



# **Cohere Medical Policy - Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (IPAPS)**

*Clinical Guidelines for Medical Necessity Review*

**Version: 4**

**Cohere Health UMC Approval Date: December 11, 2025**

Last Annual Review: March 6, 2025

Revision: December 11, 2025

Next Annual Review: March 6, 2026

# Important Notices

## Notices & Disclaimers:

**GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.**

Cohere Health, Inc. ("**Cohere**") has published these clinical guidelines to determine the medical necessity of services (the "**Guidelines**") for informational purposes only, and solely for use by Cohere's authorized "**End Users**". These Guidelines (and any attachments or linked third-party content) are not intended to be a substitute for medical advice, diagnosis, or treatment directed by an appropriately licensed healthcare professional. These Guidelines are not in any way intended to support clinical decision-making of any kind; their sole purpose and intended use is to summarize certain criteria Cohere may use when reviewing the medical necessity of any service requests submitted to Cohere by End Users. Always seek the advice of a qualified healthcare professional regarding any medical questions, treatment decisions, or other clinical guidance. The Guidelines, including any attachments or linked content, are subject to change at any time without notice. This policy may be superseded by existing and applicable Centers for Medicare & Medicaid Services (CMS) statutes.

© 2025 Cohere Health, Inc. All Rights Reserved.

---

## Other Notices:

HCPCS® and CPT® copyright 2025 American Medical Association. All rights reserved.

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

HCPCS and CPT are registered trademarks of the American Medical Association.

---

## Policy Information:

**Specialty Area:** Cardiovascular Disease

**Policy Name:** Cohere Medical Policy - Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (IPAPS)

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

## **Table of Contents**

<b>Important Notices</b>	<b>2</b>
<b>Medical Necessity Criteria</b>	<b>4</b>
<b>Service: Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (IPAPS)</b>	<b>4</b>
Description	4
Medical Necessity Criteria	4
Indications	4
Non-Indications	6
Level of Care Criteria	7
Procedure Codes (CPT/HCPCS)	7
<b>Medical Evidence</b>	<b>8</b>
<b>References</b>	<b>9</b>
<b>Clinical Guideline Revision History/Information</b>	<b>11</b>

# Medical Necessity Criteria

## **Service: Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (IPAPS)**

### Description

The Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (IPAPS) 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.

### Medical Necessity Criteria

#### Indications

**Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (IPAPS)** is considered appropriate if **ALL** of the following are **TRUE**<sup>1-9</sup>:

- 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); **AND**
- The patient was diagnosed with heart failure (HF) more than 3 months ago; **AND**
- Age greater than or equal to 18 years; **AND**
- **ANY** of the following:
  - 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<sup>1</sup>:
  - 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<sup>A</sup>; **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<sup>B</sup>; **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<sup>C</sup>; **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<sup>1</sup>; **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); **AND**
- Have access to reliable connectivity to ensure daily collection and submission of IPAPS data; **AND**
- **ANY** of the following:
  - Must not have PAPS implantation occur during hospital admission for an acute HF episode; **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)\*<sup>5</sup>; **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)\*<sup>5</sup>; **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/m<sup>2</sup><sup>5</sup>; **AND**
- **ANY** of the following<sup>6-7</sup>:
  - BMI greater than 35 kg/m<sup>2</sup> with a chest circumference less than 65 inches; **OR**
  - BMI less than or equal to 35.

<sup>A</sup> Heidenreich et al. (2022), section 7.3. *Pharmacological Treatment for HFrEF*.

<sup>B</sup> Heidenreich et al. (2022), section 7.6.1. *HF With Mildly Reduced Ejection Fraction (HFmrEF)*.

<sup>c</sup> Heidenreich et al. (2022), section 7.7.1. *HF With Preserved Ejection Fraction*.

\* [NT-proBNP and BNP Thresholds According to Ejection Fraction and BMI.](#)<sup>2</sup>

## Non-Indications

**Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (IPAPS)** is not considered appropriate if **ANY** of the following is **TRUE**<sup>4,7-8</sup>:

- A major cardiovascular event (e.g., unstable angina, percutaneous coronary intervention [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 CardioMEMS™ 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)**

<b>CPT/HCPCS Code</b>	<b>Code Description</b>
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
93264	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
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components

## 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 Optimize Heart 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.<sup>8</sup>

Lindenfield et al. (2021) performed a randomized controlled trial (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).<sup>9</sup>

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).<sup>6</sup>

## References

1. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022 May 3;145(18):e895–e1032. doi: 10.1161/CIR.0000000000001063. PMID: 35363499.
2. ClinicalTrials.gov. CardioMEMS HF system post-approval study (ClinicalTrials.gov identifier: NCT02279888). Updated April 17, 2024. <https://clinicaltrials.gov/study/NCT02279888>.
3. ClinicalTrials.gov. Hemodynamic-GUIDEd management of heart failure (GUIDE-HF) (ClinicalTrials.gov identifier: NCT03387813). Updated August 9, 2023. <https://clinicaltrials.gov/study/NCT03387813>.
4. United States Food and Drug Administration (FDA). Summary of safety and effectiveness data (SSED): CardioMEMS™ HF system (PMA approval number P100045). Published 2014. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf10/P100045S056B.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100045S056B.pdf).
5. Abbott Laboratories. CardioMEMS HF System: Patient candidate considerations. Updated 2025. <https://www.cardiovascular.abbott/content/dam/cv/cardiovascular/campaigns/cmems-patient-indication-quiz/CardioMEMS-Patient-Candidate-Considerations-Tool.pdf>.
6. Shavelle DM, Desai AS, Abraham WT, et al. Lower rates of heart failure and all-cause hospitalizations during pulmonary artery pressure-guided therapy for ambulatory heart failure: One-Year outcomes from the CardioMEMS post-approval study. *Circ Heart Fail*. 2020 Aug;13(8):e006863. doi: 10.1161/CIRCHEARTFAILURE.119.006863. PMID: 32757642; PMCID: PMC7434214.
7. CardioMEMS, Inc. CardioMEMS™ HF system (PA sensor and delivery system, model CM2000) – user’s manual. Published 2014. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf10/p100045d.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf10/p100045d.pdf).
8. 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.

9. Lindenfeld J, Zile MR, Desai AS, et al. Haemodynamic-guided management of heart failure (GUIDE-HF): A randomised controlled trial. *Lancet*. 2021 Sep 11;398(10304):991-1001. doi: 10.1016/S0140-6736(21)01754-2. PMID: 34461042.

# Clinical Guideline Revision History/Information

Original Date: May 22, 2023		
Review History		
Version 2	03/22/2024	Policy criteria reviewed and updated per medical literature.
Version 3	03/06/2025	<p>Annual review.</p> <p>Added an indication requiring enrollment in a CMS-approved Coverage with Evidence Development (CED) study, including any of the following:</p> <ul style="list-style-type: none"> <li>• CardioMEMS HF System Coverage with Evidence Development Study (NCT06779552, Abbott); <b>OR</b></li> <li>• 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).</li> </ul> <p>Updated the indication for “New York Heart Association (NYHA) class II or III HF” to include “within the past 30 days, before pulmonary artery pressure sensor (PAPS) implantation, regardless of left ventricular ejection fraction (LVEF).”</p> <p>Updated the indication for “history of HF hospitalization” to include “or urgent HF visit (e.g, emergency room or other outpatient visit</p>

		<p>requiring intravenous diuretic therapy) within the past 12 months.”</p> <p>Added indication for “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 (CMS, 2025; Heidenreich et al., 2022).</p> <p>Added indication for “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) (CMS, 2025).</p> <p>Added indication to “have access to reliable connectivity to ensure daily collection and submission of IPAPS data.”</p> <p>Added indication that the patient “must not have PAPS implantation occur during hospital admission for an acute HF episode.”</p> <p>Added indication for “elevated brain natriuretic peptide (BNP or NT-proBNP) levels within the last 30 days” to include “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.”</p> <p>Updated time frame from 6 to 12 months for the non-indication related to the patient is</p>
--	--	--

		<p>“likely to undergo heart transplantation or ventricular assist device (VAD).”</p> <p>Added non-indication for “Existing heart transplantation or VAD.”</p> <p>Rewrote the Medical Evidence section (Lindenfeld et al., 2024; Lindenfeld et al., 2021; and Shavelle et al., 2020).</p>
Version 3.1	08/04/2025	<p>Revision</p> <p>Corrected version dates in the Clinical Guideline Revision History/Information table.</p> <p>Added CPT 93264.</p> <p>No criteria changes.</p>
Version 4	12/11/2025	<p>Revision.</p> <p>Changed policy title from “Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS)” to “Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (IPAPS)”.</p> <p>Simplified description.</p> <p>Removed CED approval criteria. No other criteria changes.</p>