Cohere Medical Policy - Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS)

Clinical Guidelines for Medical Necessity Review

Version: 3
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Important Notices

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Other Notices:

Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Cohere Medicare Advantage Policy - Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS)

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Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS)

Recommended Clinical Approach

This policy is consistent with a National Coverage Analysis (NCA) published on January 13, 2025 by the Centers for Medicare and Medicaid Services (CMS) and guidelines published in 2022 by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Failure Society of America (HFSA).[1-2]

The CardioMEMS device is implanted in a pulmonary artery branch to remotely manage heart failure (HF). It allows earlier intervention to reduce congestive heart failure (CHF) exacerbations and hospitalizations. The effectiveness of using an implanted hemodynamic monitor for wireless pulmonary artery pressure monitoring to lower the risk of future HF hospitalizations continues to be debated. Specifically, this includes adult patients with New York Heart Association (NYHA) class II or III HF, a history of HF hospitalization within the past year, or elevated natriuretic peptide levels despite being on maximally tolerated stable doses of guideline-directed medical therapy (GDMT) and receiving optimal device therapy.

Among patients with NYHA class II or III HF with an HF hospitalization within the previous year, wireless monitoring of PA pressure by an implanted hemodynamic monitor provides uncertain value. Given this uncertainty of published recommendations, it is also reasonable and necessary to incorporate the inclusion and exclusion criteria from the two studies listed on the National Institutes of Health (NIH) website ClinicalTrials.gov. Abbott Medical Devices, the manufacturer of the CardioMEMS device, sponsored the *CardioMEMS HF System Post Approval Study* and the *Hemodynamic-GUIDEd Management of Heart Failure (GUIDE-HF) Study*.[3-5] The patient must meet all inclusion criteria for approval, and no exclusion criteria should be present before consideration for prior approval.

Medical Necessity Criteria

Indications

➔ **Wireless pulmonary artery pressure monitoring (CardioMEMS)** is considered appropriate if **ALL** of the following are **TRUE**[2]:

- The implantable pulmonary artery pressure sensor (IPAPS) is part of a Coverage with Evidence Development (CED) study approved by the Centers for Medicare and Medicaid Services (CMS) including **ANY** of the following[1,6]:
  - CardioMEMS HF System Coverage with Evidence Development Study (NCT06779552, Abbott); **OR**
  - Real-World Effectiveness of The Cordella Pulmonary Artery (PA) Sensor System in Patients With Chronic Heart Failure: A Comparative Analysis to Standard of Care Pharmacologic Therapy (LOWER-PAP) (NCT06783335, Edwards Lifesciences)[1]; **AND**
- New York Heart Association (NYHA) class II or III HF within the past 30 days, before pulmonary artery pressure sensor (PAPS) implantation, regardless of left ventricular ejection fraction (LVEF)[1]; **AND**
- The patient was diagnosed with heart failure (HF) more than 3 months ago[1]; **AND**
- Age greater than or equal to 18 years; **AND**
- **ANY** of the following[1]:
  - History of HF hospitalization or urgent HF visit (e.g, emergency room or other outpatient visit requiring intravenous diuretic therapy) within the past 12 months; **OR**
  - Elevated natriuretic peptides within the past 30 days; **AND**
- Optimal or maximally-tolerated GDMT before PAPS implantation including **ANY** of the following[1-2]:
  - For EF less than or equal to 40% on beta-blockers for 3 months; ACE/ARB/ARNI, SGLT2i, MRA, or diuretics for more than 1 month; or none if intolerant[A]; **OR**
  - For EF 41-49% on beta-blockers on ACE/ARB/ARNI, SGLT2i, MRA, or diuretics for more than 1 month or none if intolerant[B]; **OR**

        - For EF greater than or equal to 50% on beta-blockers, ACE/ARB/ARNI, SGLT2i, MRA, or diuretics for more than 1 month or none if intolerant[C]; **AND**
- The patient has been evaluated for and received, if appropriate, an implantable cardioverter defibrillator (ICD), CRT-defibrillator (CRT-D), cardiac resynchronization therapy (CRT)-pacemaker (CRT-P) for at least 3 months before PAPS implantation[1-2]; **AND**
- No major cardiovascular events within the last 3 months before PAPS implantation (e.g., myocardial infarction, unstable angina, percutaneous coronary intervention, open heart surgery, or stroke)[1]; **AND**
- Have access to reliable connectivity to ensure daily collection and submission of IPAPS data[1]; **AND**
- **ANY** of the following:
    - Must not have PAPS implantation occur during hospital admission for an acute HF episode[1]; **OR**
    - Elevated brain natriuretic peptide (BNP or NT-proBNP) levels within the last 30 days are **ANY** of the following:
        - LVEF less than or equal to 40%: NT-proBNP greater than or equal to 1000 pg/mL (or BNP greater than or equal to 250 pg/mL)*[7]; **OR**
        - LVEF greater than 40%: NT-proBNP greater than or equal to 700 pg/mL (or BNP greater than or equal to 175 pg/mL)*[7]; **OR**
        - Thresholds for NT-proBNP and BNP (for LVEF less than or equal to 40% and LVEF greater than 40%) must be corrected for body mass index (BMI) using a 4% reduction per BMI unit over 25 kg/m2[7]; **AND**
- **ANY** of the following[8-9]:
    - BMI greater than 35 kg/m2 with a chest circumference less than 65 inches; **OR**
    - BMI less than or equal to 35.

[A] Heidenreich et al. (2022), section 7.3. *Pharmacological Treatment for HFrEF.*
[B] Heidenreich et al. (2022), section 7.6.1. *HF With Mildly Reduced Ejection Fraction (HFmrEF).*

[C] Heidenreich et al. (2022), section 7.7.1. *HF With Preserved Ejection Fraction.*

* NT-proBNP and BNP Thresholds According to Ejection Fraction and BMI.[7]

Non-Indications

➔ **Wireless pulmonary artery pressure monitoring (CardioMEMS)** is not considered appropriate if **ANY** of the following is **TRUE**[5,7,9]:

- A major cardiovascular event (e.g., unstable angina, PCI, myocardial infarction, open heart surgery, stroke, etc.) within the previous 3 months; **OR**
- The patient cannot take dual antiplatelet or anticoagulants for 1-month post-implant; **OR**
- Intolerance to all neuro-hormonal antagonists (i.e., intolerance to angiotensin-converting enzyme inhibitors [ACE-I], angiotensin receptor blockers [ARB], angiotensin-neprilysin inhibitors [ARNi], hydralazine/isosorbide dinitrate and beta-blockers); **OR**
- Likely to undergo heart transplantation or ventricular assist device (VAD) within the next 12 months; **OR**
- Existing heart transplantation or VAD; **OR**
- ACC/AHA Stage D refractory HF (including having received or currently receiving pharmacologic circulatory support with inotropes); **OR**
- NYHA class IV HF patients; **OR**
- Implanted with mechanical right heart valve(s); **OR**
- Unrepaired severe valvular disease; **OR**
- Pregnant or planning to become pregnant in the next 12 months; **OR**
- Anticipated life expectancy of less than 12 months; **OR**
- Any condition that, in the opinion of the reviewer, would not allow for utilization of the CardioMEMSTM HF System to manage the subject using information gained from hemodynamic measurements to adjust medications; **OR**
- Presence of unexpectedly severe pulmonary hypertension (e.g., trans-pulmonary gradient greater than 15) at implant right heart catheterization (RHC); **OR**
- A history of non-compliance; **OR**

- Any other condition that would preclude CardioMEMS PA Sensor implantation.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

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

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Lindenfield et al. (2024) conducted a meta-analysis to analyze the efficacy of hemodynamic monitors for managing heart failure and reduced ejection fraction (HFrEF). The authors examined the results from the GUIDE-HF (Hemodynamic–Guided Management of Heart Failure) Study, the CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients) Study, and the LAPTOP-HF (Left Atrial Pressure Monitoring to OptimizeHeart Failure Therapy) Study. A total of 1350 patients were included in the analysis of hospitalization rates over 12 months and survival at 12- and 24-month follow-ups. The authors conclude that hospitalizations for HF improved due to hemodynamic monitors. At 24-month follow-up, hospitalizations decreased by 36%. Mortality varied by study: GUIDE-HF demonstrated "no reduction in mortality," while the CHAMPION study showed a trend of reduced mortality, and the LAPTOP-HF study demonstrated a 44% decrease.[10]

Lindenfield et al. (2021) performed an RCT on the effectiveness of pulmonary artery pressure monitoring to reduce mortality and HF events in patients with NYHA class II-IV HF (regardless of heart failure hospitalization [HFH] and level of natriuretic peptides). Results from the randomized arm of the GUIDE-HF trial identified a 28% reduction of HFH among the 1000 patients enrolled in the study. Compared with elevated brain natriuretic peptide (BNP) alone, patients with a previous HFH also had related benefits. (ClinicalTrials.gov Identifier NCT03387813).[11]

Shavelle et al. (2020) conducted a multi-center, prospective, open-label, observational, single-arm trial to determine the efficacy of pulmonary artery pressure-guided therapy. A total of 1200 patients who had NYHA class III HF with at least one hospitalization in the last 12 months due to HF were included. A 57% reduction of HFH was reported among patients; for all causes, HFH was reduced by 27% post-implantation. Patients with ejection fraction saw a 50% reduction in HFH - no differences were identified among subgroups for sex, race, and cause of HF. (ClinicalTrials.gov Identifier NCT02279888).[8]

References

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10. Lindenfeld J, Costanzo MR, Zile MR, et al. Implantable hemodynamic monitors improve survival in patients with heart failure and reduced ejection fraction. *J Am Coll Cardiol*. 2024 Feb 13;83(6):682-694. doi: 10.1016/j.jacc.2023.11.030. PMID: 38325994.
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Clinical Guideline Revision History/Information

Original Date: May 24, 2024		
Review History		
Version 2	6/11/2024	422.101 Disclaimer added

Version 3	3/6/2025	• Annual review.
		• Aligned policy with CMS National Coverage Analysis (NCA) Decision Memo: Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (CAG-00466N).
		• Added a bullet to the harms section - "Physiologic changes: Patients may experience increased wall stress, sympathetic activation, arrhythmia, and elevated heart rate. Renal function may also decrease."
		• Added a bullet to the benefits section - "Reduction in complications and adverse effects: Using CardioMEMS criteria helps avoid unnecessary interventions and associated risks to safeguard the patient. Wireless pulmonary artery pressure monitoring guidelines emphasize the importance of accurate diagnostics in preventing complications." (Heidenreich et al., 2022).
		• Added an indication requiring enrollment in a CMS-approved Coverage with Evidence Development (CED) study including any of the following:
		  ○ CardioMEMS HF System Coverage with Evidence Development Study (NCT06779552, Abbott); **OR**
		  ○ Real-World Effectiveness of The Cordella Pulmonary Artery (PA)

		Sensor System in Patients With Chronic Heart Failure: A Comparative Analysis to Standard of Care Pharmacologic Therapy (LOWER-PAP) (NCT06783335, Edwards Lifesciences). • Deleted 7 non-indications that were relative contraindications (Cohere includes absolute contraindications only). • Rewrote the Medical Evidence section (see Lindenfeld et al., 2024; Lindenfeld et al., 2021; and Shavelle et al., 2020).