iCare Policy on Implantable Pulmonary Artery Monitoring Device for Congestive Heart Failure

(CardioMEMS™)

Device : CardioMEMS HF system

Indication: The CardioMEMS HF System is approved by the FDA for wirelessly measuring and monitoring PA pressure and heart rate in New York Heart Association Class III heart failure patients who have been hospitalized for heart failure in the previous year.

Coverage guidance : There is no NCD related to the CardioMEMS™ HF System. Our Local MAC does not have an applicable LCD. In lieu of those documents, iCare is utilizing evidence-based guidelines and industry best practices.

iCare coverage determinations:

1. CardioMEMS HF system is authorized, with prior authorization ONLY if member is enrolled in a CMS clinical trial.

   https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies

2. The CardioMEMS device is considered investigational.

Supporting evidence for non-coverage for CardioMEMS

iCare is not authorizing the use of implantable hemodynamic monitoring as the evidence of this approach has not been proven. The wireless CardioMEMS pulmonary artery monitoring device has been approved by the US Food and Drug Administration to monitor pulmonary artery pressure and heart rate in patients with NYHA class III HF who have been hospitalized during the previous year. Further study is needed to determine the efficacy and safety of this device.

The 2016 ESC HF guidelines included only a very weak recommendation stating that this device may be considered in symptomatic patients with heart failure with previous heart failure hospitalization. The CardioMEMS Heart Sensor allows monitoring of pressure to improve outcomes In NYHA Class III Heart Failure Patients (CHAMPION). A randomized single-blind trial of 550 patients found that transmission of pulmonary artery pressure data from the device reduced HF-related hospitalizations at six months (31 versus 44 percent, HR 0.70, 95% CI 0.60-0.84). There was a 1.5 percent rate of device-or system-related complications. An exploratory subgroup analysis found that device-guided management reduced heart failure related hospitalization in patients with preserved left ventricle

ejection fraction (LVEF =40 percent or LVEF =50 percent), as well as in patients with LVEF <40 percent [61,62]. Another exploratory analysis found that device-guided management reduced respiratory hospitalization rates as well as HF hospitalization rates in the entire cohort, as well as in a subgroup of 187 patients with chronic obstructive pulmonary disease. A later analysis reported sustained reduction in HF-related hospitalization in the device-guided management group compared with the control at 18-month average follow-up (46 versus 68 percent, HR 0.67, 95% CI 0.55 to 0.80)]. During a subsequent open access period (mean duration 13 months), pulmonary artery pressure information was made available to guide therapy in the former control group; the rate of admission was reduced compared with that in the control group during the randomized access period (36 versus 68 percent; HR 0.52, 95% CI 0.40 to 0.69). The rate of device or system-related complications was 1 percent and the rate of procedure-related adverse events was 1 percent.

However, the efficacy of the CardioMEMS device is uncertain given concerns raised about potential bias introduced in the conduct of the CHAMPION trial (including interaction between the trial sponsor and clinical investigators on certain treatment group subjects) and the analysis of data. (UpToDate).

Dhruva, and Kumholz (JACC Heart Fail. 2016 May; 4(5): 376–379.) outlines several key concerns in the CHAMPION trial including:

1. Concern with study design , and interaction with device manufacture that may impact measurement of positive outcomes
2. Impact of intervention on woman , and potentially skewed results
3. Potential loss to follow up of participants

In conclusion, they stated “Important uncertainties remain about CardioMems’ ability to reduce Heart failure hospitalizations improve quality of life and reduce mortality. The only new planned study of the device is an observational 1200-patient post-marketing observational cohort with an estimated completion in June 2020 (https://clinicaltrials.gov/ct2/show/NCT02279888).

In their review, Pham and Grodin (Card Fail Rev. 2017 Nov; 3(2): 108–112.) noted, “One caveat when interpreting these results is that the treatment group had additional clinical contact and

support due to having a device implanted, which may have a had a confounding effect on clinical outcome. Post-marketing efficacy studies are ongoing, testing whether the benefits in the CardioMEMS device translate into improvement in real-world patient care. For example, a recent retrospective cohort study observed a reduction in heart failure hospitalizations in the 6 months after CardioMEMS implantation compared with the 6 months prior to implantation, supporting the results of the CHAMPION trial on the use of the device in addition to standard of care. At this point, however, the therapeutic role of the CardioMEMS device continues to evolve."

In the most recent evaluation by Puvanalingam Ayyadurai, et al. (Ther Adv Cardiovasc Dis. 2019; 13: 1753944719826826.) stated that, "CardioMEMS is the only device or intervention other than guideline-directed medical therapy that has been shown to impact congestive heart failure (CHF) readmission rates and is expected to show a mortality benefit in the ongoing GUIDE-HF trial." This demonstrates that current evidence-based medical care guidelines impact readmission rates with similar efficacy as an invasive investigational procedure.

Ongoing studies on impact of CardioMEMS

NCT No.	Trial name	Planned enrollment	Anticipated Completion date
NCT02693691	CardioMEMS European Monitoring Study for Heart Failure	239	Dec 2019
NCT02954341	CardioMEMS HF SystemOUS Post Market Study	800	Dec 2022
NCT 03387813	Hemodynamic-GUIDEd Management of Heart Failure	3600	April 2023
NCT 03020043	Evaluation of Longterm Outcome of New York Heart Association Class III Heart Failure Patients Receiving Telemonitoring Using a Pulmonary Artery Pressure Sensor System (CardioMEMS)	2000	TBD

We will continue to review the efficacy of these mentioned studies and any available NCD/LCD related to pulmonary artery pressure sensor to assure that our members will receive appropriate care for congestive heart failure.

REFERENCES

1. Investigational and emerging strategies for management of heart failure

   UpToDate

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2. Treatment and Prognosis of Heart Failure with Preserved Ejection Fraction

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   Authors: Barry A Borlaug, MD, Wilson S Colucci, MD
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