MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Implantable Cardiac Hemodynamic Monitoring for Heart Failure**
Policy Number	**7.01.91**
Category	**Technology Assessment**
Original Effective Date	**08/20/15**
Committee Approval Date	**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**
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Deleted Date	**N/A**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), 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 STATEMENT

Based upon our criteria and assessment of the peer-reviewed literature, cardiac hemodynamic monitoring for the management of heart failure in the outpatient setting, utilizing implantable, direct-pressure monitoring of the pulmonary artery (e.g., CardioMEMS HF system) has not been proven to be medically effective and, therefore, is considered **investigational.**

DESCRIPTION

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. This device consists of an implantable 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.

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.

RATIONALE

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:

I. 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).

Evidence from randomized, controlled trials for various pulmonary artery pressure monitors has demonstrated a correlation between increased pressure readings and increased heart failure event risk. The CHAMPION trial noted that the use of pulmonary artery pressure readings may reduce heart failure-related hospitalizations, but this study was subject to a number of potential biases. Studies of other implantable direct pulmonary artery pressure measurement devices have not demonstrated significantly improved outcomes (Adamson et al. 2011 and Bourge et al. 2008). Therefore, the evidence is insufficient to form conclusions that the CardioMEMS or any other implantable device is associated with improvements in health outcomes.

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 by computer in a 1:1 ratio to the treatment group (n=270), in which treating providers used data from the pulmonary artery pressure sensor in patient management, or the control group (n=280), in which 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) (HR=0.70; 95% CI, 0.60 to 0.84; p<0.001). This benefit was maintained over the entire randomized follow-up (mean, 15 months) (153 vs 253 hospitalizations, respectively) (HR=0.64; 95% CI, 0.55 to 0.75; p<0.001). 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 was also benefit reported for other secondary outcomes. 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 (HR=0.77; 95% CI, 0.40 to 1.51; p=0.45). During the randomized portion of the trial, the device was generally safe: freedom from device or system-related complications was 98.6%, with a 95.2% lower confidence bound of 97.3%.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

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 (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)
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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*Key Article

KEY WORDS

CardioMEMS HF, Heart Failure, Pulmonary artery pressure sensor, Wireless hemodynamic monitor, HeartPOD

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, implantable wireless direct pressure sensor in the pulmonary artery for monitoring heart failure is not addressed in National or Regional Medicare coverage determinations or policies.