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EVIDENCE-BASED CRITERIA  
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 09/19/22  
LAST REVIEW DATE: 08/06/24  
CURRENT EFFECTIVE DATE: 08/06/24  
LAST CRITERIA REVISION DATE: 08/15/23  
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 3RD QTR 2025

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## CARDIAC HEMODYNAMIC MONITORING FOR THE MANAGEMENT OF HEART FAILURE IN THE OUTPATIENT SETTING

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Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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## **CARDIAC HEMODYNAMIC MONITORING FOR THE MANAGEMENT OF HEART FAILURE IN THE OUTPATIENT SETTING**

### **Description:**

A variety of outpatient cardiac hemodynamic monitoring devices are intended to improve quality of life and reduce morbidity for individuals 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.

### **Chronic Heart Failure**

Individuals with chronic heart failure are at risk of developing acute decompensated heart failure, often requiring hospital admission. Individuals 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 individuals at risk for imminent decompensation. Programs for early identification of heart failure are characterized by frequent contact with individuals 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 individual 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 individuals 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.

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## CARDIAC HEMODYNAMIC MONITORING FOR THE MANAGEMENT OF HEART FAILURE IN THE OUTPATIENT SETTING

### Criteria:

- 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 **experimental or investigational** when any **ONE** or more of the following criteria are met:
  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

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### Resources:

Literature reviewed 08/06/24. We do not include marketing materials, poster boards and non-published literature in our review

Resources prior to 08/06/24 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Abraham J, Bharmi R, Jonsson O, et al. Association of Ambulatory Hemodynamic Monitoring of Heart Failure With Clinical Outcomes in a Concurrent Matched Cohort Analysis. *JAMA Cardiol.* Jun 1 2019;4(6):556-563. doi:10.1001/jamacardio.2019.1384
2. 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):658-66. doi:10.1016/S0140-6736(11)60101-3
3. 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):453-61. doi:10.1016/S0140-6736(15)00723-0
4. Adamson PB, Abraham WT, Aaron M, et al. CHAMPION trial rationale and design: the long-term safety and clinical efficacy of a wireless pulmonary artery pressure monitoring system. *J Card Fail.* Jan 2011;17(1):3-10. doi:10.1016/j.cardfail.2010.08.002

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6. 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)doi:10.1161/CIRCHEARTFAILURE.115.002600
7. 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. doi:10.1016/j.ijcard.2017.02.120
8. Anand IS, Greenberg BH, Fogoros RN, Libbus I, Katra RP, Music I. 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):11-6. doi:10.1016/j.cardfail.2010.08.001
9. 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):289-95. doi:10.1016/j.cardfail.2012.01.009
10. Angermann CE, Assmus B, Anker SD, et al. Pulmonary artery pressure-guided therapy in ambulatory patients with symptomatic heart failure: the CardioMEMS European Monitoring Study for Heart Failure (MEMS-HF). *Eur J Heart Fail*. Oct 2020;22(10):1891-1901. doi:10.1002/ejhf.1943
11. Assmus B, Angermann CE, Alkhout B, et al. Effects of remote haemodynamic-guided heart failure management in patients with different subtypes of pulmonary hypertension: insights from the MEMS-HF study. *Eur J Heart Fail*. Dec 2022;24(12):2320-2330. doi:10.1002/ejhf.2656
12. Brugts JJ, Radhoe SP, Clephas PRD, et al. Remote haemodynamic monitoring of pulmonary artery pressures in patients with chronic heart failure (MONITOR-HF): a randomised clinical trial. *Lancet*. Jun 24 2023;401(10394):2113-2123. doi:10.1016/S0140-6736(23)00923-6

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15. CardioMEMS Champion™ Heart Failure Monitoring System: Presentation - CardioMEMS: Oct. 9, 2013. Internet Archive Wayback Machine. Accessed May 4, 2024. <https://wayback.archive-it.org/7993/20170111163201/http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM370951.pdf>
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18. Curtain JP, Lee MMY, McMurray JJ, Gardner RS, Petrie MC, Jhund PS. Efficacy of implantable haemodynamic monitoring in heart failure across ranges of ejection fraction: a systematic review and meta-analysis. *Heart.* May 15 2023;109(11):823-831. doi:10.1136/heartjnl-2022-321885
19. DeFilippis EM, Henderson J, Axsom KM, et al. Remote Hemodynamic Monitoring Equally Reduces Heart Failure Hospitalizations in Women and Men in Clinical Practice: A Sex-Specific Analysis of the CardioMEMS Post-Approval Study. *Circ Heart Fail.* Jun 2021;14(6):e007892. doi:10.1161/CIRCHEARTFAILURE.120.007892
20. 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. doi:10.1016/j.jacc.2017.03.009

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45. Zile MR, Desai AS, Costanzo MR, et al. The GUIDE-HF trial of pulmonary artery pressure monitoring in heart failure: impact of the COVID-19 pandemic. *Eur Heart J.* Jul 14 2022;43(27):2603-2618. doi:10.1093/eurheartj/ehac114

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### Coding:

CPT: 33289, 93264, 93701





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<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
Medical Policy Panel	08/06/24	Review with revisions
Medical Policy Panel	08/15/23	Review with revisions
Medical Policy Panel	08/16/22	Approved guideline (Effective 9/19/22)

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### Policy Revisions:

08/06/24	Updated:	Resources section
08/15/23	Added:	“Insufficient evidence to support improvement of the net health outcome; or”, and “Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or” to experimental or investigational criteria.
08/15/23	Revised:	“Insufficient evidence to support improvement outside the investigational setting” from #3 to #5 in experimental or investigational criteria.
08/15/23	Updated:	Literature to Resources



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### Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, [crc@azblue.com](mailto:crc@azblue.com). You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

### Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idilkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idilkidgo beehaz'áanii hólo díí t'áá hazaadk'ehjí háká a'doowotgo bee haz'á doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í' hodilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعدته أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

