Anthem

Medical Policy

Subject: Implantable Left Atrial Hemodynamic Monitor
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Description/Scope

This document addresses implantable left atrial hemodynamic (LAH) monitors. These devices monitor left atrial pressure (LAP) with the objective of identifying pressure changes in ambulatory individuals with heart failure (HF) to potentially enable earlier intervention and prevention of clinical deterioration. The monitoring system can be used as a stand-alone device or in combination with an implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D).

Note: For information regarding other technologies for cardiac disease, see:

- MED.00053 Non-Invasive Measurement of Left Ventricular End Diastolic Pressure in the Outpatient Setting
- MED.00115 Outpatient Cardiac Hemodynamic Monitoring Using a Wireless Sensor for Heart Failure Management

Position Statement

Investigational and Not Medically Necessary:

Left atrial hemodynamic monitoring utilizing implantable device (for example, HeartPOD™ System, Promote® LAP System, and V-LAP™ System) is considered **investigational and not medically necessary** for all indications.

Rationale

The Hemodynamically Guided Home Self-Therapy in Severe Heart Failure Patients (HOMEOSTASIS) trial was a multicenter, prospective trial approved by the U.S. Food and Drug Administration (FDA) under an Investigational Devices Exemption (IDE) (Ritzema, 2007). This was the first-in-human trial of the HeartPOD System (Abbott Laboratories, Abbott Park, IL, formerly by St. Jude Medical/Savacor, Inc). The purpose was to evaluate the device's safety, reliability, and functionality. Individuals with a history of New York Heart Association (NYHA) functional class III to IV HF and at least one hospital admission, emergency department or clinic visit for acute decompensated HF requiring a parenteral diuretic, vasodilator, or positive inotrope during the previous 12 months were eligible to participate. After device implantation, participants had clinic visits at 2, 6, and 12 weeks for a clinical assessment, data retrieval, and noninvasive device calibration. Concordance between pulmonary capillary wedge pressure (PCWP) and direct LAP from the device was assessed at week 12. A total of 8 individuals participated, and none experienced procedural complications. At week 12, 87% of HeartPOD LAP measurements were within ± 5 mm Hg of PCWP, and there were no device-related complications or deaths, unplanned clinic visits or hospital admissions for HF. The investigators concluded that HeartPOD could be safely implanted and accurately measures LAP in the short-term. They also stated that additional research is needed to determine whether direct LAP measurement can result in optimized HF treatment and thereby, improve clinical outcomes.

In 2010, Ritzema and colleagues reported additional results from the HOMEOSTASIS trial. This report included a total of 40 subjects who were implanted with the HeartPOD System and had a median follow-up of 25 months (ranging from 3-38 months). Primary safety endpoint measures were met at 6 weeks with all participants free of major adverse cardiac or neurological events; the 3-year survival rate for participants without decompensation was 61%, with a decrease in episodes reported after the initial 3 months. During pressure guided therapy, the reported mean daily LAP fell from 17.6 mm Hg to 14.8 mm Hg during the initial 3 months. The authors concluded that:

> The small study size, lack of a randomized design with a concurrent control group, and observer bias from lack of blinding limit the ability to reach definitive conclusions about the safety and clinical effectiveness of this heart failure management strategy.

The 2022 American Heart Association (AHA)/American College of Cardiology (ACC)/Heart Failure Society of America (HFSA) guideline for the management of heart failure does not address use of implantable LAP devices (Heidenreich, 2022).

The Heart Failure Society of America Scientific Statements Committee published a white paper consensus statement on remote monitoring of patients with HF (Dickinson, 2018). It included an assessment of the LAPTOP-HF trial, which was a prospective, multicenter, randomized, unblinded trial of individuals who have been diagnosed with NYHA class III HF (Maurer, 2015). Participants were randomized to LAP-guided HF therapy (treatment group) or HF usual standard of care (control group). The primary endpoints assessed safety and effectiveness. The safety assessment included freedom from procedure/device-related major adverse cardiovascular and neurological events (MACNE) at 12 months. The effectiveness assessment included a composite endpoint of heart failure hospitalizations and complications of HF therapy over the entire study period. Preliminary results were presented at the 2016 Annual Scientific Meeting of the Heart Failure Society. The investigators reported that the planned enrollment was 730 individuals however, at 486 individuals, the trial was stopped by the Data and Safety Monitoring Board due to an excess of complications from the implantation procedure. In the absence of peer-reviewed data from a completed trial, the authors of this white paper concluded that:

- The LAPTOP-HF trial of a left atrial pressure monitor failed owing to an excess of complications from the implantation procedure.
- Limited data from the trial suggest that the hemodynamic monitoring and associated management algorithm for patient-directed therapy adjustments could have been effective.

However, after enrollment was terminated, the LAPTOP-HF trial's steering committee recommended that all randomized individuals who were implanted successfully should be followed through at least 12 months. At the 2016 Annual Scientific Meeting of the Heart Failure Society, the preliminary results reported by Abraham and colleagues (2016) showed that freedom from MACNE at 12 months was 90.6% in the LAP-guided HF therapy group, with a lower confidence interval (CI) of 86.7% (the prespecified level was 80%). The annual heart failure hospital rate for the LAP-guided HF therapy group was 0.40 vs. 0.68 in the control group, which represented a relative risk reduction of 41%; p=0.005. The investigators concluded that ambulatory LAP-guided HF therapy was safe and associated

with a 41% reduction in HF hospital admissions, and that this data provides insight into the potential benefits of hemodynamic monitoring. Additional randomized trials are needed to assess the safety and efficacy of this technology.

Perl and colleagues (2022) conducted the V-LAP Left Atrium Monitoring systEm for Patients With Chronic sysTOlic & Diastolic Congestive heart Failure (VECTOR-HF; NCT03775161) trial, the first-in-human trial of the V-LAP system. In this prospective, multicenter, open-label, single-arm trial, eligible participants were older than 18 years of age, diagnosed with chronic HF NYHA functional class III and had a history of at least one hospital admission due to worsening heart failure within the past year or elevated brain natriuretic peptide (BNP) > 300 pg/mL or N-terminal pro b-type natriuretic peptide (NT-proBNP) > 1500 pg/mL. Primary outcomes included successful implantation of the device, the ability to conduct initial pressure measurements, and device safety defined as freedom from major adverse cardiovascular and neurologic events. Secondary outcomes included accurate pressure measurements, transmission of information up to 3 months after implantation, device concordance with PCWP at 3 months, admissions due to heart failure, and changes in NYHA Class, 6-minute walk test, Kansas City Cardiomyopathy Questionnaire (KCCQ) results, and NT-proBNP levels at 6 months. A total of 24 individuals (83% were male) with a mean age of 67.4 ± 9.7 years underwent implantation with the V-LAP-System. All were successfully implanted with the device, and no device-related complications (defined as invasive treatment, device explant or death) or sensor failure occurred. Concordance between the V-LAP System and PCWP measurements showed a mean difference of -2.05 ± 3.33 mm Hg (Lin concordance correlation coefficient = 0.850, 95% CI, 0.676 to 0.934). At 6 months post implantation, 8 of 20 individuals had an improvement in NYHA Class (40%, 95% CI, 16.4% to 63.5%). There was no change in 6-minute walk test distance, KCCQ scores, NT-proBNP levels, or number of hospitalizations due to heart failure. The investigators stated that these initial results demonstrate that ambulatory hemodynamic monitoring with the V-LAP system is safe and feasible. They also stated that additional well-designed randomized trials are still needed.

Restivo and colleagues (2022) reported long-term outcomes of a subset of the VECTOR-HF study participants. The purpose was to describe the largest (n=5) and longest (median follow-up 18 months) single-center experience with the V-LAP device. Individuals who underwent V-LAP System implantation had an improvement in their 6-minute walk test distance (352.5 ± 86.2 meters at baseline to 441.2 ± 125.2 meters at last follow-up) and KCCQ overall scores 63.82 ± 16.36 vs. 81.92 ± 9.63 and KCCQ clinical score 68.47 ± 19.48 vs. 83.70 ± 15.58. The investigators concluded that their findings were promising however, additional research to confirm the device's reliability as well as its clinical benefit is needed.

Background/Overview

Description of Relevant Disease

According to the Centers for Disease Control and Prevention, approximately 6.2 million Americans are currently diagnosed with HF, and more than 960,000 new cases are diagnosed each year (CDC, 2020). Approximately 50% of individuals with HF die within 5 years of diagnosis. As a result of HF, the weakened heart muscle causes inadequate filling of the left ventricle, as well as a backflow of blood into the left atrium, both resulting in decreased cardiac output and increased symptoms for the afflicted individual. Symptoms can include shortness of breath, fatigue, swelling in the ankles, feet, legs, abdomen and veins in the neck. Currently there is no cure for HF; medical therapy includes a combination of diuretics, digoxin, angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARB), beta-blockers, and aldosterone antagonists. Some individuals may remain symptomatic, despite medical therapy. Ongoing studies evaluate other treatment options to assist physicians in the medical management of individuals with severe heart failure.

HeartPOD System:

This device is indicated for individuals with ischemic or non-ischemic cardiomyopathy with systolic or diastolic dysfunction for at least 6 months or HF classified by NYHA Class III. The HeartPOD system is a stand-alone device for use in individuals not requiring ICD or CRT-D therapy, or who already received ICD or CRT-D therapy. The system monitors LAP with a permanently implantable sensor used in ambulatory individuals with heart failure (HF). These implanted intracardiac sensors allow the individual to directly monitor left atrial pressure, the intracardiac electrogram, and core body temperature. The implant's readings are communicated with a hand-held computer called a PAM. The information is used to adjust medications on a dose-by-dose basis according to the physician's prescriptive instructions. The HeartPOD System is not available for commercial use in the U.S.

The Promote LAP System:

The Promote LAP System (St. Jude Medical, Inc., St. Paul, MN) is indicated for individuals with ischemic or non-ischemic cardiomyopathy and Class III HF. The Promote LAP system is a combination device for individuals who require ICD or CRT-D therapy in addition to LAP monitoring. This Promote LAP System is not available for commercial use in the U.S. Enrollment for an FDA IDE study was completed in 2016; study results have not been published.

V-LAP System:

The V-LAP System (Vectorious Medical Technologies, Tel Aviv, Israel) is an implanted device that is placed percutaneously across the inter-atrial septum and measures LAP. Individuals with HF may be monitored remotely through bidirectional communication with an external unit. Data from the device are transmitted to a Patient Advisor Module (PAM) that provides the individual with specific instructions on changes that should be made to their HF therapy. The changes are based on the individual's hemodynamic measurements and physician's directions. The goal of the device is to shift from crisis management to health maintenance by detecting an impending HF exacerbation (i.e., before the onset of symptoms) allowing for alterations in HF medications and thereby, avoiding complications. The V-LAP System is limited to investigational use in the U.S.

Definitions

Cardiomyopathy: A disease in which the heart muscle becomes inflamed and doesn't work as well as it should; there are three main types of cardiomyopathy:

- Dilated - This is the most common form, in which the heart cavity is enlarged and stretched (cardiac dilation). The heart is weak and doesn't pump normally, and most individuals develop congestive heart failure. Abnormal heart rhythms and disturbances in the heart's electrical conduction may also occur.
- Hypertrophic - In this condition, the muscle mass of the left ventricle enlarges or "hypertrophies." In one form of the disease, the wall between the two pumping chambers becomes enlarged and obstructs the blood flow from the left ventricle. In the other form of the disease, non-obstructive hypertrophic cardiomyopathy, the enlarged muscle doesn't obstruct blood flow.
- Restrictive - This is the least common type in the United States. The myocardium (heart muscle) of the ventricles becomes excessively "rigid," making it more difficult for the ventricles to fill with blood between heartbeats. This type of cardiomyopathy is usually due to another disease process.

Congestive Heart failure (CHF), also referred to as Heart Failure (HF): A condition in which the heart no longer adequately functions

as a pump. As blood flow out of the heart slows, blood returning to the heart through the veins backs up, causing congestion in the lungs and other organs.

Investigational Device Exemption (IDE): Allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification [510(k)] submission to FDA.

Ischemic dilated cardiomyopathy (IDCM): Left ventricular systolic dysfunction (or disease of the heart muscle) associated with at least 75 percent narrowing of at least one of the three major coronary arteries (marked stenosis) or a documented history of myocardial infarction.

New York Heart Association (NYHA) definitions: The NYHA classification of heart failure is a 4-tier system that categorizes based on subjective impression of the degree of functional compromise. The four NYHA functional classes are as follows:

- Class I - individuals with cardiac disease but without resulting limitation of physical activity; ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain; symptoms only occur on severe exertion;
- Class II - individuals with cardiac disease resulting in slight limitation of physical activity; they are comfortable at rest; ordinary physical activity, (e.g., moderate physical exertion, such as carrying shopping bags up several flights of stairs) results in fatigue, palpitation, dyspnea, or anginal pain;
- Class III - individuals with cardiac disease resulting in marked limitation of physical activity; they are comfortable at rest; less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain;
- Class IV - individuals with cardiac disease resulting in inability to carry on any physical activity without discomfort; symptoms of heart failure or the anginal syndrome may be present even at rest; if any physical activity is undertaken, discomfort is increased.

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 insertion of left atrial hemodynamic monitor]
ICD-10 Procedure	
02H700Z-02H740Z	Insertion of pressure sensor monitoring device into left atrium [by approach; includes codes 02H700Z, 02H730Z, 02H740Z]
	For the following codes **when specified as left atrial monitoring**
0JH600Z-0JH630Z	Insertion of hemodynamic monitoring device into chest subcutaneous tissue and fascia [by approach; includes codes 0JH600Z, 0JH630Z]
0JH800Z-0JH830Z	Insertion of hemodynamic monitoring device into abdomen subcutaneous tissue and fascia [by approach; includes codes 0JH800Z, 0JH830Z]
ICD-10 Diagnosis	
	All diagnoses

References

Peer Reviewed Publications:

1. Abraham WT, Adamson PB, Costanzo MR, et al. Hemodynamic monitoring in advanced heart failure: Results from the LAPTOP-HF trial. J Card Fail. 2016; 22(11):940.
2. Maurer MS, Adamson PB, Costanzo MR, et al. Rationale and design of the left atrial pressure monitoring to optimize heart failure therapy study (LAPTOP-HF). J Card Fail. 2015; 21(6):479-488.
3. Perl L, Meerkin D, D'amario D, et al. The V-LAP System for remote left atrial pressure monitoring of patients with heart failure: Remote left atrial pressure monitoring. J Card Fail. 2022; 28(6):963-972.
4. Restivo A, D'Amario D, Paglianiti DA, et al. A 3-year single center experience with left atrial pressure remote monitoring: The long and winding road. Front Cardiovasc Med. 2022; 9:899656.
5. Ritzema J, Melton IC, Richards AM, et al. Direct left atrial pressure monitoring in ambulatory heart failure patients: initial experience with a new permanent implantable device. Circulation. 2007; 116(25):2952-2959.
6. Ritzema J, Troughton R, Melton I, et al.; Hemodynamically Guided Home Self-Therapy in Severe Heart Failure Patients (HOMEOSTASIS) Study Group. Physician-directed patient self-management of left atrial pressure in advanced chronic heart failure. Circulation. 2010; 121(9):1086-1095.
7. Troughton RW, Ritzema J, Eigler NL, et al. Direct left atrial pressure monitoring in severe heart failure: long-term sensor performance. J Cardiovasc Transl Res. 2011; 4(1):3-13.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Dickinson MG, Allen LA, Albert NA, et al. Remote monitoring of patients with heart failure: a White Paper From the Heart Failure Society of America Scientific Statements Committee. J Card Fail. 2018; 24(10):682-694.
2. 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. Circulation. 2022. 145:e895-e1032.
3. U.S. Food and Drug Administration. The Center for Devices and Radiological Health (CDRH). Investigational Devices Exemption (IDE). Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm. Accessed on June28, 2023.

Websites for Additional Information

1. American Heart Association. Available at: http://www.americanheart.org. Accessed on June 28, 2023.
2. Centers for Disease Control and Prevention. Heart failure. Last updated September 8, 2020. Available at: Heart Failure | cdc.gov. Accessed on June 28, 2023.

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	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated the Rationale, Background, References, Websites, and Index sections.
Reviewed	08/11/2022	MPTAC review. Updated Rationale, References and Websites sections.
Reviewed	08/12/2021	MPTAC review. Updated Rationale, Background, References and Websites sections.
Revised	08/13/2020	MPTAC review. Clarified INV and NMN statement, updating examples to include V-LAP™ System. Updated Rationale, References and Websites sections.
Reviewed	08/22/2019	MPTAC review. Updated Rationale, Background, References and Websites sections.
Reviewed	09/13/2018	MPTAC review. Updated Description, Rationale, References and Websites sections.
Reviewed	11/02/2017	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale, Background, References, and Websites sections. Updated Coding section with 01/01/2018 CPT changes; removed 0293T, 0294T deleted 12/31/2017.
Reviewed	11/03/2016	MPTAC review. *Revised title:* Implantable Left Atrial Hemodynamic Monitor. Updated Description, Rationale, Background, Definitions and Reference sections.
Reviewed	11/05/2015	MPTAC review. Updated Description, Rationale, References and Websites sections. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Updated Background and References.
Reviewed	11/14/2013	MPTAC review. No change to Position Statement. Updated Rationale, Background, References and Websites.
Reviewed	11/08/2012	MPTAC review. Updated References and Websites.
New	11/17/2011	MPTAC review. Initial document development.

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.