
Medical Policy



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***Current Policy Effective Date: 7/1/18**
(See policy history boxes for previous effective dates)

Title: Left Atrial Pressure Monitoring Devices for Heart Failure in the Ambulatory Care and Outpatient Setting

Description / Background

Heart failure (HF) is a condition in which the heart cannot pump blood effectively enough to meet the body's needs. Currently, symptoms like shortness of breath, reduced exercise capacity, swelling of the ankles, fatigue and weakness are used to evaluate HF and to determine the best course of treatment. However, by the time symptoms appear, HF may have already progressed to a critical point.

Elevated pressure in the left atrium of the heart is a manifestation of left-sided HF, which accounts for approximately 40 percent of all cases of HF. The rise in left atrial pressure (LAP) is gradual and typically precedes the onset of symptoms such as pulmonary congestion and edema. Monitoring the LAP in high-risk patients could potentially promote earlier identification of hemodynamic changes associated with HF and allow for therapeutic interventions prior to an acute event.

Permanent implantable devices that can measure LAP in the outpatient setting have been developed. These devices consist of an implantable sensor lead and a coil antenna. The sensor component at the distal end of the lead has a pressure transducer, which threaded up into the heart through a vein and affixed to the atrial septum with tiny anchors. The sensor lead can be implanted through large vein or during an open heart surgery. The sensor is connected to an antenna, which is implanted in the patient's abdomen under the skin.

The devices are designed to store and transmit information, including LAP, electrocardiogram and temperature, to an external, hand-held pocket computer by wireless frequency communication. The pocket computer powers the implant and can alert patients about various aspects of their care, including when to alter their medication regimens, how to modify their activities and when to contact their physician. The physician can take readings from the device

and evaluate the status of the patient at any time, without the need for inpatient cardiac monitoring.

Regulatory Status

N/A

Medical Policy Statement

Left atrial pressure monitoring devices for heart failure in the ambulatory care and outpatient setting are experimental/ investigational.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

CPT / HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

N/A

N/A

Rationale

Ritzema et al (2007) studied subjects who were enrolled in a prospective, multicenter, nonrandomized, open-label feasibility clinical trial called Hemodynamically Guided Home Self-Therapy in Severe Heart Failure Patients (HOMEOSTASIS I). The authors described the first human experience with a permanently implantable, left atrial pressure (LAP) monitoring system in ambulatory patients with chronic heart failure: "Eight patients with established heart failure and at least one heart failure hospitalization or unplanned visit for parenteral therapy in the last year underwent device implantation. All subjects received aspirin 150 mg and clopidogrel 75 mg daily. Subjects measured LAP twice daily and attended a clinic regularly for data upload and device calibration. Right heart catheterization was performed at the time of device implantation and at 12 weeks. The device was implanted in all subjects with no procedural complications...during short-term follow-up there were no device-related complications or systemic emboli. There were no deaths, no unplanned heart failure clinic visits and no admissions for heart failure." The researchers concluded that ambulatory monitoring of direct LAP with a new implantable device was well tolerated, feasible and

accurate at a short-term follow-up. Additionally, the researchers indicated that further follow-up and investigation are warranted to evaluate the clinical utility of LAP monitoring in patients with heart failure.

The HOMEOSTASIS researchers conducted a follow-up study in which 84 subjects were implanted with LAP monitoring devices (Ritzema et al, 2010). Freedom from device failure was 95 percent at two years and 88 percent at four years. Causes of failure were identified and mitigated with 100 percent freedom from device failure and less severe anomalies in the last 41 consecutive patients. The researchers concluded that accurate and reliable LAP measurement using a chronic implanted monitoring system is safe and feasible in patients with advanced heart failure. Suboptimal sensor performance in this trial was a technical issue affecting long-term implanted sensor performance, and it was noted that more experience and controlled randomized trials are needed to evaluate the safety and effectiveness of these devices.

In 2010, St. Jude sponsored a pivotal, randomized, controlled, prospective, multi-center clinical investigation to evaluate the safety and effectiveness of the company's implantable left atrial pressure (LAP) heart failure system. Knight (2014) reported that in early June 2014, the Data and Safety Monitoring Board terminated the LAPTOP-HF trial before completion. The decision was apparently based on futility to reach the primary endpoint, and a concern over a high number of implant-related complications related to transseptal catheterization. Much was learned during the LAPTOP-HF trial related to the ability to directly measure LAP in patients with HF. There may also be a lot to learn from the early study termination of LAPTOP-HF.

Despite the power and appeal of the data obtained from a permanently implanted lead in the left atrial that is able to continuously measure intracardiac pressure in patients with HF, there may be some data that we just can't have. For some technologies, the risks related to getting the information are just not worth the benefit to the patient. Specifically, we learned from LAPTOP-HF that transseptal catheterization is a procedure that has inherent risks that cannot always be avoided, even in the hands of seasoned clinical investigators, is associated with severe complications such as aortic puncture and cardiac perforation, is more challenging when performed in patients with advanced HF and a severely dilated heart, and is a skill that requires a great deal of experience and expertise. It is a lesson that should be strongly considered when, and if, new therapies such as left atrial appendage occlusion, which requires transseptal catheterization, becomes commercially available and decisions are made regarding the training and background that will be required by physicians who will be doing these procedures.

Clinical Trial

The Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy (LAPTOP-HF) was a randomized trial to evaluate the safety and clinical effectiveness of an implantable device, the HeartPOD™ System or Promote® LAP System, for left atrial pressure measurements to manage heart failure (NCT01121107). According to ClinicalTrials.gov, last updated May 2016, the study was completed April 2015, however the results are not posted. Trial was terminated related to severe complications of aortic puncture and cardiac perforation.

No other ongoing studies noted at this time.

PRACTICE GUIDELINES AND POSITION STATEMENTS

The ACCF/AHA Guideline for the Management of Heart Failure offers no recommendations for use of ambulatory monitoring devices.

The National Institute for Health and Clinical Excellence (NICE) clinical guideline on chronic heart failure management does not include outpatient hemodynamic monitoring as a recommendation.

Government Regulations

National / Local:

There is no national or local coverage determination on this topic.

Michigan Department of Health and Human Services:

MDHHS does not have any information on this topic. According to the MDHHS Outpatient Prospective Payment System, procedure codes 0293T and 0294T are non-covered items.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Ambulatory Event Monitors and Mobile Cardiac Outpatient Telemetry
 - Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting
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References

1. Blue Cross Blue Shield Association, "Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting," *Medical Policy Reference Manual*, Policy #2.02.24, original policy date July 2010, last review date May 19, 2016.
2. Hamlin, Shannan K., RN, MSN, ACNP, CCRN, et al, "Role of Diastole in Left Ventricular Function, II: Diagnosis And Treatment," *American Journal Of Critical Care*, November 2004, Volume 13, No. 6, pp. 453-468.
3. Knight, Bradley P., MD, FACC, FHRS, Editor-in-Chief, "Some Things We Just Can't Have: The Demise of the LAPTOP," *EP Lab Digest*, July 2014, Volume 14, No. 7
4. National Institute for Health and Care Excellence, "Chronic heart failure in adults: management," NICE guidelines CG108, Published date August 2010; retrieved 3/07/17 from: <https://www.nice.org.uk/guidance/cg108>.
5. National Institutes of Health, Clinical Trials, "Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy (LAPTOP-HF)," last verified June 2015; retrieved 3/22/16 from: <http://clinicaltrials.gov/ct2/show/NCT01121107>.
6. Ritzema, Jay, et al., "Direct Left Atrial Pressure Monitoring in Ambulatory Heart Failure Patients Initial Experience With a New Permanent Implantable Device," *Circulation*, 2007, 116: pp. 2952-2959.

7. Ritzema, Jay, et al., "Physician-directed patient self-management of left atrial pressure in advanced chronic heart failure," *Circulation*, 2012, Volume 121, Issue 9, pp. 1086-1095.
8. Troughton, Richard W., et al., "Direct Left Atrial Pressure Monitoring in Severe Heart Failure: Long-Term Sensor Performance," *J. of Cardiovasc. Trans. Res.*, 2011, 4:3–13.
9. Walton, Antony S. and Henry Krum, "The Heartpod Implantable Heart Failure Therapy System," *Heart, Lung and Circulation*, Vol. 14, Supp. 2, 2005, pp. S31-33.
10. Yancy CW, Jessup M, Bozkurt B et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation* 2013; retrieved 3/22/16 from: <http://content.onlinejacc.org/article.aspx?articleid=1695825>.
11. Mant J, Al-Mohammad A, Swain S et al. Management of chronic heart failure in adults: synopsis of the National *Institute for Health and clinical excellence guideline*. *Ann Intern Med* 2011; 155(4):252-9.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 11/17/17, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/12	10/11/11	10/31/11	Joint policy established
3/1/13	12/11/12	12/31/12	Routine maintenance
7/1/14	4/10/14	4/15/14	Routine maintenance
7/1/15	4/24/15	5/8/15	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
7/1/17	4/18/17	4/18/17	Routine maintenance
7/1/18	4/17/18	4/17/18	• Routine maintenance • Recommend for retirement • T codes deleted

Next Review Date: Policy retired; No longer subject to routine review

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: LEFT ATRIAL PRESSURE MONITORING DEVICES FOR HEART FAILURE IN THE
AMBULATORY CARE AND OUTPATIENT SETTING

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Not covered
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.