Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: AmeriHealth Caritas Pennsylvania and Keystone First	**Submission Date**: 11/1/2024
Policy Number: ccp.1259	**Effective Date:** 1/2017 **Revision Date:** October 1, 2024
Policy Name: Wireless pulmonary artery pressure monitoring devices for heart failure	

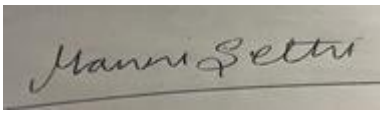
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☒ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Statewide PDL**

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

See tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Wireless pulmonary artery pressure monitoring devices for heart failure

Clinical Policy ID: CCP.1259

Recent review date: 10/2024

Next review date: 2/2026

Policy contains: CardioMEMS, chronic heart failure, pulmonary artery pressure monitoring.

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First- CHIP, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First- CHIP's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.

Coverage policy

Wireless pulmonary artery pressure monitoring devices for heart failure are investigational/not clinically proven, and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Self-contained pacemaker monitors.
- Implantable hemodynamic monitors.
- Guideline-directed medical management.

Background

Heart failure occurs when the heart is unable to pump enough blood and oxygen to the body's organs. About 6.2 million Americans have chronic heart failure (Centers for Disease Control and Prevention, 2023). This can result in increased hospitalization, morbidity, and death. One of the most preventable causes of decompensation is lack of compliance with appropriate diet or prescribed medications.

The main focus of heart failure treatment is to lower the ventricular filling pressure without affecting cardiac output. To manage decompensated heart failure, monitoring pulmonary artery pressure is critical. Traditionally, hemodynamic monitoring did not occur until the onset of symptoms and during the patient's encounter with the provider. It required an invasive right heart catheterization (Mangi, 2017).

Providers and researchers have tried to develop methods to more accurately predict impending heart failure and reduce hospitalizations from decompensated heart failure. These methods have included use of biochemical markers, echocardiography, right heart catheterization, tele-monitoring, pro-B-type natriuretic peptide, chest radiograph, and cardiac implanted electronic devices such as pacemaker and defibrillator. Despite some progress, further improvements are needed (Mangi, 2017).

More than a decade ago, researchers created a new wireless pressure sensor implanted during a right heart catheterization procedure in patients with heart failure to monitor pulmonary artery pressure. The rationale behind its use is that increases in pulmonary arterial pressures are detectable several weeks prior to worsening of clinical symptoms and signs. Preliminary research found a significant correlation between pulmonary artery pressure monitoring by the sensor and Swan-Ganz catheterization and echocardiography in ambulatory patients with heart failure (all $P < .01$) (Verdejo, 2007). Ambulatory monitoring of pulmonary artery pressure offers the potential to reduce hospital admissions and improve survival. Readings could be transmitted to the provider's external monitor to help in clinical decision making while the patient remains at home (Mangi, 2017).

In 2014, the U.S. Food and Drug Administration gave premarket approval for the CardioMEMS™ HF System, which includes the CM2000 implantable PA Sensor/Monitor and transvenous catheter delivery system, the CM1000 Patient Electronics System, the CM1010 Patient Electronics System, and CM3000 Hospital Electronics System. The system measures/monitors pulmonary artery pressure and heart rate in patients with New York Heart Association Class III heart failure who were hospitalized for heart failure in the prior year (U.S. Food and Drug Administration, 2014). The results of the CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients (CHAMPION) study provided data for regulatory approval (ClinicalTrials.gov identifier: NCT00531661).

In 2022, the Administration expanded approval for CardioMEMS for use in patients with Class II heart failure and elevated natriuretic peptides in the previous 30 days based clinical data from the Hemodynamic-Guided Management of Heart Failure trial (GUIDE-HF; ClinicalTrials.gov identifier NCT03387813). Natriuretic peptides serve as surrogates for worsening congestion in patients with heart failure. The results suggest patients with Class II heart failure and elevated natriuretic peptides had better outcomes when their therapy was guided by pulmonary pressure monitoring, after adjusting for the impact of COVID-19 (U.S. Food and Drug Administration, 2022).

Champion CardioMEMS is a heart failure monitoring system that uses a sensor to monitor cardiac output and pulmonary artery pressure and communicate the information wirelessly. The sensor is small (15 mm x 3 mm) and is implanted into the pulmonary artery through the femoral vein using a Swan-Ganz catheter based system. After discharge, the patient takes 20 second readings from the device. Any pressure changes are picked up by an external antenna wand and data are transmitted to a web site for provider use (Barghash, 2015; Brugts, 2021).

Findings

An updated American College of Cardiology/American Heart Association/Heart Failure Society of America guideline on heart failure issued two recommendation statements for wireless pulmonary artery pressure monitoring (Heidenreich, 2022):

- In selected adult patients with New York Heart Association class III heart failure and history of a heart failure hospitalization in the past year or elevated natriuretic peptide levels, on maximally tolerated stable doses of guideline-directed medical therapy with optimal device therapy, the usefulness of remote pulmonary artery pressure monitoring by an implanted hemodynamic monitor to reduce the risk of subsequent heart failure hospitalizations is uncertain.
- In patients with New York Heart Association class III heart failure with a heart failure hospitalization within the previous year, wireless monitoring of pulmonary artery pressure by an implanted hemodynamic monitor provides uncertain value.

Current evidence from randomized and nonrandomized trials provided mixed results on the impact of an implantable pulmonary artery pressure sensor to reduce the risk of heart failure hospitalization in selected patients with heart failure. It is unclear if any benefits in patients with moderate heart failure symptoms extend to patients with a wider array of symptoms (New York Heart Association class II or IV) or to patients with elevated natriuretic peptides without a recent heart failure hospitalization (Heidenreich, 2022).

It is also unclear if wireless hemodynamic monitoring is more cost effective than less invasive telemonitoring, since direct comparisons between the two systems have not been conducted. Evidence from modeling studies suggest the cost effectiveness of CardioMEMS implantation is highly dependent on its effect on mortality and duration of treatment benefit, both of which remain unclear. Additional data on clinical outcomes following CardioMEMS implantation and cost effectiveness from new trial findings will improve estimates of its economic value (Heidenreich, 2022).

In 2016, the European Society of Cardiology issued a guideline on heart failure, including a statement that wireless monitoring devices may be considered for monitoring symptomatic patients with heart failure (Ponikowski, 2016). A heart failure guideline from the National Institute of Health and Care Excellence did not mention wireless monitoring devices (National Institute of Health and Care Excellence, 2018).

A systematic review of five randomized and non-randomized trials and a meta-analysis of two trials found patients who underwent remote pulmonary artery monitoring were less likely to be hospitalized than those who did not (odds ratio 0.52; 95% confidence interval 0.39 to 0.69). Most participants were overweight males in their mid-sixties with hypertension, Class III heart failure with reduced ejection fraction, and a mean pulmonary artery pressure of 27.2 mm Hg. The follow-up periods ranged from 90 days to 12 months. Sixty-four adverse events were reported. The most common were not serious and included sensor dislodgement, arrhythmia, hemoptysis, and infection. Serious but rare adverse events included pulmonary artery perforation, cardiac decompensation, endocarditis, renal failure, pseudoaneurysm formation, and sudden death (Thakker, 2022).

One systematic review/meta-analysis compared reductions in hospitalizations between tele-monitoring (61 studies, 55 randomized/controlled, n = 31,501), and hemodynamic monitoring sensors (12 studies, eight randomized/controlled articles from three studies, n = 4,831). Hemodynamic monitoring included eight studies of the CardioMEMS sensor. Both groups had significant declines in hospitalizations rates ($P < .0001$ and $P <$

.001). However, the hemodynamic sensor groups had larger declines in hospitalizations under six months (45% versus 24%), over 12 months (37% to 27%), and overall (40% versus 26%). Direct comparisons between telemonitoring and more invasive hemodynamic monitoring are needed to assess relative cost effectiveness (Tse, 2018).

A systematic review of seven studies (n = 1,912) compared the ability of types of hemodynamic monitoring to reduce future hospitalizations for heart failure patients. The study on left atrium pressure showed the highest reduction (59.0%) in heart failure hospitalization, followed by the pulmonary artery pressure (CardioMEMS, 56.3%) and right ventricle pressure (31.0%). However, only one of the seven studies was of left atrium pressure, so authors caution not to conclude this method is most effective (Minhas, 2017).

A study randomized heart failure patients (n = 1,437) into those at home with remote monitors and telephone calls and those given conventional care. The readmission rate 180 days after discharge was similar between the two groups, at 50.8% and 49.2%, *P* = .74). No differences exist in readmission rates at 30 days or mortality rates at 180 days, but 180-day quality of life was superior in the intervention group (Ong, 2016).

A systematic review of 14 studies (n = 5,454) compared devices for continuous monitoring of heart failure versus controls. There was no difference between groups in heart failure-related admissions rate, or all-cause mortality. A subgroup analysis of only pressure sensors devices revealed no difference in all-cause mortality, but a significantly lower admissions rate (*P* = .02) (Halawa, 2019).

The initial large-scale study of the efficacy (and safety) of wireless sensors for heart failure was the prospective, single-blind, randomized controlled trial CHAMPION study of the CardioMEMS system, at 64 U.S. medical centers (n = 550). The results of the initial trial and follow up studies are presented below:

- The initial trial included New York Heart Association class III patients who had at least one previous hospitalization for heart failure in the past 12 months. Patients were randomly assigned to the treatment group (medication adjustment based on sensor readings) or control group. In the treatment group, heart failure hospitalization rates were reduced by 28% in six months and by 37% in 15 months without increasing other causes of hospitalization (both *P* < .0001) (Abraham, 2011).
- Of these enrollees, 347 completed the randomized access period and also transitioned to the open access period during which pulmonary artery pressure information became available to the control group to guide therapy. In the control group, heart failure hospitalization rates were reduced by 48% (*P* < .0001) compared with their hospitalization rates during randomized access (Abraham, 2016).
- A subgroup analysis of the 245 Medicare-eligible subjects found medications were changed more often in the treatment group using pressure sensor information compared with the control group using symptoms and daily weights alone. During the 515 days follow-up after implant, the overall heart failure hospitalization rate was 49% lower in the treatment group compared with control (*P* < .0001). All-cause 30-day readmissions were 58% lower in the treatment group compared to the control group (*P* = .0080) (Adamson, 2016).
- Another subgroup analysis of 1,087 Medicare patients who received CardioMEMS implants from June 1, 2014 to March 31, 2016 was compared with 1,087 controls, also Medicare patients who had been hospitalized for heart failure during that time. After 12 months of follow up, the treatment group had significantly fewer hospitalizations (616 versus 784, *P* < .001), deaths (241 versus 325, *P* < .001) and

average hospital days for heart failure (3.7 versus 4.4, *P* < .001). The number of ventricular assist devices and heart transplants was also lower (13 versus 20) but not statistically significant (Abraham, 2019).

- A subgroup analysis found patients with recurring Class III heart failure following cardiac resynchronization therapy who underwent CardioMEMS-guided management had a 30% lower heart failure hospitalization rate (*P* = .028), more medication adjustments (*P* < .001), a greater reduction in mean pulmonary artery pressure (*P* = .002), and greater quality of life improvement on the Minnesota Living with Heart Failure Questionnaire (*P* = .006) compared to those who were managed with usual care after 18 months of follow-up (Varma, 2021).
- Three model-based studies estimated the cost-effectiveness of wireless pulmonary artery pressure monitoring based on data from the CHAMPION-HF trial. All three studies estimated an increase in survival and quality-adjusted life years but also increased costs from the U.S. perspective. Its cost effectiveness was attributable to the reduction in heart failure hospitalization rates and depended on sustained treatment effectiveness and mortality benefit over time (Martinson, 2017; Sandhu, 2016; Schmier, 2017).

The first large-scale study of wireless pulmonary artery pressure monitors aside from the initial clinical trials included 1,114 patients. The number of heart failure-related hospitalizations in the six months before and after implantation dropped dramatically from 1020 to 381. The follow-up period included 139 deaths, and 17 ventricular assist device implantations and/or transplants (Desai, 2017).

A CardioMEMS post-approval study of 1,200 patients with heart failure (New York Hospital Association Class III) with ambulatory hemodynamic monitoring using a pulmonary artery sensor evaluated subjects for a year. The study revealed significant declines in pulmonary artery pressure, heart failure hospitalizations (*P* < .0001), and all-cause hospitalizations (*P* < .0001) (ClinicalTrials.gov identifier: NCT02279888; Shavelle, 2020).

The Haemodynamic-GUIDEed management of Heart Failure (GUIDE-HF) randomized controlled trial enrolled 1,022 patients across 118 centers in the United States and Canada between March 15, 2018 and December 20, 2019. The study examined the safety and efficacy of remote CardioMEMS monitoring versus usual care in patients with Class II to IV heart failure, including those with elevated natriuretic peptides but without a recent heart failure hospitalization. The primary endpoint was a composite of all-cause mortality and total heart failure events (heart failure hospitalizations and urgent care visits) at 12 months. CardioMEMS-guided management did not reduce the cumulative incidence of heart failure events relative to controls in the overall analysis (*P* = .096). A subgroup analysis suggested a possible benefit of CardioMEMS-guided management on the primary outcome in the pre-COVID-19 period, primarily driven by a lower heart failure hospitalization rate, compared with the control group (ClinicalTrials.gov identifier: NCT03387813; Lindenfeld, 2021).

In 2022, we updated the latest cardiology guideline on the management of heart failure (Heidenreich, 2022) and added a systematic review (Thakker, 2022), four analyses from the CHAMPION trial (Martinson, 2017; Sandhu, 2016; Schmier, 2017; Varma, 2021), and a new clinical trial that enrolled a broader range of patients with heart failure symptoms (Lindenfeld, 2021). No policy changes are warranted.

In 2023, we updated the references and added an updated analysis of the GUIDE-HF trial data (Desai, 2023), a systematic review (Azari, 2023), and a meta-analysis (Iaconelli, 2023). The CardioMEMS wireless monitoring system may reduce risk of hospitalization, but its effect on mortality is less clear. Sufficiently powered studies to conduct mortality analyses and more complete data on medical history and long-term outcomes are needed to

clarify its role in the management of patients with New York Heart Association functional class II to IV heart failure. No policy changes are warranted.

An analysis of the GUIDE-HF trial data examined the efficacy and safety of CardioMEMS in 442 participants with New York Heart Association functional class II to IV heart failure and elevated natriuretic peptides within 30 days but no recent heart failure hospitalization. Participants who enrolled on the basis of elevated natriuretic peptides achieved a reduction in heart failure hospitalization comparable to those with previous heart failure hospitalization within 12 months. The results suggest a possible expanded role for invasive hemodynamic monitoring as a strategy for heart failure management for patients with better functional capacity who have not been previously hospitalized (Desai, 2023).

A systematic review analyzed the cost effectiveness of the CardioMEMS wireless monitoring system versus standard of care based on the results of five published economic evaluations employing Markov and decision tree models. All but one study were conducted in the United States. Clinical effectiveness outcomes such as mortality and hospitalization, were derived from the CHAMPION trial using a time horizon of five years in most simulations. From a U.S. societal perspective, compared to standard of care, CardioMEMS produced higher quality adjusted life-years (2.73 vs. 2.3) and could be a cost effective option. Limitations of the analysis included lack of long-term efficacy and safety data and variable cost inputs across U.S. sites, which can influence incremental cost effectiveness ratios (Azari, 2023).

A meta-analysis combined the results of four randomized clinical trials representing three implanted hemodynamic monitoring devices (Chronicle, Chronicle/ICD and CardioMEMS). Use of these devices reduced the risk of hospitalization for heart failure (hazard ratio = 0.75, 95% confidence interval 0.58 to 0.96, *P* = .03) but not mortality (relative risk = 0.92, 95% confidence interval 0.68 to 1.26, *P* = .48). Treatment guided by hemodynamic monitoring reduce pulmonary artery pressure by only 5% (a reduction of 1.6 mmHg in absolute terms) compared to no changes observed in the control group. The optimal method of achieving control of pulmonary artery pressures with or without frequent hemodynamic monitoring needs further exploration (Iaconelli, 2023).

In 2024, we found a review article (n=1,786) that examined three main studies evaluating the CardioMEMS Heart Failure system for remote pulmonary artery pressure monitoring in patients with chronic heart failure. The CHAMPION trial, a randomized controlled trial (n=550), included 270 patients in the treatment group and 280 in the control group and demonstrated a significant reduction in heart failure-related hospitalizations. The GUIDE-Heart Failure trial, another randomized controlled trial (n=1,000), included 497 patients in the treatment group and 503 in the control group and showed mixed results, with a borderline significant benefit in the pre-COVID-19 analysis. The MEMS-Heart Failure study, a non-randomized post-marketing study (n=236), reported a 62% reduction in heart failure-related hospitalizations compared to the 12 months prior to device implantation. In total, these three key studies were encompassed in the review. This evidence suggests the potential benefits of wireless pulmonary artery pressure monitoring in reducing heart failure-related hospitalizations, although results varied across studies and patient populations (Clephas, 2023). No policy changes are warranted.

References

On September 10, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “(pulmonary artery (MeSH),” “heart failure

(MeSH)," "CardioMEMs," "remote pulmonary artery pressure monitor*," and "wireless pulmonary artery pressure monitor." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

9/2016: initial review date and clinical policy effective date: 1/2017

9/2017: Policy references updated.

9/2018: Policy references updated.

10/2019: Policy references updated. Policy ID changed to CCP.1259.

10/2020: Policy references updated.

10/2021: Policy references updated.

10/2022: Policy references updated.

10/2023: Policy references updated.

10/2024: Policy references updated.