



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 12/30/15
LAST REVIEW DATE: 06/19/18
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

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

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 Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline 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.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Several cardiac hemodynamic monitoring techniques have been investigated for the management of heart failure.

Arterial Pressure During Valsalva to Estimate Left Ventricular End Diastolic Pressure (LVEDP):

LVEDP is elevated in acute decompensated heart failure. Noninvasive measurement of LVEDP for the management of heart failure has been investigated based on the observation that arterial pressure during the Valsalva maneuver may directly reflect the LVEDP. Arterial pressures during repeated Valsalva maneuvers are recorded and analyzed to estimate LVEDP.

Implantable Direct Pressure Monitoring of the Pulmonary Artery:

An implantable sensor placed in the pulmonary artery wall via right heart catheterization has been investigated to wirelessly transmit pressure readings to external monitors and estimate LVEDP. The CardioMEMS Champion Heart Failure Monitoring System was cleared for marketing by the FDA in May, 2014.

Inert Gas Rebreathing:

Inert gas rebreathing has been investigated as a noninvasive measurement of cardiac output based on the observation that the absorption of a blood-soluble gas is proportional to cardiac blood flow. The individual breathes and re-breathes from a rebreathing bag containing oxygen mixed with foreign gases; typically nitrous oxide and sulphur 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 sulphur 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 CO₂ are measured continuously and simultaneously at the mouthpiece.

Thoracic Bioimpedance:

Bioimpedance is the electrical resistance of tissue to the flow of current. When small electrical signals are transmitted through the thorax, the current travels along the blood-filled aorta. This technique is also known as impedance and impedance cardiography (ICG).

CARDIAC HEMODYNAMIC MONITORING FOR THE MANAGEMENT OF HEART FAILURE IN THE OUTPATIENT SETTING (cont.)

Criteria:

- Cardiac hemodynamic monitoring for the management of heart failure utilizing the following techniques is considered ***experimental or investigational*** based upon:
1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

These techniques include, *but are not limited to*:

- Arterial pressure during Valsalva
- Implantable direct pressure monitoring of the pulmonary artery
- Inert gas rebreathing
- Thoracic Bioimpedance

Resources:

Literature reviewed 06/19/18. We do not include marketing materials, poster boards and non-published literature in our review

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 2.02.24 BCBS Association Medical Policy Reference Manual. Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting. Re-issue date 05/04/2018, Issue date 07/08/2010.
2. California Technology Assessment Forum. CardioMEMS HF System and Sacubitril-Valsartan for Management of CHF. *Blue Shield of California Foundation*. 12/01/2015.
3. Lang C. C., Karlin P., Haythe J., Tsao L., Mancini D. M. Ease of noninvasive measurement of cardiac output coupled with peak VO₂ determination at rest and during exercise in patients with heart failure. *Am J Cardiol*. 2007 Feb 1 2007;99(3):404-405.
4. Villani F., Meazza R., Materazzo C. Non-invasive monitoring of cardiac hemodynamic parameters in doxorubicin-treated patients: comparison with echocardiography. *Anticancer Res*. 2006 Jan-Feb 2006;26(1B):797-801.



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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. 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'idíłkídogo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíłkídogo beehaz'áanii hółqo díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojį' bich'į' hodíłnih 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 تساعد 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.

