Medical Policy

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

Table of Contents

Policy Number: 287

BCBSA Reference Number: 2.02.24
NCD/LCD: National Coverage Determination (NCD) for Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB) (20.16)

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

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 policy only addresses use of these techniques in ambulatory care and outpatient settings.

Medicare HMO Blue^{SM} and Medicare PPO Blue^{SM} Members

Medical necessity criteria and coding guidance can be found through the link below.

[National Coverage Determination (NCD) for Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB) (20.16)](#)

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.
Commercial PPO and Indemnity	This is **not** a covered service.
Medicare HMO Blue^{SM}	Prior authorization is **not required**.
Medicare PPO Blue^{SM}	Prior authorization is **not required**.

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 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.

Left Ventricular End-Diastolic Pressure Estimation

Pulmonary Artery Pressure Measurement to Estimate Left Ventricular End-Diastolic Pressure
Left ventricular end-diastolic pressure (LVEDP) can be approximated by direct pressure measurement of an implantable sensor in the pulmonary artery wall or right ventricular outflow tract. The sensor is implanted via right heart catheterization and transmits pressure readings wirelessly to external monitors. One device, the CardioMEMS Champion Heart Failure Monitoring System, has approval from the U.S. Food and Drug Administration (FDA) for the ambulatory management of heart failure patient. The CardioMEMS device is implanted using a heart catheter system fed through the femoral vein and generally requires patients have an overnight hospital admission for observation after implantation.

Thoracic Bioimpedance
Bioimpedance is defined as the electrical resistance of current flow through tissue. For example, when small electrical signals are transmitted through the thorax, the current travels along the blood-filled aorta, which is the most conductive area. Changes in bioimpedance, measured during each beat of the heart, are inversely related to pulsatile changes in volume and velocity of blood in the aorta. Cardiac output is the product of stroke volume by heart rate and, thus, can be calculated from bioimpedance. Cardiac output is generally reduced in patients with systolic heart failure. Acute decompensation is characterized by worsening of cardiac output from the patient's baseline status. The technique is alternatively known as impedance cardiography.

Inert Gas Rebreathing
Inert gas rebreathing is based on the observation that the absorption and disappearance of a blood-soluble gas are proportional to cardiac blood flow. The patient is asked to breathe and rebreathe from a bag filled with oxygen mixed with a fixed proportion of 2 inert gases, typically nitrous oxide and sulfur hexafluoride. The nitrous oxide is soluble in blood and is therefore absorbed during the blood's passage through the lungs at a rate proportional to the blood flow. The sulfur hexafluoride is insoluble in blood and therefore stays in the gas phase and is used to determine the lung volume from which the soluble gas is removed. These gases and carbon dioxide are measured continuously and simultaneously at the mouthpiece.

Arterial Pressure During Valsalva Maneuver to Estimate LVEDP

LVEDP is elevated with acute decompensated heart failure. While direct catheter measurement of LVEDP is possible for patients undergoing cardiac catheterization for diagnostic or therapeutic reasons, its invasive nature precludes outpatient use. Noninvasive measurements of LVEDP have been developed based on the observation that arterial pressure during the strain phase of the Valsalva maneuver may directly reflect the LVEDP. Arterial pressure responses during repeated Valsalva maneuvers can be recorded and analyzed to produce values that correlate to the LVEDP.

Summary

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.

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. 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 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 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 on health outcomes.

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring by thoracic impedance, with inert gas rebreathing, or of arterial pressure during the Valsalva maneuver, the evidence includes uncontrolled prospective studies and case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. There is a lack of randomized controlled trial evidence evaluating whether the use of these technologies improves health outcomes over standard active management of heart failure patient. The case series have reported physiologic measurement-related outcomes and/or associations between monitoring information and heart failure exacerbations, but do not provide definitive evidence on device efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
1/2019	Clarified coding information.
7/2018	BCBSA National medical policy review. Policy statement clarified. 7/1/2018
6/2017	New references added from BCBSA National medical policy.
7/2016	New references added from BCBSA National medical policy.
8/2015	New references added from BCBSA National medical policy.
1/2015	Clarified coding information.
10/2014	Clarified coding information.

9/2014	New references added from BCBSA National medical policy.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
5/2014	New references from BCBSA National medical policy.
10/2013	New references from BCBSA National medical policy.
5/2013	New references from BCBSA National medical policy.
11/2011-4/2012	Medical policy ICD 10 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

References

1. Opasich C, Rapezzi C, Lucci D, et al. Precipitating factors and decision-making processes of short-term worsening heart failure despite "optimal" treatment (from the IN-CHF Registry). *Am J Cardiol.* Aug 15 2001;88(4):382-387. PMID 11545758
2. McAlister FA, Stewart S, Ferrua S, et al. Multidisciplinary strategies for the management of heart failure patients at high risk for admission: a systematic review of randomized trials. *J Am Coll Cardiol.* Aug 18 2004;44(4):810-819. PMID 15312864
3. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): CardioMEMS HF System. 2014; https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100045b.pdf. Accessed April 17, 2018.
4. Loh JP, Barbash IM, Waksman R. Overview of the 2011 Food and Drug Administration Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting on the CardioMEMS Champion Heart Failure Monitoring System. *J Am Coll Cardiol.* Apr 16 2013;61(15):1571-1576. PMID 23352783
5. Abraham WT, Adamson PB, Bourge RC, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. *Lancet.* Feb 19 2011;377(9766):658-666. PMID 21315441
6. Abraham WT, Stevenson LW, Bourge RC, et al. Sustained efficacy of pulmonary artery pressure to guide adjustment of chronic heart failure therapy: complete follow-up results from the CHAMPION randomised trial. *Lancet.* Jan 30 2016;387(10017):453-461. PMID 26560249
7. CardioMEMSChampion™ Heart Failure Monitoring System: Presentation - CardioMEMS: Oct. 9, 2013. 2013; https://wayback.archive-it.org/7993/20170111163201/http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM370951.pdf. Accessed April 17, 2018.
8. CardioMEMS Champion™ HF Monitoring System: FDA Review of P100045/A004FDA Presentation - CardioMEMS: Oct. 9, 2013. 2013; https://wayback.archive-it.org/7993/20170111163259/http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM370955.pdf. Accessed April 17, 2018.
9. Givertz MM, Stevenson LW, Costanzo MR, et al. Pulmonary artery pressure-guided management of patients with heart failure and reduced ejection fraction. *J Am Coll Cardiol.* Oct 10 2017;70(15):1875-1886. PMID 28982501

10. Adamson PB, Abraham WT, Bourge RC, et al. Wireless pulmonary artery pressure monitoring guides management to reduce decompensation in heart failure with preserved ejection fraction. *Circ Heart Fail.* Nov 2014;7(6):935-944. PMID 25286913

11. Adamson PB, Abraham WT, Stevenson LW, et al. Pulmonary Artery Pressure-Guided Heart Failure Management Reduces 30-Day Readmissions. *Circ Heart Fail.* Jun 2016;9(6). PMID 27220593

12. Krahnke JS, Abraham WT, Adamson PB, et al. Heart failure and respiratory hospitalizations are reduced in patients with heart failure and chronic obstructive pulmonary disease with the use of an implantable pulmonary artery pressure monitoring device. *J Card Fail.* Mar 2015;21(3):240-249. PMID 25541376

13. Desai AS, Bhimaraj A, Bharmi R, et al. Ambulatory Hemodynamic Monitoring Reduces Heart Failure Hospitalizations in "Real-World" Clinical Practice. *J Am Coll Cardiol.* May 16 2017;69(19):2357-2365. PMID 28330751

14. Vaduganathan M, DeFilippis EM, Fonarow GC, et al. ostmarketing adverse events related to the CardioMEMS HF System. *JAMA Cardiol.* Nov 1 2017;2(11):1277-1279. PMID 28975249

15. Heywood JT, Jermyn R, Shavelle D, et al. Impact of Practice-Based Management of Pulmonary Artery Pressures in 2000 Patients Implanted With the CardioMEMS Sensor. *Circulation.* Apr 18 2017;135(16):1509-1517. PMID 28219895

16. Kamath SA, Drazner MH, Tasissa G, et al. Correlation of impedance cardiography with invasive hemodynamic measurements in patients with advanced heart failure: the BioImpedance CardioGraphy (BIG) substudy of the Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE) Trial. *Am Heart J.* Aug 2009;158(2):217-223. PMID 19619697

17. Anand IS, Greenberg BH, Fogoros RN, et al. Design of the Multi-Sensor Monitoring in Congestive Heart Failure (MUSIC) study: prospective trial to assess the utility of continuous wireless physiologic monitoring in heart failure. *J Card Fail.* Jan 2011;17(1):11-16. PMID 21187259

18. Anand IS, Tang WH, Greenberg BH, et al. Design and performance of a multisensor heart failure monitoring algorithm: results from the multisensor monitoring in congestive heart failure (MUSIC) study. *J Card Fail.* Apr 2012;18(4):289-295. PMID 22464769

19. Packer M, Abraham WT, Mehra MR, et al. Utility of impedance cardiography for the identification of short-term risk of clinical decompensation in stable patients with chronic heart failure. *J Am Coll Cardiol.* Jun 6 2006;47(11):2245-2252. PMID 16750691

20. Amir O, Ben-Gal T, Weinstein JM, et al. Evaluation of remote dielectric sensing (ReDS) technology-guided therapy for decreasing heart failure re-hospitalizations. *Int J Cardiol.* Aug 1 2017;240:279-284. PMID 28341372

21. Silber HA, Trost JC, Johnston PV, et al. Finger photoplethysmography during the Valsalva maneuver reflects left ventricular filling pressure. *Am J Physiol Heart Circ Physiol.* May 2012;302(10):H2043-2047. PMID 22389389

22. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. *J Am Coll Cardiol.* Aug 8 2017;70(6):776-803. PMID 28461007

23. Kirchhof P, Benussi S, Kotecha D, et al. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. *Eur Heart J.* Oct 7 2016;37(38):2893-2962. PMID 27567408

24. Mant J, Al-Mohammad A, Swain S, et al. Management of chronic heart failure in adults: synopsis of the National Institute for Health and Clinical Excellence guideline. *Ann Intern Med.* Aug 16 2011;155(4):252-259. PMID 21844551

25. National Institute for Health and Care Excellence (NICE). Insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure [IPG463]. 2013; https://www.nice.org.uk/guidance/ipg463. Accessed April 4, 2016.

26. Centers for Medicare & Medicaid Services (CMS). National coverage decision for cardiac output monitoring by thoracic electrical bioimpedance (TEB) (20.16). 2006; http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=267&ncdver=3&NCAId=82&NcaName=Electrical+Bioimpedance+for+Cardiac+Output+Monitoring&IsPopup=y&bc=AAAAAAAACAAAAA%3D%3D&. Accessed May 6, 2015.