Anthem

Medical Policy

Subject: Non-Invasive Measurement of Left Ventricular End Diastolic Pressure in the Outpatient Setting
Document #: MED.00053 **Publish Date:** 04/10/2024
Status: Reviewed **Last Review Date:** 02/15/2024

Description/Scope

This document addresses non-invasive measurement of left ventricular end diastolic pressure in the outpatient setting. Left ventricular end diastolic pressure (LVEDP) is elevated in the setting of congestive heart failure, and its measurement may be useful in the management of individuals with heart failure. The VeriCor® device is an example of a device for the non-invasive measurement of LVEDP.

Position Statement

Investigational and Not Medically Necessary:

Non-invasive measurement of left ventricular end diastolic pressure in the outpatient setting is considered **investigational and not medically necessary.**

Rationale

Most individuals with suspected heart failure (HF) do not require invasive testing for confirmation of diagnosis, but no single noninvasive test is considered gold standard for diagnosis. Left ventricular end diastolic pressure (LVEDP) is elevated in the setting of HF, and its measurement has been proposed to be useful in the management of HF. However, to date, measurement of LVEDP has required cardiac catheterization, either by direct measurement by placing a catheter in the left ventricle, or indirect measurement by placing a catheter in the pulmonary artery to measure the pulmonary capillary wedge pressure (PCWP), the latter of which is the current clinical gold standard. Non-invasive measurements of LVEDP have been developed based on the observation that the arterial pressure during the strain phase of the Valsalva maneuver may directly reflect the LVEDP. (See the Definitions section for information about Valsalva maneuvers).

The ability to perform measurements of LVEDP non-invasively permits the outpatient use of this technology and potentially broadens the selection criteria for LVEDP measurement, to potentially include its role in the ongoing monitoring and management of stable individuals with HF. The manufacturer of the VeriCor device (CVP Diagnostics, Inc., Boston MA) suggests that the device may be used to determine the need for hospitalization or to monitor individuals with HF to maintain LVEDP within a targeted range to prevent future hospitalizations.

Although published studies have shown a high correlation between invasive and non-invasive measurements of LVEDP, to date, there have been limited evidence-based trials to demonstrate equivalence to the current established gold standard for HF assessment, which remains cardiac catheterization. Sharma and colleagues performed simultaneous measurements of LVEDP based on three techniques: direct measurement of LVEDP (by left cardiac catheterization); indirect measurement using PCWP; and noninvasive measurement using the VeriCor device in 49 subjects scheduled for elective cardiac catheterization. It was noted that the VeriCor measurements correlated well with the direct measures of LVEDP (R^2=0.86) and outperformed the PCWP, which had a correlation coefficient of 0.81, compared to the gold standard (Sharma, 2002). In 2011, Sharma conducted another small prospective study which examined if non-invasive monitoring of LVEDP would reduce re-hospitalization rates in individuals hospitalized for HF. A total of 50 subjects admitted for HF were randomized to management guided by daily non-invasive estimated LVEDP monitoring (group I, open) to a target LVEDP of less than 20 mm Hg or management based on clinical assessment alone without knowledge of the estimated LVEDP (group II, blinded). Non-invasive estimated LVEDP was measured by the VeriCor monitor. The primary endpoints were the reduction of estimated LVEDP at discharge and the HF re-hospitalization rate on follow-up. Estimated LVEDP was significantly reduced at discharge in the open group compared with the blinded group (mean estimated LVEDP 19.7 ± 1.3 mm Hg versus 25.6 ± 1.5 mm Hg, respectively, p=0.01). The re-hospitalization rates for HF on follow-up were significantly improved in the open group compared with the blinded group (at 1 month: 0% versus 25%, respectively [p=0.05]; at 3 months: 0% versus 32% [p=0.01]; at 6 months: 4% versus 36% [p=0.01]; at 1 year: 16% versus 48% [p=0.03]). The authors concluded that therapy guided by estimated LVEDP monitoring optimizes filling pressures and reduces HF re-hospitalization rates. However, it was acknowledged that the findings of this small study need to be validated in larger well-designed trials (Sharma, 2011).

At the present time, there is inadequate data to permit scientific conclusions regarding the clinical utility of non-invasive LVEDP technology. To date, there are no large, well-designed, published studies that examined whether including routine measurement of LVEDP in the outpatient setting resulted in improved management of HF, as evidenced by improvement in the clinical signs and symptoms or the need for hospitalization.

Background/Overview

The heart is a muscle that acts as an automatic pump to circulate blood throughout the body. Congestive heart failure (CHF), or the more recently used term, heart failure (HF), is a condition in which the heart's function as a pump is inadequate to meet the body's needs. Approximately 2 out of every 100 people between the ages of 27 and 74 have HF. HF becomes more common with advancing age. A poor blood supply resulting from HF may cause the body's organ systems to fail. When the heart's pumping action is inadequate as a result of HF, the blood "backs up" (becomes congested) in the venous system that leads to the heart. This congestion can lead to fluid accumulation in the lungs and body tissues. HF is a grouping of clinical findings, rather than a specific diagnosis or a single disease, and can be considered a symptom of impairment of the pumping action of the heart that is caused by an underlying disease.

The VeriCor device (CVP Diagnostics, Inc., Boston MA) obtained clearance from the U.S. Food and Drug Administration (FDA) for the non-invasive measurement of LVEDP on June 7, 2004 through the 510(k) approval process. The FDA labeled indication is as follows:

> The VeriCor System is indicated for use in estimating (noninvasively) left ventricular end-diastolic (LVEDP) pressure. 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 to use 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 (FDA, 2004).

The device consists of a digital expiratory manometer coupled with a continuous arterial pressure monitor and a medical grade computer. A tonometric sensor is attached to the subject's wrist with a blood pressure cuff attached to the arm. After an 8-minute tonometric calibration period is completed, the VeriCor system is ready for use. For the test, the subject is prompted to perform a Valsalva maneuver by blowing into the mouthpiece of the digital manometer to produce an expiratory pressure of 20 to 30 mm Hg for a minimum of 8 seconds. The digital signals are collected and stored on a medical grade computer. The arterial pressure signals are then analyzed according to algorithms that were developed to most accurately predict PCWP.

The American College of Cardiology/American Heart Association (ACC/AHA) 2001 Guideline for the Evaluation and Management of Heart Failure stated that, "Invasive and noninvasive hemodynamic measurements in the management of heart failure remain uncertain" (Hunt, 2001). The 2005 ACC/AHA Guideline update for the Diagnosis and Management of Chronic Heart Failure in the Adult states that, "There has been no established role for periodic invasive or noninvasive hemodynamic measurements in the management of heart failure" (Hunt, 2005). This position was repeated in the 2009 focused update from the ACC/AHA Guidelines for the Diagnosis and Management of Heart Failure in Adults (Hunt, 2009) and in the American College of Cardiology Foundation (ACCF), American Heart Association (AHA) Guidelines for the Diagnosis and Management of Heart Failure in Adults (Jessup, 2009) with no change regarding hemodynamic measurements, and the above statement is considered current. Additional updated guidelines from the ACC/AHA (2022) do not address non-invasive measurements of LVEDP (Heidenreich, 2022).

The following is excerpted from the 2009 updated guidelines regarding the basis for their position:

> Most drugs used for the treatment of heart failure (HF) are prescribed on the basis of their ability to improve symptoms or survival rather than their effect on hemodynamic variables. Moreover, the initial and target doses of these drugs are selected on the basis of experience in controlled trials and are not based on the changes they may produce in cardiac output or pulmonary wedge pressure…Nevertheless, invasive hemodynamic measurements may assist in the determination of volume status and in distinguishing HF from other disorders that may cause circulatory instability, such as pulmonary diseases and sepsis. Measurements of cardiac output and pulmonary wedge pressure through a pulmonary artery catheter have also been used in patients with refractory HF to assess pulmonary vascular resistance, a determinant of eligibility for heart transplantation. Cardiac output can also be measured by noninvasive methods (Hunt, 2009; Jessup, 2009).

The Valsalva maneuver may be contraindicated in a variety of cardiovascular conditions, for example, hypertrophic obstructive cardiomyopathy, significant aortic valvular disease and recent myocardial infarction (FDA, 2004).

Definitions

Congestive heart failure (CHF) also known as heart failure (HF): A condition in which the heart cannot pump enough blood to supply the body's tissues with sufficient nutrients that results in a back-up of blood in the vessels and lungs and causes the build-up of fluid in the tissues.

Left ventricular end diastolic pressure (LVEDP): The pressure at the end of the filling phase of the heartbeat contraction, which is the clinical definition of preload.

Valsalva maneuver: The act of attempting to forcibly exhale while keeping the mouth and nose closed. It is used as a diagnostic tool to evaluate the condition of the heart and is sometimes done as a treatment to correct abnormal heart rhythms or to relieve chest pain.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

93799	Unlisted cardiovascular service or procedure [when specified as left ventricular filling pressure; indirect measurement by computerized calibration of the arterial waveform response to Valsalva maneuver]

ICD-10 Diagnosis

	All diagnoses

References

Peer Reviewed Publications:

1. Felker GM, Cuculich PS, Gheorghiade M. The Valsalva maneuver: a bedside "biomarker" for heart failure. Am J Med. 2006; 119(2):117-122.
2. Lancellotti P, Galderisi M, Edvardsen T, et al. Echo-Doppler estimation of left ventricular filling pressure: results of the multicenter EACVI Euro-Filling study. Eur Heart J Cardiovasc Imaging. 2017; 18(9):961-968.
3. McIntyre KM, Vita JA, Lambrew CT, et al. A noninvasive method of predicting pulmonary-capillary wedge pressure. N Engl J Med. 1992; 327(24):1715-1720.
4. Sharma GV, Woods PA, Lambrew CT, et al. Evaluation of a noninvasive system for determining left ventricular filling pressure. Arch Int. Med. 2002; 162(18):2084-2088.
5. Sharma GV, Woods PA, Lindsey N, et al. Noninvasive monitoring of left ventricular end-diastolic pressure reduces re-hospitalization rates in patients hospitalized for heart failure: a randomized controlled trial. J Card Fail. 2011; 17(9):718-725.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of

the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2022; 79(17): e263-e421.
2. Hunt SA, Abraham WT, Chin MH, et al. ACC/AHA 2005 guideline update for the diagnosis and management of chronic heart failure in the adult: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure). Circulation. 2005; 112(12):e154-e235. Available at: http://circ.ahajournals.org/cgi/reprint/112/12/e154. Accessed on January14, 2024.
3. Jessup M, Abraham WT, Casey DE, et al. writing on behalf of the 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult Writing Committee. 2009 Focused update: ACCF/AHA guidelines for the diagnosis and management of heart failure in adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2009; 119(14):1977-2016. Available at: http://circ.ahajournals.org/content/119/14/1977.full.pdf. Accessed on January 14, 2024.
4. McMurray JJ, Adamopoulos S, Anker SD, et al.; Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology (ESC) Committee for Practice Guidelines. ESC guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology (ESC). Developed in collaboration with the Heart Failure Association (HFA) of the ESC. Eur J Heart Fail. 2012; 14(8):803-869.
5. U.S. Food and Drug Administration (FDA) Center for Devices and Radiologic Health. VeriCor® (CVP Diagnostics, Inc., Boston MA). 510(k) Approval. Summary of Safety and Effectiveness No. K031327. Rockville, MD: FDA. June 7, 2004. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf3/K031327.pdf. Accessed on January 14, 2024.

Websites for Additional Information

1. American Heart Association: Congestive Heart Failure. Available at:https://www.heart.org/en/health-topics/heart-failure. Accessed on January 14, 2024.
2. Cleveland Clinic. Heart failure. Available at:https://pages.clevelandclinic.org/heart-failure-index-3.html?utm_source=bing_ppc&utm_medium=cpc&utm_campaign=Heart+-+Heart+Failure+-+General+-+Region+1,+2,+3&utm_term=heart%20failure&gclsrc=aw.ds&msclkid=757deb98fdaa10b1e5688824b0609089. Accessed on January 14, 2024.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale, Background/Overview and References sections.
Reviewed	02/16/2023	MPTAC review. Updated Background and References sections.
Reviewed	02/17/2022	MPTAC review. References were updated.
Reviewed	02/11/2021	MPTAC review. References were updated.
Reviewed	02/20/2020	MPTAC review. References were updated.
Revised	03/21/2019	MPTAC review. The acronym (LVEDP) was removed from the title and position statement. References were updated.
Reviewed	05/03/2018	MPTAC review. The document header wording was updated from “Current Effective Date” to “Publish Date.” References were updated.
Reviewed	05/04/2017	MPTAC review. References were updated.
Reviewed	05/05/2016	MPTAC review. References were updated. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. References were updated.
Reviewed	05/15/2014	MPTAC review. References were updated.
Reviewed	05/09/2013	MPTAC review. The Rationale, Background, and References were updated.
Reviewed	05/10/2012	MPTAC review. The Rationale, Background and References were updated.
Reviewed	05/19/2011	MPTAC review. References were updated.
Reviewed	05/13/2010	MPTAC review. References were updated.
	01/01/2010	Updated Coding section with 01/01/2010 CPT changes; removed CPT 0086T deleted 12/31/2009.
Reviewed	05/21/2009	MPTAC review. The Rationale and References were updated.
Reviewed	05/15/2008	MPTAC review. References were updated.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	05/17/2007	MPTAC review. References section was updated.
Reviewed	06/08/2006	MPTAC review. References were revised to add the 2005 updated ACC/AHA Guideline for the Diagnosis and Management of Heart Failure in the Adult.
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger Wellpoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	01/13/2005	MED.00053	Non-Invasive Measurement of Left Ventricular End Diastolic Pressure (LVEDP) in the Outpatient Setting

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.