MEDICAL POLICY

Medical Policy Title	**Heart Failure Monitoring Devices**
Policy Number	**7.01.91**
Current Effective Date	May 15, 2025
Next Review Date	May 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Cardiac pressure sensor devices for heart failure management in the outpatient setting (e.g., CardioMEMS HF system and V-Lap), are considered **investigational.**

RELATED POLICIES

Corporate Medical Policy

11.01.27 New/Emerging Technology and Services

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

CardioMEMs

The CardioMEMs Champion Heart Failure Monitoring System (CardioMEMs) device consists of an implantable pulmonary artery (PA) sensor that is implanted in the distal PA, a transvenous delivery system, and an electronic sensor that processes signals from the implantable PA sensor and transmits PA pressure measurements to a secure database. where clinicians and clinical staff may use information to guide treatment decisions and to monitor individuals from their home or other non-clinical setting. It is postulated that these PA pressure readings can supplement the patient's characteristic signs and symptoms and improve the clinician's ability to intervene early, to prevent acute decompensation.

V-Lap

V-Lap is a miniature, wireless, and battery-free microcomputer that rests directly on the heart's interatrial septum, delivered in a minimally invasive catheterization procedure. The V-LAP system includes a personal, home-based unit that allows heart failure patients to independently monitor their own disease. To operate the system, patients put on a light belt that induces power to the implant. Then it wirelessly syncs and transmits real-time data automatically to a cloud-based system. The patient app provides daily LAP readings, when pressure is outside of the optimal range, the patient is

guided to adjust diuretics based on a pre-defined treatment plan. If pressures are suboptimal, this clinic intervenes to provide additional instructions.

Several additional devices that monitor cardiac output through measurements of pressure changes in the PA or right ventricular outflow tract have been investigated in the research setting but have not received FDA approval. These include the Chronicle implantable continuous hemodynamic monitoring device (Medtronic Inc., Minneapolis, MN), which includes a sensor implanted in the right ventricular outflow tract, and the ImPressure device (Remon Medical Technologies, Caesara, Israel), which includes a sensor implanted in the PA.

SUPPORTIVE LITERATURE

CardioMEMS Device

The CHAMPION Trial Study (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Patients) was a prospective, single-blind, randomized, controlled trial conducted at 64 centers in the United States. This trial was designed to evaluate the safety and efficacy of an implanted, passive, wireless, pulmonary artery pressure monitor developed by CardioMEMS for the ambulatory management of heart failure patients. The CHAMPION study enrolled 550 patients who had at least one previous hospitalization for heart failure in the past 12 months and were classified as having NYHA Class III heart failure for at least three months. Left ventricular ejection fraction (LVEF) was not a criterion for participation, but patients were required to be on medication and stabilized for one month before participating in the study if LVEF was reduced. All enrolled patients received implantation of the CardioMEMS pulmonary artery radiofrequency pressure sensor monitor, as well as standard of care heart failure disease management. Heart failure disease management followed American College of Cardiology and American Heart Association guidelines, along with local disease management programs. Patients were randomized in a 1:1 ratio. In the treatment group (n=270), treating providers used data from the pulmonary artery pressure sensor in patient management. In the control group (n=280), providers did not incorporate pulmonary artery pressure sensor data into patient management. All patients took daily pulmonary artery pressure readings but were masked to their treatment groups for the first six months. The trial's primary efficacy outcome was the rate of heart failure-related hospitalizations in the six months after implantation. The primary safety outcomes were device-related or system-related complications and pressure-sensor failures. The investigators reported a statistically significant reduction in readmissions for heart failure at six months, by 30% in the treatment group (n=83) over the control group (n=120). This benefit was maintained over the entire randomized follow-up (mean, 15 months) (153 vs 253 hospitalizations, respectively). The primary safety outcome, freedom from device-related complications, was 98.6%, with no occurrences of pressure-sensor failure. However, 15 adverse events occurred, including eight that were device-related and seven that were procedure-related. Additionally, length of stay for these hospitalizations was significantly shorter in the treatment group, compared with the control group (2.2 days versus 3.8 days, respectively, p=0.02). There were improvements in the secondary outcomes of mean pulmonary pressure and quality of life at six months. There was no difference in overall mortality, although the trial was not designed with sufficient power to evaluate mortality benefit. There were 15 deaths in the treatment group and 26 deaths in the control group at six months.

V-Lap

V-Lap Clinical trials are underway to assess safety, useability and performance of the V-LAP. The VECTOR-HF (Left Atrium Monitoring systEm for Patients With Chronic sysTOlic & Diastolic Congestive heaRt Failure) trial is a first in human multicenter, open-label, prospective study evaluating the safety, usability and performance of the V-LAP in patients with NYHA Class III HF, however the results have yet to be posted as the study was estimated to complete in December 2024.

PROFESSIONAL GUIDELINE(S)

In 2022 the American Heart Association, American College of Cardiology and Heart Failure Society of America Guideline for the management of Heart Failure, they address the use of remote monitoring. The guideline states:

- "The usefulness of wireless monitoring of PA pressure by an implanted hemodynamic monitor to reduce the risk of subsequent HF hospitalizations is uncertain" Class of Recommendation 2b (moderate) Level of Evidence B-R (moderate).

REGULATORY STATUS

In May 2014, the FDA approved the CardioMEMS Champion Heart Failure Monitoring System (CardioMEMS, now St. Jude Medical, St. Paul, MN) through the premarket approval process as indicated for measuring pulmonary artery (PA) pressure and heart rate in individuals who have undergone hospitalization for New York Heart Association (NYHA) Class III heart failure in the past year.

In 2020, the FDA granted breakthrough device designation for the V-Lap device by Vectorious Medical Technologies.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0607T (E/I)	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (e.g., ECG data), transmitted to a remote 24-hour attended surveillance center; set-up and patient education on use of equipment

Code	Description
	(Remote monitoring physiologic parameters, initial during same monitoring period)
0608T (E/I)	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (e.g., ECG data), transmitted to a remote 24-hour attended surveillance center; analysis of data received and transmission of reports to the physician or other qualified health care professional (Remote monitoring physiologic parameters, each 30 days, during same monitoring period)
0933T (E/I)	Transcatheter implantation of wireless left atrial pressure sensor for long-term left atrial pressure monitoring, including sensor calibration and deployment, right heart catheterization, transseptal puncture, imaging guidance, and radiological supervision and interpretation (effective 01/01/2025)
0934T (E/I)	Remote monitoring of a wireless left atrial pressure sensor for up to 30 days, including data from daily uploads of left atrial pressure recordings, interpretation(s) and trend analysis, with adjustments to the diuretics plan, treatment paradigm thresholds, medications or lifestyle modifications, when performed, and report(s) by a physician or other qualified health care professional (effective 01/01/2025)
33289 (E/I)	Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed
93264 (E/I)	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional

HCPCS Codes

Code	Description
C2624 (E/I)	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components
C9741 (E/I)	Right heart catheterization with wireless pressure sensor in the pulmonary artery, including any type of measurement, angiography, imaging supervision, interpretation, and report

ICD10 Codes

Code	Description
I50.2-I50.9	Heart failure (code range)

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Implantable wireless direct pressure sensor devices for monitoring heart failure are not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.

- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
10/20/16, 09/21/17, 09/20/18, 09/19/19, 09/17/20, 09/16/21, 09/15/22, 09/21/23, 09/18/24, 01/23/25	
Date	**Summary of Changes**
01/23/25	• Off-cycle policy update. code edit, added 0933T and 0934T. Policy intent unchanged. • Title change. Policy statement revised to align with new title and add V-Lap device.
01/01/25	• Summary of changes tracking implemented.
08/20/15	• Original effective date