



MASSACHUSETTS

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Medical Policy

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

Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)

Policy Number: 287

BCBSA Reference Number: 2.02.24 (For Plan internal use only)

Related Policies

Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure, #101

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Ambulatory Care and Outpatient Setting

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**. (This includes inpatient placement of the device.)

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is not a covered service in the outpatient setting. This is not a covered service in the inpatient setting.
Commercial PPO and Indemnity	This is not a covered service in the outpatient setting. This is not a covered service in the inpatient setting.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine

coverage or non-coverage as it applies to an individual member. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following CPT and HCPCS codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO and Indemnity:

CPT Codes

CPT codes:	Code Description
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
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
93701	Bioimpedance-derived physiologic cardiovascular analysis.

HCPCS Codes

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

Description

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.¹

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.²

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 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.

Summary

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 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 (FDA) approval. The pivotal CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA III Heart Failure Patients (CHAMPION) RCT reported a statistically significant 28% decrease in heart failure-related hospitalizations (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 Hemodynamic GUIDEd Management of Heart Failure (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 (HR) 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 light of the absence of a

demonstrated 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 device remains uncertain. Concerns may be clarified by the ongoing GUIDE-HF RCT that proposes to enroll 2600 subjects for its open access phase and the recruiting 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.

Policy History

Date	Action
9/2022	Annual policy review. References added. Policy statement unchanged.
12/2021	Policy clarified to include that placement of implantable cardiac hemodynamic devices in the inpatient setting is considered investigational.
6/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
7/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
6/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2019	Clarified coding information.
7/2018	Annual policy review. Policy statement clarified. 7/1/2018
6/2017	Annual policy review. New references added.
7/2016	Annual policy review. New references added.
8/2015	Annual policy review. New references added.
1/2015	Clarified coding information.
10/2014	Clarified coding information.
9/2014	Annual policy review. New references added.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.

5/2014	Annual policy review. New references added.
10/2013	Annual policy review. New references added.
5/2013	Annual policy review. New references added.
11/2011-4/2012	Medical policy ICD10 remediation: Formatting, editing and coding updates. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
11/10/2011	Medical policy #287. Effective 11/10/2011.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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