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.

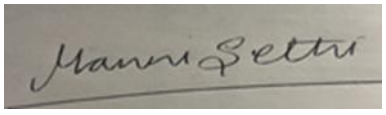
Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date: 11/1/2025
Policy Number: CCP.1259	Effective Date:1/3/2017 Revision Date:10/1/2025
Policy Name: Wireless pulmonary artery pressure monitoring devices for heart failure	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

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

Please provide any clarifying information for the policy below:

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

Keystone First
Family of Health Plans

Wireless pulmonary artery pressure monitoring devices for heart failure

Clinical Policy ID: CCP.1259

Recent review date: 10/2025

Next review date: 2/2027

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

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First'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, 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'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's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First'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. In the United States, an estimated 6.7 million people live with heart failure. Its prevalence is projected to increase further, affecting more than eight million adults age 18 years and older by 2030 (Martin, 2025). Initial hospitalizations and rehospitalizations (30- and 90-day) account for the largest component of direct medical costs attributed to heart failure diagnoses (Osenenko, 2022).

Current methods to reduce decompensation leading to heart failure hospitalizations include frequent weight monitoring, blood pressure measurements, Holter monitoring, and telehealth platforms for structured

assessment of symptoms. However, these methods often reflect later changes in decompensation and are time-consuming and resource-intensive. Remote monitoring devices, broadly categorized as either implantable or less invasive wearable options, have been developed to detect impending signs of heart failure decompensation and reduce heart failure hospitalization (Kobe, 2023).

Wireless pulmonary artery pressure monitoring involves implanting a small sensor in the pulmonary artery during a right heart catheterization procedure to detect changes in pulmonary artery pressure that may precede the worsening of clinical signs and symptoms. 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).

The U.S. Food and Drug Administration has issued premarket approval to two wireless pulmonary artery pressure monitoring systems for detecting heart failure. Both devices are intended to aid clinicians in the assessment and management of heart failure, with the goal of reducing heart failure hospitalizations.

The CardioMEMS™ HF System (CardioMEMS Inc., Atlanta, Georgia) gathers and transmits pulmonary artery pressure information from the patient while lying supine on a special pillow for a short time each day. It is indicated for:

- 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; ClinicalTrials.gov identifier: NCT00531661) study provided data for regulatory approval.
- Patients with New York Heart Association Class II heart failure and elevated natriuretic peptides in the previous 30 days (U.S. Food and Drug Administration, 2022). Findings from the Hemodynamic-Guided Management of Heart Failure trial provided the basis for approval (GUIDE-HF; ClinicalTrials.gov identifier NCT03387813).

The Cordella Pulmonary Artery Sensor System (CorPASS) (Endotronix, Inc., Naperville, Illinois) measures pulmonary artery pressure while in a seated position. It is indicated for patients with New York Heart Association Class III heart failure who are at home on diuretics and guideline-directed medical therapy and have been stable for 30 days on guideline-directed medical therapy (U.S. Food and Drug Administration, 2024). The results of the PROACTIVE-HF IDE Trial Heart Failure NYHA Class III pivotal trial provided the basis for device approval (PROACTIVE-HF; ClinicalTrials.gov identifier NCT04089059).

Findings

Guidelines

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, based primarily on the results of the CHAMPION and GUIDE-HF trials (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 and 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 (2b recommendation, based on moderate quality evidence from randomized controlled trials or meta-analyses of such trials).

- 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.

The European Society of Cardiology issued a Class IIb recommendation that wireless monitoring devices may be considered for monitoring symptomatic patients with heart failure, which indicates efficacy is less well established by evidence/opinion (McDonagh, 2021). The National Institute for Health and Care Excellence Evidence (2021) found sufficient evidence on the safety and efficacy to support using percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure, provided that standard arrangements are in place for clinical governance, consent and audit; evidence of efficacy focused on reducing heart failure-related admissions.

The Heart Failure Society of America issued a scientific statement on several novel device-based therapies in heart failure, include the CardioMEMS and Cordella devices. Based on aggregated updated evidence from clinical trials of CardioMEMS and other comparable device-based, pressure-monitoring strategies, a strategy that targets filling pressures represents an important factor in decreasing the risk of heart failure hospitalization. New trial data “are expected to influence a future higher guideline recommendation for use” (Estep, 2024). The Heart Failure Association of the European Society of Cardiology issued a similar consensus statement (Bayes-Genis, 2025).

Evidence review

The evidence of safety and effectiveness for ambulatory pulmonary artery pressure monitoring in heart failure is expanding across settings and devices. For CardioMEMS, the highest quality, published evidence consists of several analyses from three randomized controlled trials. The CHAMPION and GUIDE-HF trials and post-approval studies were carried out in North America. The Pulmonary Artery Sensor System Pressure Monitoring to Improve Heart Failure Outcomes trial (MONITOR-HF; International Clinical Trials Registry number NL7430) was carried out in the Netherlands. For the new Cordella system, the evidence is derived from the open label PROACTIVE-HF trial. Descriptions of these trials are summarized in the Appendix.

CardioMEMS

Current evidence from randomized and nonrandomized trials shows that CardioMEMS is safe with freedom from device and system-related complications and system failure at one year exceeding 97% in most cases (Clephas, 2023; Kapelios, 2025). Infrequent, serious injury to the pulmonary artery and device-related death have been reported, and there may be a need for reintervention or device recalibration (Iaconelli, 2023).

Current evidence from randomized trials of CardioMEMS provided mixed results on the impact of ambulatory pulmonary artery pressure sensor monitoring in selected patients with heart failure. In syntheses of randomized trials, CardioMEMS-guided therapy reduced heart failure hospitalizations by 25% (Iaconelli, 2023) to 30% (Clephas, 2023) in participants with New York Heart Association Class III heart failure compared to standard care. Benefits were maintained up to one year and were realized irrespective of left ventricular ejection fraction or severity of pulmonary hypertension at baseline, although those with more severe pulmonary hypertension achieved the greatest benefit (Clephas, 2023, 2024). Similar benefits to reduced hospitalization and quality of life were observed in nonrandomized, real-world settings (Kapelios, 2025).

However, the confidence intervals around these estimates were wide, producing low statistical certainty. Changes in treatment associated with hemodynamic monitoring often resulted in a modest relative reduction (approximately 5%) and absolute reduction (− 1.6 mmHg) in mean pulmonary artery pressure compared to no changes observed in the control group (Iaconelli, 2023). The effect on mortality was unclear, as none of the randomized trials was powered for mortality outcomes (Clephas, 2023; Iaconelli, 2023). The cost effectiveness of more intensive wireless hemodynamic monitoring relative to less invasive strategies has not been determined,

since direct comparisons between the two systems have not been conducted (Azari, 2023; Heidenreich, 2022; Iaconelli, 2023).

Based on the results of the GUIDE-HF trial, it is unclear if these benefits 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). Initially, CardioMEMS achieved modest reductions in pulmonary artery pressures, but when the trial was disrupted by the COVID-19 pandemic, any differences between study arms disappeared, suggesting that improved treatment adherence and lifestyle modifications may have influenced the results (Iaconelli, 2023). CardioMEMS-guided management did not reduce the cumulative incidence of heart failure events relative to controls in the overall analysis (P = .096) (Lindenfeld, 2021).

Azari (2023) estimated the cost effectiveness of CardioMEMS using the results of five published economic evaluations employing Markov and decision tree models and clinical effectiveness outcomes 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-guided treatment produced higher quality adjusted life-years (2.73 vs. 2.3). However, the cost effectiveness of CardioMEMS implantation is highly dependent on its effect on mortality and long-term safety and efficacy, which remain unclear.

Cordella

Results of the PROACTIVE-HF trial suggest Cordella may have a similar risk-benefit profile to CardioMEMS. The six-month event rate was significantly lower than the performance goal derived from prior remote hemodynamic monitoring trials (0.15 versus 0.43, P < .0001). Through six months, freedom from device- or system-related complications was 99.2%, and freedom from sensor failure was 99.8%. These safety and effectiveness endpoints align with those of the CHAMPION trial. Serious adverse events occurred in 196 (39.8%) patients, and 36 (7.3%) patients had procedure-related adverse events. The most frequently reported serious adverse events were worsening heart failure (30%), renal insufficiency or failure (10%), hypo- or hypertension (6%), allergic reaction (3%), reaction to contrast media or medication (3%), and gastrointestinal bleed (3%) (Guichard, 2024).

In 2022, we updated the references. No policy changes are warranted.

In 2023, we updated the references. No policy changes are warranted.

In 2024, we updated the references. No policy changes are warranted.

In 2025, we updated the references and added results from the MONITOR-HF and PROACTIVE-HF trials, including the newly approved Cordella system. No policy changes are warranted.

References

On August 25, 2025, 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.

10/2025: Policy references updated.

Appendix

Descriptions of the individual trials for CardioMEMs and Cordella and their results are presented briefly below.

CHAMPION trial

CHAMPION was the initial large-scale prospective, single-blind, randomized controlled trial of the CardioMEMS system, conducted at 64 U.S. medical centers (n = 550). The trial enrolled participants with New York Heart Association Class III heart failure and at least one previous hospitalization for heart failure in the past 12 months. 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). Subgroup analyses reported similar benefits in reduced hospitalizations (Abraham, 2016, 2019; Adamson, 2016; Varma, 2021),

A post-approval study with one-year follow-up (n = 1,200) reported significant declines in pulmonary artery pressure, heart failure hospitalizations ($P < .0001$), and all-cause hospitalizations ($P < .0001$). Notably, those with a baseline mean pulmonary artery pressure ≥ 35 mmHg achieved the greatest response to treatment intensification during follow-up one year of observation, but reductions in heart failure hospitalization rates were achieved regardless of baseline pulmonary artery pressures compared with the year pre-implant (ClinicalTrials.gov identifier: NCT02279888; Shavelle, 2020). Patients surveyed at the 24-month follow-up visit (n = 135) experienced high level of patient satisfaction with the monitoring device, improved sense of control, and an interest in engaging in future heart failure (Rathman, 2025).

GUIDE-HF trial

Between March 15, 2018 and December 20, 2019, 1,022 participants were enrolled across 118 centers in the United States and Canada. Included were participants with New York Heart Association 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 achieved modest reductions in pulmonary artery pressures, but when the trial was disrupted by the COVID-19 pandemic, any differences between study arms disappeared. CardioMEMS-guided management did not reduce the cumulative incidence of heart failure events relative to controls in the overall analysis (P = .096) (ClinicalTrials.gov identifier: NCT03387813; Lindenfeld, 2021). In a subgroup analysis of 442 participants who were enrolled on the basis of elevated natriuretic peptides alone, the reduction in heart failure hospitalization was comparable to those who had a previous heart failure hospitalization within 12 months (Desai, 2023).

MONITOR-HF trial

Conducted between 2019 and 2023, MONITOR-HF examined the role of CardioMEMS in a European healthcare system. The trial was unblinded and enrolled 348 participants from the Netherlands with New York Heart Association Class III heart failure and a hospitalization for heart failure in the past 12 months. Participants were randomized to contemporary standard of care with or without CardioMEMS-guided therapy. The primary safety endpoints were device-related or system-related complications and sensor failures. The freedom from device or safety-related complications was 97.7% and freedom from sensor failures was 98.8%. The results showed significant improvement in quality of life and reductions in the number of heart failure hospitalizations with CardioMEMS-guided heart failure therapy compared to standard of care. Results were consistent over a range of subgroups of participants with chronic heart failure and were consistent with the results of the CHAMPION trial (Brugts, 2023; Clephas, 2024).

PROACTIVE-HF trial

Originally designed as a randomized controlled trial, PROACTIVE-HF was changed to a single-arm, unblinded, open-label trial of the Cordella system conducted at 75 centers in the United States and Europe. The rationale for the change was three-fold: new clinical evidence from the CardioMEMS trials citing a positive clinical benefit; increased reimbursement and accessibility to patients outside of clinical trial settings; and the disruption of the COVID-19 pandemic. The trial used prespecified safety and effectiveness endpoints to assess if Cordella and CardioMEMS had similar risk/benefit profiles. The trial enrolled 456 participants with New York Heart Association Class III heart failure (irrespective of the left ventricular ejection fraction) and recent heart failure hospitalization and/or elevated natriuretic peptides. Following implantation, treatment was guided by a target trend seated mean pulmonary artery pressure of 5 to 20 mm Hg. The primary safety and effectiveness endpoints aligned with those of the CHAMPION trial (Guichard, 2024).