature review was updated through May 5, 2023.

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) and nonrandomized studies. 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 28% decrease in heart failure-related hospitalizations (HFH) in patients implanted with CardioMEMS device compared with usual care. However, the 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 manufacture conducted multiple analyses to address potential bias from the nurse interventions. Results were reviewed favorably by FDA. While these analyses demonstrated consistency of benefit from the CardioMEMS device, all such analyses have methodologic limitations. Early safety data is suggestive of a higher rate of procedural complications, particularly related to pulmonary artery injury. While the U.S. CardioMEMS post-approval study and CardioMEMS European Monitoring Study for Heart Failure (MEMS-HF) study reported a significant decrease in heart-failure related hospitalizations with few device- or system-related complications at 1 year, the impact of nursing interventions remains unclear. The subsequent GUIDE-HF RCT failed to meet its primary efficacy endpoint, the composite of HFH, urgent heart failure visits, and death at 1 year. With the approval of the FDA, the statistical analysis plan was updated to pre-specify sensitivity analyses to assess the impact of COVID-19 on the trial. For the 72% of patients who completed follow-up prior to the public health emergency declaration in March 2020, a statistically significant 19% reduction in the primary endpoint was reported, driven by a 28% reduction in HFH. However, lifestyle changes during the COVID-19 pandemic such as changes in physical activity, exposure to infections, willingness to seek medical care, and adherence to medications are unmeasured and add imprecision to treatment effect estimates, as do alterations in provider behaviors. Enrollment of NYHA Class II patients was significantly enriched in the first 500 patients, potentially impacting the pre-COVID-19 analysis. Overall, the beneficial effect of CardioMEMS, if any, appears to be on the hospitalization outcome of the composite. Both urgent heart failure visits and death outcomes had hazard ratios favoring the control group with wide confidence intervals including the null value in pre-COVID-19, during-COVID-19, and overall analyses of the GUIDE-HF trial. No significant differences were observed in secondary quality of life and functional status outcomes. While the HFH reduction of 28%found in the pre-COVID-19 analysis is consistent with findings from the CHAMPION trial, it is unclear whether physician knowledge of treatment assignment biases the decision to hospitalize and administer intravenous diuretics. Given that the intervention is invasive and intended to be used for a highly prevalent condition, and in the of the absence of a demonstrated benefit on mortality and functional outcomes, the lack of periprocedural safety data, and unclear impact of COVID-19 n remote monitoring in the GUIDE-HF trial, the net benefit remains uncertain. Concerns may be clarified by the ongoing open access phase of the GUIDE-HF RCT and the German non-industry

sponsored PASSPORT-HF trial. The evidence is insufficient to determine that the technology results in an improvement in net health outcomes.

For individuals who have heart failure in outpatient setting 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 RCT evidence evaluating whether 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 or non-invasive pulmonary fluid monitoring, 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 left ventricular end-diastolic pressure (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.

Practice Guidelines and Positions Statements

American College of Cardiology et al

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

In the 2022 update to the heart failure management guidelines, 2 recommendations were provided regarding remote hemodynamic monitoring in heart failure. These recommendations are summarized below.

2022 ACC/AHA/HFSA Recommendation for Wearables and Remote Monitoring (including Telemonitoring and Device Monitoring)

Recommendation	Class of Recommendation	Level of Evidence
"In selected adult patients with NYHA class III HF and history of HF hospitalization in the past year or elevated natriuretic peptide levels, on maximally tolerated doses of GDMT with optimal device therapy, the usefulness of wireless monitoring of PA pressure by an implanted hemodynamic monitor to reduce the risk of subsequent HF hospitalizations is uncertain."	2b (Weak Evidence)	B-R (Moderate quality randomized evidence)
"In patients with NYHA class III HF with a HF hospitalization within the previous year, wireless monitoring of the PA pressure by an implanted hemodynamic monitor provides uncertain value."	Value Statement: Uncertain Value (B-NR) (Moderate quality nonrandomized evidence)	

ACC: American College of Cardiology; AHA: American Heart Association; GDMT: guideline-directed medical therapy; HF: heart failure; HFSA: Heart Failure Society of America; NYHA: New York Heart Association; PA: pulmonary artery.

National Institute for Health and Clinical Excellence
In 2021, the National Institute for Health and Care Excellence (NICE) issued a new interventional procedures guidance regarding the use of percutaneous implantation of pulmonary artery pressure sensors for monitoring the treatment of chronic heart failure. The Institute's recommendation stated that "Evidence on the safety and efficacy of percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure is adequate to support using this procedure provided that standard arrangements are in place for clinical governance, consent, and audit."

Heart Failure Society of America
In 2018, the Heart Failure Society of America Scientific Statements Committee published a white paper consensus statement on remote monitoring of patients with heart failure.

The committee concluded that: "Based on available evidence, routine use of external RPM devices is not recommended. Implanted devices that monitor pulmonary arterial pressure and/or other parameters may be beneficial in selected patients or when used in structured programs, but the value of these devices in routine care requires further study."

U.S. Preventive Services Task Force Recommendations
Not applicable

KEY WORDS:

Thoracic electrical bioimpedance, TEB, impedance cardiography, ICD, cardiac output, CO, thermodilution, inert gas rebreathing, BioZ®, Innocor, VeriCor®, Endosure®, Implantable Direct Pulmonary Artery Pressure, Left Ventricular End Diastolic Pressure, LVEDP, Noninvasive Measurement, CardioMEMS, thoracic bioimpedance, TEBCO®, IQ™, Zoe®, Cheetah NICOM®, PhysioFlow®, Cardiography, ZOLL, MicroCor, uCor, HFAMS, Heart Failure and Arrhythmia Management System, ReDSTM Wearable System, Bodyport Cardiac Scale, Bodyport, ReDSTM

APPROVED BY GOVERNING BODIES:

Noninvasive Left Ventricular End Diastolic Pressure Measurement Devices

In June 2004, the VeriCor® (CVP Diagnostics, Boston, MA), a noninvasive left ventricular end diastolic pressure measurement device, was cleared for marketing by the 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."

Thoracic Bioimpedance Devices

Multiple thoracic impedance measurement devices that do not require invasive placement have been cleared for marketing by the U.S. Food and Drug Administration (FDA) 510(k) process. FDA determined that this device was substantially equivalent to existing devices for use for peripheral blood flow monitoring. Table 1 includes a representative list of devices, but is not meant to be comprehensive (FDA product code: DSB).

Table 1: Noninvasive Thoracic Impedance Plethysmography Devices

Device	Manufacturer	Year of FDA Clearance
BioZ ® Thoracic Impedance Plethysmograph	SonoSite (Bothell, WA)	2009
Zoe® Fluid Status Monitor	Noninvasive Medical Technologies LLC (Las Vegas, NV)	2004

Cheetah Starling SV	Cheetah Medical Inc.	2008
Physioflow® Signal Morphology-based Impedance Cardiography (SM-ICG™)	Vasocom Inc., now Neumedx Inc. (Bristol, PA)	2008
ReDSTM Wearable System	Sensible Medical Innovations (Philadelphia, PA)	2015
Bodyport Cardiac Scale	Bodyport Inc.	2022

FDA: U.S. Food and Drug Administration.

Non-invasive Pulmonary Fluid Monitoring
In May 2018, the ZOLL uCor (MicroCor) Heart Failure and Arrhythmia Management System (HFAMS) was approved by the FDA through the 510(k) process. The device is described as a "wireless system that employs novel radiofrequency technology to monitor pulmonary fluid levels…ZOLL HFAMS continuously records, stores, and transmits patient data, including Thoracic Fluid Index, heart rate, respiration rate, activity, posture, and heart rhythm."

Inert Gas Rebreathing Devices
In March 2006, the Innocor® (Innovision, Denmark), 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 May 2014, the CardioMEMS™ Heart Failure Monitoring System (CardioMEMS, now Abbott) was approved 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 decided that there was no reasonable assurance that the discussed monitoring system would be effective, particularly in certain subpopulations, although it was agreed that this monitoring system was safe for use in the indicated patient population. In 2022, the CardioMEMS™ HF Monitoring System received expanded approval for the treatment of NYHA Class II-III patients who had been hospitalized at least 1 time in the prior year and/or had elevated natriuretic peptides.

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, Minneapolis, MN), which includes a sensor implanted in the right

ventricular outflow tract, and the ImPressure® device (Remon Medical Technologies, Caesara, Israel), which includes a sensor implanted in the PA.

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

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

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 (Effective 01/01/2019)
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 (Effective 01/01/2019)

There is a specific CPT code for bioimpedance:

93701	Bioimpedance-derived physiologic cardiovascular analysis

There is a specific CPT code for non-invasive pulmonary monitoring:

0607T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (e.g., ECG data), transmitted to a remote 24-hour attended surveillance center; set-up and patient education on use of equipment (Effective 07/01/2020)
0608T	analysis of data received and transmission of reports to the physician or other qualified health care professional (Effective 07/01/2020)

Inert gas rebreathing measurement and LVEDP should be reported using the unlisted code 93799.

There is no specific CPT code for implantable direct pressure monitoring of the pulmonary artery. The unlisted code 93799 would be used.

93799	Unlisted cardiovascular service or procedure

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POLICY HISTORY:

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Medical Policy Group, August 2011
Medical Policy Group, July 2012
Medical Policy Group, July 2013
Medical Policy Group, July 2014
Medical Policy Group, September 2014
Medical Policy Group, November 2014
Medical Policy Group, November 2015
Medical Policy Group, May 2016
Medical Policy Group, June 2016
Medical Policy Group, June 2017

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Medical Policy Group, December 2018: 2019 CPT Coding Update
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Medical Policy Group, June 2021
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