Molina Clinical Policy
Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS) for Congestive Heart Failure: Policy No. 393

Last Approval: 8/10/2022
Next Review Due By: August 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Congestive heart failure (CHF) is a condition in which fluid accumulates in the body as the heart fills or pumps blood inefficiently. CHF is caused by conditions that weaken the heart muscle, such as coronary artery disease, myocardial infarction, cardiomyopathy, and hypertension, and is a major public health concern. Treatment of CHF is guided by treating the underlying cause, which is often a chronic systemic disease process and includes hypertension, diabetes, coronary artery disease, valvular heart disease, or myocarditis as well as lifestyle improvements (e.g., diet, exercise, smoking cessation). Despite the availability of evidence-based medical and device therapies for CHF, morbidity, mortality, and costs remain high. The severity of CHF is frequently classified by patient functional status using the New York Heart Association (NYHA) system. Treatment guidelines and as enrollment criteria for CHF clinical trials (CDC, NHLBI; Colucci et al.; Borlaug et al; Yancy et al.):

The CardioMEMS™ Heart Failure (HF) System (Abbott) is a wireless implantable hemodynamic monitor (IHM) for use at home to reduce HF hospitalizations in NYHA class III patients (refer to 'Supplemental Information' section for description of classes). The system consists of an implantable pulmonary artery (PA) sensor, which 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. The CM-IHM system is permanently implanted in the pulmonary artery via a right-heart catheterization procedure that can be performed in an outpatient setting by a cardiac surgeon. This device allows remote hemodynamic monitoring via a wireless system that measures systolic, diastolic, and mean PA pressures every 18 seconds. An electronic system transmits the generated data to a secure network where it is available for the interpretation by the treating physician and clinical team to access, review, and make any necessary treatment adjustments with the goal of reducing HF hospitalizations (FDA, NLM, Hayes).

Regulatory Status

At this time, only the CardioMEMS device has been granted approval by the FDA. Other devices (such as Chronicle® and ImPressure®) that monitor cardiac output by measuring changes in pressure in the pulmonary artery or the right ventricular outflow tract are not supported by the evidence that is currently available.

The CardioMEMS™ Champion Heart Failure Monitoring System was approved for marketing by the FDA through the premarket approval process (PMA) under the product code MOM (P100045) (system, hemodynamic, implantable) in May 2014. The CardioMEMS HF System was initially approved for use in NYHA Class III HF patients who had been hospitalized for HF within the previous year (FDA).

The FDA extended approval for the system in February 2022 for use in patients with Class II HF and those whose blood tests reported high levels of natriuretic peptides, indicating worsening HF.

The CardioMEMS HF System's expanded indication was supported by clinical data from the GUIDE-HF trial. Based on study data adjusted for the impact of COVID-19, both Class II HF patients and patients with elevated natriuretic peptides were suggested to have better outcomes when their therapy was guided by pulmonary pressure monitoring, with a respective 34% and 25% reduction in HF hospitalizations, emergency visits and death.

COVERAGE POLICY

The Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS) for Congestive Heart Failure **is considered experimental, investigational, and unproven** due to insufficient published evidence to assess the safety and/or impact on health outcomes.

SUMMARY OF MEDICAL EVIDENCE

The current peer reviewed published evidence is insufficient to support the use of ambulatory cardiac hemodynamic monitoring using an implantable pulmonary artery pressure measurement device in individuals with HF in an outpatient setting. Additional well-designed and high quality RCTs are necessary to establish whether health outcomes are significantly improved relative to standard of care for HF management. Furthermore, there is a lack of evidence on the device's accuracy and therapeutic value for usage in additional NYHA functional classes. A summary of the studies is provided below.

The CardioMEMS Heart Sensor Allows Monitoring of Pressures to Improve Outcomes in NYHA III Heart Failure Patients (CHAMPION) trial is the pivotal trial evaluating the effectiveness of the implantable hemodynamic monitoring system (IHMS). Its preliminary findings were published in February 2011.

CHAMPION was a multicenter, randomized, single-blind trial at 64 U.S. sites. 550 individuals were implanted with CardioMEMS (n = 270 in the treatment arm and n= 280 in the control arm) and admitted overnight for observation (Abraham et al. 2011; 2016). Prior to hospital discharge, participants were randomized (1:1) to a treatment arm and a control arm (in which treating clinicians could not access readings from the device). To ensure blinding, all patients were instructed to obtain daily blood pressure readings. In the treatment group, invasive hemodynamic data were examined weekly or more often if treatments changed. Both groups saw their clinician at 1, 3, and 6 months, then every 6 months. Each study location had to balance experimental and control patient encounters. Six-month outcomes included HF hospitalizations, device-related problems, and pressure sensor failure. Change in mean pulmonary artery pressure, proportion of HF-related hospitalizations, days alive outside the hospital, and quality of life defined by the Minnesota Living with Heart Failure Questionnaire (MLHFQ) were all measured at six months. An independent, blinded committee assessed and adjudicated results.

The CHAMPION trial included adults who had been diagnosed with HF for at least 3 months and had at least one HF-related hospitalization in the previous 12 months. Patients qualified regardless of their left ventricular ejection fraction. Patients must have been on optimum or well-tolerated guideline-directed HF therapy to be eligible. A history of recurrent pulmonary embolism or deep venous thrombosis, Stage IV or V chronic renal disease, recent significant adverse cardiovascular events, and hypersensitivity to aspirin or clopidogrel were key exclusion factors. Patients were randomly assigned to one of two groups: the CardioMEMS group, in which daily uploaded pulmonary artery pressures were used to guide medical therapy, or the control group, in which daily uploaded pressures were not made available to investigators and patients continued to receive standard of care management, including drug adjustments in response to clinical signs and symptoms. In the treatment group, clinicians measured daily pulmonary artery pressures in addition to standard care, whereas in the control group, standard care was employed alone. The primary efficacy endpoint was the rate of hospitalizations due to HF at 6 months. At 6 months, the safety endpoints evaluated were the absence of device- or system-related complications (DSRC) and the absence of pressure-sensor failures. All analyses were performed using the intention to treat method.

For the primary efficacy outcome of heart failure-related hospitalizations at up to 6 months, there were fewer events in the treatment arm (84 events, 0.32 events per patient per 6 months) than in the control arm (120 events, 0.44 events per patient per 6 months), a statistically significant reduction of 28%. During randomized follow-up, the authors reported a statistically significant reduction in HR-related hospitalizations in the control arm. For the safety-related primary endpoints, there were no pressure sensor failures and 15 serious procedure-related or device-related adverse events (4 bleeding events, 3 events related to interruption of anticoagulation, 2 exacerbations of atrial arrhythmias, 2 febrile illnesses, 1 in-situ pulmonary thrombus, 1 episode of cardiogenic shock, 1 episode of atypical chest pain, and 1 delivery-system failure that required snare retrieval). The Champion trial reported the following:

- Transmission of PA pressure data from the device reduced HF-related hospitalizations at 6 months (31% versus 44%) (Colucci 2021; Givertz et al. 2017; Abraham et al. 2011). A further analysis demonstrated a sustained reduction in HF-related hospitalization in the device-guided management group at 18-month average follow-up (46% versus 68%) (Abraham et al. 2016).
- During a 13-month open access period, pulmonary artery pressure information was made available to guide therapy in the former control group. Admissions were lower than in the control group during the randomized access period (36% versus 68%). 1% of complications were device- or system-related, and 1% were procedure-related.
- Concerns were raised by the FDA about potential sponsor influence during randomization in this trial (Colucci 2021; Hayes Evidence Analysis Research Brief; Loh et al. 2013).
- Study limitations include lack of power to perform mortality analysis, lack of baseline quality-of-life data, and possibility for sponsor to influence patient management (Hayes Evidence Analysis Research Brief)

An UpToDate review on "Treatment and prognosis of heart failure with preserved ejection fraction" (Borlaug and Colucci, 2022) indicates that device-based therapies (e.g., intreratrial shunt device, remote pulmonary artery pressure monitor) are not routinely used for the treatment of patients with HF with preserved ejection fraction.

Desai et al. (2017) performed a retrospective cohort study of Medicare administrative claims data for people who had the CardioMEMS device after FDA approval. The Medicare claims data from patients who had PAP sensor implantation in the U.S. between June 1, 2014 and December 31, 2015 were used in the study. Among 1,114 implanted patients, there were 1,020 HF hospitalization in the 6 months before, compared with 381 HF hospitalization, 139 deaths, and 17 ventricular assist device (VAD)/transplants in the 6 months after implantation. In the subset of 480 patients with complete data available for 12 months before and after implantation, similar decreases in HF hospitalization and expenditures were observed. The use of ambulatory hemodynamic monitoring in clinical practice, as in clinical trials, resulted in lower expenditures for HF hospitalization and total HF, according to the authors. These improvements were sustained for one year, demonstrating the usefulness of this HF management strategy in the "real world." This retrospective study is limited by the absence of data on medical history, ejection fraction, and indication for implantation, as well as the possibility of confounding due to the increased contact with the health care system required by the implantation of the device.

National and Specialty Organizations

The American College of Cardiology published a 2021 update to the *2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure with Reduced Ejection Fraction: A Report of the American College of Cardiology Solution Set Oversight Committee.*

The CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III HF Patients; Abraham et al. 2011) trial outcomes suggest that in carefully selected patients with recurrent congestion, this highly specialized monitoring strategy may inform therapeutic decision-making. The effect on mortality is unknown, but it is being studiedin an RCT called GUIDE-HF (Hemodynamic-Guided Management of HF; Costanzo et al. 2016). To best implement this monitoring strategy, a collaborative approach may be required (see Section 5.8 of the report).

The California Technology Assessment Forum (CTAF) (Ollendorf, 2015) completed a clinical comparative effectiveness review of the *CardioMEMS HF System for CHF*. The review concluded that the current body of evidence was promising but inconclusive.

SUPPLEMENTAL INFORMATION

NYHA classification has served as a vital tool for risk stratification of HF and for determining clinical trial eligibility and medication and device candidate eligibility.

- 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 HF or the anginal syndrome may be present even at rest; if any physical activity is undertaken, discomfort is increased.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
33289	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	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.
93799	Unlisted cardiovascular service or procedure [when specified as implantation of a wireless pressure sensor in the pulmonary artery]

HCPCS Code

HCPCS	Description
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

8/10/2022	Policy reviewed and updated. No changes in coverage position. Updated references. Updated policy from 'Wireless Pulmonary Artery Pressure Monitoring' to: 'Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS) for Congestive Heart Failure'
2/8/2021	New policy.
12/17/2020	Policy reviewed on December 17, 2020 by an IRO board-certified, practicing physician in the areas of Cardiovascular Disease, Interventional Cardiology, Internal Medicine.

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Government Agencies

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Peer Reviewed Publications

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*