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OVERVIEW

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.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Thoracic Electrical Bioimpedance (TEB)

BlueCHiP for Medicare

Cardiac hemodynamic monitoring for the management of heart failure using thoracic electrical bioimpedance is covered.

Note: Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all BlueCHiP for Medicare policies. Therefore, BlueCHiP for Medicare policies may differ from Commercial products. In some instances, benefits for BlueCHiP for Medicare may be greater than what is allowed by the CMS.

Commercial Products

Cardiac hemodynamic monitoring for the management of heart failure using thoracic electrical bioimpedance (TEB) is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

Implantable Direct Pressure Monitoring, Inert Gas Rebreathing and Arterial Pressure during Valsalva Maneuver

BlueCHiP for Medicare

Cardiac hemodynamic monitoring for the management of heart failure using implantable direct pressure monitoring of the pulmonary artery, inert gas rebreathing, and arterial pressure during the Valsalva maneuver is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Cardiac hemodynamic monitoring for the management of heart failure using implantable direct pressure monitoring of the pulmonary artery, inert gas rebreathing, and arterial pressure during the Valsalva maneuver is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage for diagnostic services and for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

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 and with education or 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 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.

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 is proportional to cardiac blood flow. The patient is asked to breathe and rebreathe from a rebreathing bag filled with oxygen mixed with a fixed proportion of two 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 that is 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 to Estimate LVEDP

Left ventricular end diastolic pressure (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.

REGULATORY STATUS

Noninvasive Left Ventricular End-Diastolic Pressure Measurement Devices (LVEDP)

In 2004, the VeriCor® (CVP Diagnostics), a noninvasive LVEDP measurement device, was cleared for marketing by FDA through the 510(k) process. 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 FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices used for peripheral blood flow monitoring.

Inert Gas Rebreathing Devices

In 2006, the Innocor® (Innovision), 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.

Implantable Pulmonary Artery Pressure Sensor Devices

In 2014, the CardioMEMSTM Champion Heart Failure Monitoring System (CardioMEMS, now St. Jude Medical now Abbott) was cleared 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 found no reasonable assurance that the monitoring system would be effective, particularly in certain subpopulations, although FDA agreed this monitoring system was safe for use in the indicated patient population.

Several other devices that monitor cardiac output by measuring pressure changes in the PA or right ventricular outflow tract have been investigated in the research setting but have not received 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.

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring with an implantable pulmonary artery pressure sensor device, 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 is insufficient to determine the effects of the technology on health outcomes.

CODING

The following code is covered for BlueCHiP for Medicare and is considered not medically necessary for Commercial Products.

93701 Bioimpedance-derived physiologic cardiovascular analysis

The following CPT codes for implantation and monitoring of a wireless pulmonary artery pressure sensor are new codes effective 1/1/2019. They are not covered for BlueCHiP for Medicare and not medically necessary for Commercial products. Effective 1/1/2019, the Unlisted CPT code below should no longer be used for these services.

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 (New Code Effective 1/1/2019)

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 (New Code Effective 1/1/2019)

BlueCHiP for Medicare and Commercial Products

There is no specific code for inert gas rebreathing measurement or left ventricular end diastolic pressure and should be reported using the unlisted code:

93799 Unlisted cardiovascular service or procedure

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, December 2019
Provider Update, November 2018
Provider Update, August 2018
Provider Update, December 2017
Provider Update, October 2016

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. International Consortium for Health Outcomes Measurement, Inc (ICHOM). Heart Failure version 1.1.4. Oct 2017. Accessed Apr 2, 2019.
6. Zannad, FF, Garcia, AA, Anker, SS, Armstrong, PP, Calvo, GG, Cleland, JJ, Cohn, JJ, Dickstein, KK, Domanski, MM, Ekman, II, Filippatos, GG, Gheorghiade, MM, Hernandez, AA, Jaarsma, TT, Koglin, JJ, Konstam, MM, Kupfer, SS, Maggioni, AA, Mebazaa, AA, Metra, MM, Nowack, CC, Pieske, BB, Piña, II, Pocock, SS, Ponikowski, PP, Rosano, GG, Ruilope, LL, Ruschitzka, FF, Severin, TT, Solomon, SS, Stein, KK, Stockbridge, NN, Stough, WW, Swedberg, KK, Tavazzi, LL, Voors, AA, Wasserman, SS, Woehrle, HH, Zalewski, AA, McMurray, JJ. Clinical outcome endpoints in heart failure trials: a European Society of Cardiology Heart Failure Association consensus document. *Eur. J. Heart Fail.*, 2013 Jun 22;15(10). PMID 23787718
7. CardioMEMSChampionTM Heart Failure Monitoring System: Presentation - CardioMEMS: Oct. 9, 2013. 2013; <https://wayback.archiveit.org/7993/20170111163201/http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM370951.pdf>. Accessed April 17, 2018.
8. CardioMEMS ChampionTM HF Monitoring System: FDA Review of P100045/A004FDA Presentation - CardioMEMS: Oct. 9, 2013. 2013; <https://wayback.archiveit.org/7993/20170111163259/http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM370955.pdf>. Accessed April 17, 2018.
9. 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
10. 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
11. Krahne 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
12. 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
13. 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
14. 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

15. Vaduganathan M, DeFilippis EM, Fonarow GC, et al. Postmarketing adverse events related to the CardioMEMS HF System. *JAMA Cardiol.* Nov 1 2017;2(11):1277-1279. PMID 28975249
16. 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
17. 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
18. 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
19. 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
20. 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
21. Amir O, Ben-Gal T, Weinstein JM, et al. Evaluation of remote dielectric sensing (ReDS) technology-guided therapy for decreasing heart failure rehospitalizations. *Int J Cardiol.* Aug 1 2017;240:279-284. PMID 28341372
22. 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
23. 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
24. National Institute for Health and Care Excellence (NICE). Chronic heart failure in adults: diagnosis and management; NICE guideline NG106. Sep 2018. Accessed Apr 2, 2019.
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. Dickinson MM, Allen LL, Albert NN, DiSalvo TT, Ewald GG, Vest AA, Whellan DD, Zile MM, Givertz MM. Remote Monitoring of Patients With Heart Failure: A White Paper From the Heart Failure Society of America Scientific Statements Committee. *J. Card. Fail.*, 2018 Oct 12;24(10). PMID 30308242
27. Centers for Medicare & Medicaid Services (CMS). National coverage decision for cardiac output monitoring by thoracic electrical bioimpedance (TEB) (2016). 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=AAAAAAAACAAAA%3D%3D&>. Accessed May 6, 2015.

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