

## Clinical Review Criteria

### Implantable Pulmonary Artery Pressure Monitoring Device for Patients with Heart Failure

- CardioMEMS

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## Criteria

### For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, <b><i>Implantable Pulmonary Artery Pressure Monitoring Device for Patients with Heart Failure</i></b> , for medical necessity determinations. Use the Non-Medicare criteria below.

### For Non-Medicare Members

#### Kaiser Interregional New Technologies Committee

There is insufficient evidence to determine whether CardioMEMS is a medically appropriate option for patients with NYHA functional class III heart failure. The existing evidence is of insufficient quantity and quality. Patients undergoing IRB clinical trials could be potential candidates if the IRB trial has a well-designed protocol, appropriate informed consent, and structured follow-up.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

## Background

Heart failure (HF) is a major public health problem in the United States and worldwide. It is estimated that more than six million Americans are currently living with heart failure, and that approximately 550,000 new cases are diagnosed in the US every year. Hospitalization for patients with chronic HF is also on the rise despite the major advances in medical and device therapies. Statistics show that HF is the primary diagnosis in over one million hospitalizations annually, and that patients hospitalized for HF are at high risk for all-cause rehospitalization with a 1-month readmission rate of 25%. The prognosis of these patients is suboptimal especially for those with serial readmissions (Hoppe 2009, Adamson 2011, Go 2013, Yancy 2013, Sandhu 2018).

More than 90% of hospitalizations for worsening HF are due to signs and symptoms of congestion leading to the decompensated state. Investigators found that increases in the intracardiac and pulmonary artery (PA) pressures are the cause of clinical congestion and that these begin several days or weeks before the onset of overt clinical signs and symptoms that are commonly used as indicators of congestion and volume overload leading to hospitalization. Thus, outpatient monitoring of markers for impending hemodynamic decompensation may allow early interventions to reduce both morbidity and hospitalization. Researchers also found that successful treatment of acutely decompensated HF patients is associated with a decrease

in diastolic pressures to values equivalent or below those present at baseline, and that continuous monitoring pressure during treatment may allow the clinicians to tailor the treatment more accurately. Based on these observations, it was hypothesized that ambulatory implantable hemodynamic monitoring (IHM) may provide information that would help avoid discharging patients from the hospital before decreasing the pressure sufficiently and returning the patient to a chronic compensated state. Continuous hemodynamic monitoring after the hospital discharge is also believed to proactively detect signs of congestion and reduce the risk of rehospitalization (Hoppe 2009, Abraham 2011, Adamson 2011, Mooney 2015, Sandhu 2018, Ayyadurai 2019).

Research has thus focused on ambulatory hemodynamic monitoring of chronic HF as a surrogate measure to guide the patients' medical therapy before the onset of acute hemodynamic decompensation. Several implantable systems have been developed to measure various cardiac pressures and tailor medical therapy accordingly "pressure guided therapy". Among these devices is the CardioMEMS HF System, which is the focus of the current review.

The CardioMEMS™ HF System (Abbott [previously St Jude Medical], Inc, USA) is a leadless battery-free, permanently implantable pressure measurement system designed to directly measure systolic, diastolic, and mean pulmonary artery pressure (PAP) to help guide heart failure management in an outpatient setting. The design of the system is based on the microelectromechanical principles of resonance whereby an external antenna wand emitting radiofrequency energy can cause varying degrees of oscillations in the sensor depending on the ambient pressure. The CardioMEMS HF System consists of three main components: 1. A miniaturized wireless electromechanical leadless sensor (15mm x 3mm x 2mm) that comprises a coil and capacitor encased in silicone case, with a nitinol wire loop at each end of the sensor to keep the device in place in a pulmonary artery. The capacity and coil of the sensor creates

an electrical circuit that resonates at a given frequency that varies depending on the pulmonary artery pressure 2. A transverse delivery system designed to deploy the implantable sensor in the distal PA; and 3. The Champion Electronics System, which acquires and processes signals from the implantable sensor and wirelessly transfers PA pressure measurements to a secure database to be reviewed and evaluated by the treating physician (Loh 2013, Adamson 2011, Mooney 2015, Ayyaduri 2019, FDA website).

The CardioMEMS sensor is delivered during a standard right heart catheterization procedure and implanted in a descending branch of the pulmonary artery via a delivery catheter. The implanted patients are started on aspirin and clopidogrel for one month followed by aspirin monotherapy. At home, HF patients use a portable electronic unit and a special pillow containing an antenna to take daily sensor readings. The reading takes place when the antenna is held against the body or when the patients lies on the pillow. The pressure readings are then wirelessly transmitted to a secure website and accessed by the clinicians to guide treatment decisions. Automated alerts will be sent to health care providers if pressure readings fall outside of prespecified ranges (Poor Ghaz 2019).

The U.S. Food and drug Administration (FDA) premarket approval (PMA) of CardioMEMS HF System was first rejected in 2011 due to concerns on the validity of the pivotal study results. After discussing additional follow-up data and further analyses of the results provided by the investigators and sponsors, the FDA cautiously approved the system in May 2014 to "*Remotely measure and monitor PA pressure and heart rate in New York Heart Association (NYHA) functional Class III heart failure patients who have been hospitalized for heart failure in the previous year*". According to the FDA, the system may be used by the physician in the hospital or medical office to better manage the patients and potentially reduce HF-related hospitalizations. Continued FDA approval of CardioMEMS HF System is contingent upon the submission of periodic reports at intervals of one year (unless otherwise specified) from the date of approval of the original PMA, as well as conducting two post-approval studies (FDA Website).

The CardioMEMS HF system may not be appropriate for patients with an active infection, history of recurrent deep vein thrombosis or pulmonary embolism, are unable tolerate a right heart catheterization, have congenital heart disease or mechanical right heart valve, with known coagulation disorders, hypersensitivity to aspirin or clopidogrel, with an estimated GFR <25 ml/min and not responsive to diuretics or are on chronic renal dialysis, also for patients who had undergone implantation of CRT-D within the past 3 months, or have BMI >35 kg/m<sup>2</sup> (Ayyaduri 2019).

## **Medical Technology Assessment Committee (MTAC)**

### **Implantable Pulmonary Artery Pressure Monitoring Device (CardioMEMS HF System) For Patients with Heart Failure**

**Date: 01/13/2020**

**Evidence Conclusion:**

- The CHAMPION trial remains the only published RCT that evaluated CardioMEMS HF device for monitoring NYHA functional class III heart failure patients.
- There is no additional evidence from published RCTs with valid methodology and long-term follow-up that would change the conclusion of the MTAC 2016 evidence review:
  - The results of the CHAMPION study show that previously hospitalized NYHA functional class III heart failure patients who received pressure guided management in addition to the standard care, had statistically significant lower hospital admission rates compared to those managed according to standard of care alone. It is unclear if the hospitalizations prevented in the device-guided management group were among the lower risk patients, and whether it had any impact on mortality.
  - It is hard to make a firm conclusion on the safety and effectiveness of CardioMEMS HF System from one single-blinded randomized trial, with an intermediate endpoint, potential performance bias, strict inclusion/exclusion criteria, conducted under a controlled environment, with a relatively short follow-up period, and funded by the manufacturer of the device that was also responsible for data collection and analysis. In addition, the principal investigators who analyzed, interpreted, and /or wrote the report had financial ties to the manufacturer.
- More RCTs with valid methodology and long-term clinical outcomes are needed to provide stronger evidence on the safety and efficacy of CardioMEMS HF System in monitoring patients with HF.

**Articles:** The updated literature search on CardioMEMS HF System for patients with Heart failure did not identify any RCTs published after the pivotal CHAMPION trial. The search revealed a propensity matched retrospective study, several review articles on pulmonary artery pressure guided management of patients with heart failure, sub-analyses of data from CHAMPION trial, and case series of patients implanted with CardioMEMS. A CardioMEMS post approval study was presented by Shavelle D, MD, in the 2019 annual meeting of the American College of Cardiology but, have not been published, to date, in a peer reviewed journal. The propensity matched study (Abraham et al, 2019) as well as the results of the CardioMEMS post- approval study (Shavelle 2019) \*\* were reviewed and summarized. See [Evidence Table](#).

The use of Implantable Pulmonary Artery Pressure Monitoring Device (CardioMEMS HF System) For Patients with Heart Failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## Applicable Codes

### Considered Not Medically Necessary

CPT® or HCPC Codes	Description
<b>C2624</b>	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components
<b>33289</b>	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
<b>93264</b>	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

**\*Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

\*\*To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Date Created	Date Reviewed	Date Last Revised
07/05/2016	07/05/2016 <sup>MPC</sup> , 05/02/2017 <sup>MPC</sup> , 03/06/2018 <sup>MPC</sup> , 02/05/2019 <sup>MPC</sup> , 02/04/2020 <sup>MPC</sup> , 02/02/2021 <sup>MPC</sup> , 02/01/2022 <sup>MPC</sup> , 02/07/2023 <sup>MPC</sup> , 03/12/2024 <sup>MPC</sup>	07/05/2016

<sup>MPC</sup> Medical Policy Committee

Revision History	Description
02/10/2021	Added MTAC review from July 2020 for CardioMems