

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

Policy # 00287

Original Effective Date: 01/31/2005

Current Effective Date: 08/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers cardiac hemodynamic monitoring for the management of heart failure using **ANY** of the following in the ambulatory care and outpatient setting to be **investigational***:

- Implantable direct pressure monitoring of the pulmonary artery (e.g., CardioMEMS^{TM†} Heart Failure Monitoring System, Cordella^{TM†} PA Sensor System); **OR**
- Thoracic bioimpedance devices (e.g., BioZ^{®†} Thoracic Impedance Plethysmograph, Zoe^{®†} Fluid Status Monitor, etc.); **OR**
- Inert gas rebreathing devices (e.g., Innocor^{®†}); **OR**
- Hemodynamic monitoring of arterial pressure during the Valsalva maneuver (noninvasive left ventricular end-diastolic pressure monitoring, e.g., VeriCor^{®†}).

Policy Guidelines

This policy refers only to the use of stand-alone cardiac output measurement devices designed for use in ambulatory care and outpatient settings.

Background/Overview

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.

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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 (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 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 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Noninvasive Left Ventricular End-Diastolic Pressure Measurement Devices

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."

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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
Bodyport Cardiac Scale	Bodyport Inc.	2022
Hemosphere Alta ^{™†} Advanced Monitoring Platform	Edwards Lifesciences, LLC	2023
Sensinel Cardiopulmonary Management (CPM) System	Analog Devices	2024

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 the FDA through the 510(k) process. The 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^{™†} Heart Failure Monitoring System (CardioMEMS, now Abbott) was approved for marketing by the FDA through the premarket approval process. This device consists of an implantable 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

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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. In 2022, the CardioMEMS Heart Failure Monitoring System received expanded approval for the treatment of New York Heart Association (NYHA) Class II-III patients who had been hospitalized at least 1 time in the prior year and/or had elevated natriuretic peptides.

In 2024, the Cordella^{TM†} PA Sensor System (Endotronix, Inc.) received FDA approval through the premarket approval process. This system consists of an implantable PA sensor placed in the right PA, a catheter delivery system, a handheld patient reader with a dock, calibration equipment, and a data analysis platform that transmits PA pressure measurements to a secure database for clinician review. The device was approved for measuring PA pressure in NYHA Class III heart failure patients who are at home on diuretics and guideline-directed medical therapy, with the goal of reducing hospitalizations for heart failure. The FDA is requiring a post-approval study to collect additional evidence of continued safety and effectiveness in the NYHA Class III 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 medical policy only addresses the use of these technologies in ambulatory care and outpatient settings.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

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.

Summary of Evidence

For individuals with New York Heart Association (NYHA) class II-IV heart failure in outpatient settings who have had a hospitalization in the past year and/or have elevated natriuretic peptides who receive hemodynamic monitoring with an implantable pulmonary artery pressure sensor device, the

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evidence includes 3 meta-analyses, 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 (FDA) approval. The pivotal CHAMPION RCT reported a statistically significant 28% decrease in heart failure hospitalization (HFH) in patients implanted with the CardioMEMS device compared with usual care. However, trial results were potentially biased in favor of the treatment group due to the 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 FDA. While these analyses demonstrated the consistency of benefit of 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. While the U.S. CardioMEMS post-approval study and CardioMEMS European Monitoring Study for Heart Failure (MEMS-HF) study reported a significant decrease in HFH 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. The MONITOR-HF trial, an open-label RCT conducted in the Netherlands, showed that hemodynamic monitoring significantly improved quality of life on the Kansas City Cardiomyopathy Questionnaire (KCCQ) and reduced HFH but did not impact mortality at 1-year follow-up. 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. The MONITOR-HF trial found improvement in quality of life on the KCCQ for the CardioMEMS group relative to the control, but no significant differences were observed in secondary quality of life and functional status outcomes in the other included trials. 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. Evidence for the Cordella System is limited to 3 prospective, single-arm studies. The pivotal PROACTIVE-HF trial was a prospective, multicenter, single-arm study evaluating the Cordella System in NYHA Class III heart failure patients with recent HFH or elevated natriuretic peptides. The trial, which was modified from its original randomized design with FDA input, met its primary endpoint by reporting a 6-month event rate (heart failure hospitalization or all-cause mortality) of 0.15 events per patient, significantly lower than the prespecified benchmark of 0.43, which was derived from a composite of non-contemporaneous control arms from prior CardioMEMS trials. Secondary endpoints showed improvements in KCCQ score, 6-minute walk

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distance, and NYHA class. Device safety was high, with 99.2% freedom from complications and 99.8% freedom from sensor failure at 6 months. The SIRONA 1 and 2 feasibility studies similarly demonstrated a low rate of adverse events with the Cordella device and an improvement in NYHA class for the majority of participants; however, quality-of-life and functional outcomes did not show significant improvement. The 2 included meta-analyses showed a reduction in HFHs with hemodynamic monitoring in heart failure patients but had discordant findings regarding the impact on mortality. One meta-analysis found no pooled difference in mortality between hemodynamic monitoring and control groups; however, a patient-level meta-analysis revealed a significant 25% decrease in mortality associated with hemodynamic monitoring in patients with heart failure with reduced ejection fraction. Given that the intervention is invasive and intended to be used for a highly prevalent condition and, in light of the conflicting evidence of benefit on mortality and functional outcomes, the lack of periprocedural safety data, and unclear impact of COVID-19 on remote monitoring in the GUIDE-HF trial, the net benefit of the CardioMEMS and Cordella devices remains uncertain. Concerns may be clarified by the ongoing open access phase of the GUIDE-HF RCT and the PROACTIVE-HF trial, as well as the German non-industry-sponsored PASSPORT-HF trial. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 RCT 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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

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Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Cardiology et al

In 2017, the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Failure Society of America (HFSA) issued joint guidelines on the management of heart failure that offered no recommendations for the 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 in Table 2.

Table 2. 2022 ACC/AHA/HFSA Recommendation for Wearables and Remote Monitoring (including Telemonitoring and Device Monitoring)

Class of Recommendation	Level of Evidence	Recommendation
2b (Weak Evidence)	B-R (Moderate quality randomized evidence)	1. "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."
Value Statement: Uncertain Value (B-NR) (Moderate quality nonrandomized evidence)		2. "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."

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.

Adapted from Heidenreich et al (2022).

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European Society of Cardiology

The 2025 consensus statement from the Heart Failure Association of the European Society of Cardiology (ESC) endorses remote pulmonary artery pressure-guided management as a tool to manage heart failure and prevent hospitalizations. The panel highlights that pulmonary artery pressure-guided therapy allows early detection of hemodynamic congestion, enabling timely adjustments in therapy such as diuretics, vasodilators, or other guideline-directed medical therapy. The panel issued the following advice with a high strength of evidence based on RCT data: 'CardioMEMS is useful in patients with symptomatic heart failure at moderate to high risk of new worsening heart failure events as shown by a hospitalization for heart failure in the previous year.' The society defines the ideal candidate as an individual with symptomatic heart failure, regardless of left ventricular ejection fraction, who is classified as NYHA class II or III, has experienced at least one heart failure-related hospitalization or urgent care visit in the past year, or has elevated natriuretic peptide levels, and does not have end-stage heart failure or significant primary lung disease.

National Institute for Health and Care Excellence

In 2021, the 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 (2018) 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.

Medicare National Coverage

Effective January 13, 2025, CMS issued NCD 20.36 covering FDA-approved implantable pulmonary artery pressure sensors (IPAPS) for heart failure management exclusively under Coverage with Evidence Development (CED), currently applicable to the CardioMEMS HF System (Abbott) and the Cordella PA Sensor System (Edwards Lifesciences). CMS determined that evidence from the pivotal RCTs (CHAMPION, GUIDE-HF, MONITOR-HF) and the single-arm PROACTIVE-HF trial demonstrates a suggestive but not definitive reduction in HF hospitalizations without conclusive mortality benefit, with insufficient generalizability to the Medicare population — necessitating prospective evidence generation through CED.

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Patient eligibility requires chronic HF ≥ 3 months with NYHA Class II/III regardless of LVEF, documented HF hospitalization or urgent visit requiring IV diuretics within 12 months (or elevated natriuretic peptides within 30 days), ≥ 3 months on GDMT, prior ICD/CRT evaluation and implantation if appropriate, no major cardiovascular event within 3 months, reliable daily connectivity, and implantation outside an acute HF admission. CMS-approved CED studies must evaluate HF hospitalization and/or all-cause mortality with ≥ 24 -month follow-up, include an active comparator, incorporate a physician-led care management protocol, and conduct prespecified subgroup analyses by age, sex, race/ethnicity, LVEF, NYHA class, CKD stage, and qualifying entry criterion.

Two CED studies were approved on February 7, 2025 — the CED CardioMEMS Study (NCT06779552) and the LOWER-PAP Cordella Study (NCT06783335) — enabling coverage for all qualifying Medicare and Medicare Advantage beneficiaries, while IPAPS remains non-covered outside an approved CED study. Key evidence gaps to be addressed include mortality effect across the EF spectrum, effectiveness in underrepresented populations, incremental benefit over contemporary GDMT (including SGLT2 inhibitors and ARNIs), long-term device performance, and replicability of trial outcomes in real-world community practice settings — consistent with the current Class IIb recommendation (Level B evidence) assigned by ACC/AHA/HFSA (2022) and ESC (2021) guidelines.

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:

- Differentiation of cardiogenic from pulmonary causes of acute dyspnea;
- Optimization of atrioventricular interval for patients with atrioventricular sequential cardiac pacemakers;
- Monitoring of continuous inotropic therapy for patients with terminal heart failure;
- Evaluation for rejection in patients with a heart transplant as a predetermined alternative to myocardial biopsy; and
- Optimization of fluid management in patients with congestive heart failure.

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."

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

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT04398654	Pulmonary Artery Sensor System Pressure Monitoring to Improve Heart Failure (HF) Outcomes (PASSPORT-HF)	554	Dec 2026 (recruiting)
NCT04441203	Patient SELF-management With Hemodynamic Monitoring: Virtual Heart Failure Clinic and Outcomes (SELFie-HF)	150	Dec 2025 (recruiting)
NCT03020043	CardioMEMS Registry of the Frankfurt Heart Failure Center	500	Dec 2025 (Unknown status)
NCT04419480 ^a	Hemodynamic Monitoring to Prevent Adverse Events following cardiogenic Shock Trial	40	Dec 2026 (Recruiting)
NCT05284955 ^a	Screening for Advanced Heart Failure in Stable Outpatients - The SAINTS Study (SAINTS B) (SAINTS B)	60	Dec 2025 (recruiting)
NCT03020043 ^a	Evaluation of Longterm Outcome of New York Heart Association Class III Heart Failure Patients Receiving Telemonitoring Using a Pulmonary Artery Pressure Sensor System (CardioMEMS)	500	Dec 2025 (Unknown status)
NCT04452149 ^a	Algorithm Using LINQ Sensors for Evaluation and Treatment of Heart Failure (ALLEVIATE- HF)	826	May 2025 (Completed - no results posted)
NCT06306573 ^a	CardioMEMS TM HF System Real-World Evidence Post-Approval Study	2500	Dec 2028 (recruiting)
NCT06779552 ^a	CardioMEMS HF System Coverage with Evidence Development Study	1000	Mar 2032 (recruiting)
NCT03375710 ^a	A Prospective, Multi-Center, Open-Label, Single-Arm Clinical Trial Evaluating the Safety and	15	Feb 2029 (Completed)

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	Efficacy of the Cordella™ [‡] Heart Failure System in (New York Heart Association) NYHA Class III Heart Failure Patients		- no results posted)
NCT04012944 ^a	A Prospective, Multi-Center, Open-Label, Single-Arm Clinical Trial Evaluating the Safety and Efficacy of the Cordella™ [‡] Pulmonary Artery Sensor System in New York Heart Association (NYHA) Class III Heart Failure Patients (SIRONA 2 Trial)	81	Jul 2027 (Active - not recruiting)
NCT04089059 ^a	A Prospective, Multi-Center, Open Label, Single Arm Clinical Trial Evaluating the Safety and Efficacy of the Cordella™ [‡] Pulmonary Artery Sensor System in NYHA Class III Heart Failure Patients (PROACTIVE- HF Trial)	738	April 2028 (Active - not recruiting)
NCT05934487 ^a	A Prospective, Multi-Center, Open Label, Randomized Control Clinical Trial Evaluating the Safety and Efficacy of the Cordella™ [‡] Pulmonary Artery Sensor System in New York Heart Association (NYHA) Class II-III Heart Failure Patients	1750	August 2033 (recruiting)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Policy History

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12/07/2004 Medical Director review

12/14/2004 Medical Policy Committee review

01/31/2005 Managed Care Advisory Council approval

07/07/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged

02/07/2007 Medical Director review

02/21/2007 Medical Policy Committee approval. Coverage eligibility unchanged. Rationale/Source and reference updated.

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02/04/2009	Medical Director review
02/19/2009	Medical Policy Committee approval. No change to coverage eligibility.
02/04/2010	Medical Policy Committee approval
02/17/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/03/2011	Medical Policy Committee review
03/16/2011	Medical Policy Implementation Committee approval. This policy replaces medical policies 00116 and 00151 to create a single policy addressing cardiac hemodynamic monitoring for the management of heart failure in the outpatient setting.
03/01/2012	Medical Policy Committee review
03/21/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/16/2012	Policy Retired
06/02/2016	Medical Policy Committee review
06/20/2016	Medical Policy Implementation Committee approval. Policy returned to active status.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Changed “arterial pressure/Valsalva” to “arterial pressure during the Valsalva maneuver”. Coverage eligibility unchanged.
01/01/2019	Coding update
07/03/2019	Medical Policy Committee review
07/18/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/10/2019	Coding update
06/10/2020	Coding update
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/01/2021	Medical Policy Committee review
07/14/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2021	Coding update
06/24/2022	Coding update
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Rearranged the order of considerations in the investigational statement. Coverage eligibility unchanged.
07/06/2023	Medical Policy Committee review
07/12/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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07/02/2024	Medical Policy Committee review
07/10/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/11/2024	Coding update
07/03/2025	Medical Policy Committee review
07/09/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/04/2025	Medical Policy Committee review
09/10/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/02/2026	Medical Policy Committee review
07/08/2026	Medical Policy Implementation Committee review
07/16/2026	Medical Quality Management Committee approval. Added hemodynamic monitoring to the last investigational bullet for arterial pressure during the Valsalva maneuver. Added examples to all of the investigational bullets. Coverage eligibility unchanged.

Next Scheduled Review Date: 07/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	33289, 93264, 93701, 93799
HCPCS	C2624, G0555
ICD-10 Diagnosis	All Related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same

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service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.