MEDICAL POLICY

Excellus
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Medical Policy Title	**Heart Failure Management Devices**
Policy Number	**7.01.91**
Current Effective Date	**June 15, 2026**
Next Review Date	**February 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Heart failure management devices in the outpatient setting are considered **investigational** including **ANY** of the following:

   A. Carotid baroreflex activation therapy (e.g., Barostim device);

   B. Cardiac pressure sensor devices (e.g., CardioMEMS HF system and V-Lap).

II. Cardiac contractility modulation (CCM) (e.g., Optimizer Smart) and combined CCM with ICD devices (CCM-D) (e.g., Optimizer Integra CCM-D System) are considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

7.01.58 Permanent Pacemakers and Cardiac Resynchronization Therapy (CRT) Devices

11.01.03 Experimental or Investigational Services

11.01.27 New/Emerging Technology and 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 patients with heart failure 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 pulmonary artery.

Carotid baroreflex activation therapy (e.g., Barostim device)

The Barostim device is being purposed as a potential treatment for individuals with sympathetic heart failure with reduced left ventricular ejection fraction. The device uses a subcutaneously implanted pulse generator and electrodes to deliver electrical pulses to the carotid artery baroreceptors; aiming to decrease sympathetic activity and increasing parasympathetic activity.

Cardiac Contractility Modulation Devices (CCM) (e.g., Optimizer Smart) and (e.g., Optimizer Integra CCM-D System)

Cardiac contractility modulation devices deliver electrical signals during the ventricular absolute refractory period. This does not generate an action potential or mechanical contraction. It is proposed to enhance ventricular contractile strength and potential treatment option for individuals with symptomatic heart failure with reduced left ventricular (LV) ejection fraction who are not candidates for CRT. CCM has previously been used along with a separate ICD. The CCM-D combines CCM and ICD into one device.

SUPPORTIVE LITERATURE

CardioMEMS Device

Abraham et al (2016) reported the results of the CHAMPION Trial. It was a prospective, single-blind, randomized controlled study conducted at 64 U.S. centers to evaluate the safety and efficacy of the implanted CardioMEMS pulmonary artery pressure monitor in patients with NYHA Class III heart failure. The study enrolled 550 patients with at least one heart-failure hospitalization in the prior year, regardless of left ventricular ejection fraction, and all participants received the device along with guideline-directed medical therapy. Patients were randomized 1:1, with providers in the treatment group using pulmonary artery pressure data to guide management, while the control group did not use these data; all patients performed daily pressure readings and remained blinded for six months. The trial showed a 30% reduction in heart-failure hospitalizations at six months in the treatment

group (83 vs. 120), a benefit that persisted over a mean 15-month follow-up (153 vs. 253). Safety outcomes were favorable, with 98.6% freedom from device-related complications, no sensor failures, and 15 total adverse events (eight device-related and seven procedure-related). Hospital length of stay was significantly shorter with pressure-guided management (2.2 vs. 3.8 days, p=0.02), and patients demonstrated improvements in pulmonary artery pressures and quality of life. Mortality did not significantly differ between groups (15 vs. 26 deaths at six months), although the study was not powered to detect mortality differences.

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.

Carotid Baroreflex Activation Therapy (e.g., Barostim device)

Wang et al (2025) conducted a retrospective study of Baroreceptor activation therapy (BAT) in patients with heart failure with reduced ejection fraction (HFrEF). This study evaluated long-term outcomes in 23 HFrEF patients treated with BAT at Hannover Medical School between 2014 and 2023. Most participants were male (83%), with a mean age of 66 years, and had severe heart failure (NYHA class III) and low ejection fraction (23%). Over an average follow-up of three years, BAT significantly improved NYHA classification in 52% of patients and increased ejection fraction by 9% after one year and 11% after two years. NT-proBNP levels showed a modest but significant reduction after two years. Complications were rare, occurring in only one patient, and seven patients required device replacement during follow-up. Four patients died during the observation period. Overall, BAT demonstrated sustained improvements in symptoms and cardiac function, supporting its potential as a long-term therapeutic option for HFrEF.

Coats et al (2022) conducted a meta-analysis of randomized controlled trials to evaluate the effect of baroreflex activation therapy (BAT) on heart failure symptoms, QoL and N-terminal pro-brain natriuretic peptide (NT-proBNP) in HFrEF. The trials compared baroreflex activation therapy (BAT) plus guideline-directed medical therapy (GDMT) versus GDMT alone. Among 554 patients, BAT significantly improved 6-minute walk distance by 49 meters, reduced Minnesota Living With Heart Failure scores by 13 points, and increased the odds of improving at least one NYHA class by 3.4 times over six months. Benefits were consistent across patient subgroups and were particularly notable in those with baseline NT-proBNP levels below 1600 pg/ml. Overall, BAT enhances exercise capacity, quality of life, and NYHA class, with additional NT-proBNP improvement in patients with lower baseline levels.

Cardiac Contractility Modulation Devices (CCM)

Wigen et al (2020) conducted a non-randomized study that looked at the FIX-HF-5C2 (2-lead CCM system study) and FIX-HF-5C (3-lead system study) randomized control trials and tested the safety and effectiveness of a 2-lead CCM system compared with the 3-lead CCM system. Individuals that participated in the trail had NYHA III/IVa symptoms despite medical therapy, LVEF 25% to 45%, and

not eligible for CRT. All participants received an Optimizer 2-lead implant. The primary end point was the estimated difference in the change of peak VO_2 from baseline to 24 weeks between FIX-HF-5C2 subjects relative to control subjects from the FIX-HF-5C. Secondary endpoint was changes in the NYHA functional classification. The primary safety end point was the comparison of device related adverse events between the two studies participants. Sixty subjects, 88% male, 66±9 years old with left ventricular ejection fraction 34±6% were included. Baseline characteristics were similar between FIX-HF-5C and FIX-HF-5C2 subjects except that 15% of FIX-HF-5C2 subjects had permanent atrial fibrillation versus 0% in FIX-HF-5C. CCM delivery did not differ significantly between 2-and 3-lead systems (19 892±3472 versus 19 583±4998 CCM signals/day, CI of difference [−1228 to 1847]). The change of peak VO_2 from baseline to 24 weeks was 1.72mL/kg per minute greater in the 2-lead device group versus controls. 83.1% of 2-lead subjects compared with 42.7% of controls experienced ≥1 class NYHA improvement (P<0.001). There were decreased Optimizer-related adverse events with the 2-lead system compared with the 3-lead system (0% versus 8%; P=0.03). Overall, device-related adverse effects were less with the 2-lead system. The 2-lead system effectively delivers comparable amount of CCM signals as the 3-lead system that includes subjects with AF and is equally as safe and improves peak VO_2 and NYHA functional class. Limitations that need to be addressed include that the study is non-randomized, unblinded, with a small number of participants.

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

The United States Food and Drug Administration (FDA) regulates cardiac devices as medical devices. All [device] including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Dec 23]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls on our website by the date that the FDA posts the information on our website. Available from: Medical Device Recalls | FDA [accessed 2025 Dec 23]

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.

In 2018 OPTIMIZER Smart System was FDA approved and is indicated to improve 6-minute hall walk distance, quality of life, and functional status of NYHA Class III heart failure patients who remain symptomatic despite guideline directed medical therapy, who are in normal sinus rhythm, are not indicated for Cardiac Resynchronization Therapy, and have a left ventricular ejection fraction ranging from 25% to 45%.

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
0408T (E/I)	Insertion or replacement of permanent cardiac contractility modulation (CCM) system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes
0409T (E/I)	pulse generator only
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
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
0915T (E/I)	Insertion of permanent cardiac contractility modulation-defibrillation system component(s), including fluoroscopic guidance, and evaluation and programming of sensing and therapeutic parameters; pulse generator and dual transvenous electrodes/leads (pacing and defibrillation)
0916T (E/I)	pulse generator only

Code	Description
0923T (E/I)	Removal and replacement of permanent cardiac contractility modulation-defibrillation pulse generator only
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
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 (includes reporting once per 30 day period)
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
64654 (E/I) Effective 01/01/26 0266T (E/I) Termed 12/31/25	Initial open implantation of baroreflex activation therapy (BAT) modulation system, including lead placement onto the carotid sinus, lead tunnelling, connection to a pulse generator placed in a distant subcutaneous pocket (i.e., total system), and intraoperative interrogation and programming (effective 01/01/2026) (Replacing code 0266T) Implantation or replacement of carotid sinus baroflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, 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,

Code	Description
	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.

Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (NCA CAG-00466N) - Decision Memo [accessed 2025 Dec 18].

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	
08/20/15, 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, 02/19/26	
Date	**Summary of Changes**
02/19/26	• Annual review. Policy title updated. Policy statement was revised to allow the baroreflex activation therapy (e.g., BaroStim) devices to be added as an investigational device for heart failure management. Policy statement added for cardiac contractility modulation devices, and added codes 0408T-0409T, 0915T-0916T & 0923T. Code 64654 added to replace code 0266T.
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