Cohere Medicare Advantage Policy - Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS)

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: June 11, 2024

Important Notices

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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) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS)

Benefit Category

Not applicable.

Recommended Clinical Approach

The CardioMEMS device is implanted in a pulmonary artery branch to help manage heart failure remotely. Its purpose is to allow earlier intervention to reduce CHF exacerbations and hospitalizations. This document is based on guidelines published in 2022 by the American College of Cardiology (ACC) and the American Heart Association (AHA) Joint Committee on Clinical Practice Guidelines.[1] For certain adult patients with NYHA class III heart failure (HF), a history of HF hospitalization within the past year, or elevated natriuretic peptide levels, despite being on maximally tolerated stable doses of GDMT and receiving optimal device therapy, the effectiveness of using an implanted hemodynamic monitor for wireless PA pressure monitoring to lower the risk of future HF hospitalizations remains uncertain. In patients with NYHA class III HF with an HF hospitalization within the previous year, wireless monitoring of the PA pressure by an implanted hemodynamic monitor provides uncertain value. Given the uncertainty of the 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. The studies were sponsored by Abbott Medical Devices, the manufacturer of the CardioMEMS device. This includes the *CardioMEMS HF System Post Approval* study and the *Hemodynamic-GUIDEd Management of Heart Failure (GUIDE-HF)* study[2-3]. All inclusion criteria should be met and no exclusion criteria should be present before consideration for prior approval.

Evaluation of Clinical Benefits and Potential Harms

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of wireless pulmonary artery pressure monitoring using the CardioMEMS system. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, adverse reactions, and infection.

The potential clinical harms of using these criteria may include:

- Adverse effects from delayed or denied treatment: Delays or denials in the use of CardioMEMS can lead to increased symptoms and complications such as recurrent hospitalizations, especially in patients with NYHA Class III heart failure. The 2022 AHA/ACC/HFSA guideline for the management of heart failure highlights the importance of timely intervention to prevent adverse outcomes in patients with significant heart failure.[1]
- Risks with inappropriate surgical procedures: This includes infection, bleeding, injury to neurovascular structures, anesthetic risk, and the need for repeat or additional procedures due to complications. The CardioMEMS HF System post-approval study underscores the importance of appropriate patient selection to minimize surgical risks and enhance the benefits of wireless pulmonary artery pressure monitoring.[2]
- Increased healthcare costs and complications: This includes inappropriate use of emergency services and additional treatments. Proper use of CardioMEMS criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. The Hemodynamic-GUIDEd management of heart failure (GUIDE-HF) study supports the necessity of appropriate diagnostic and treatment procedures to prevent unnecessary healthcare utilization.[3]

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to CardioMEMS for the patients selected for best outcomes. The goal is to provide accurate diagnostics and effective treatment planning, reducing the risk of complications and improving overall patient health. Heidenreich et al. noted the diagnostic accuracy of imaging and monitoring procedures in managing patients with heart failure.[1]
- Enhanced diagnostic accuracy: This is crucial for complex cardiovascular conditions where traditional diagnostic methods may pose additional risks. Advanced imaging and monitoring techniques offer the advantage of detailed vascular assessment, aiding in decision-making regarding interventions.[4]

Reduction in complications and adverse effects: Proper use of CardioMEMS criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. The guidelines on the use of wireless pulmonary artery pressure monitoring emphasize the importance of accurate diagnostics in preventing complications.[1]

- Enhanced overall patient satisfaction: Ensuring that CardioMEMS procedures are used appropriately leads to better patient outcomes and higher satisfaction rates due to effective treatment and reduced complications. The ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure support the necessity of appropriate use criteria to minimize healthcare costs and prevent complications.[1]

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

➔ **Wireless pulmonary artery pressure monitoring (CardioMEMS)** is considered appropriate if **ALL** of the following are **TRUE**[1-3]:

- NYHA class III HF; **AND**
- Heart failure was diagnosed more than three (3) months ago; **AND**
- Age greater than or equal to 18 years; **AND**
- **ANY** of the following:
  - History of a heart failure hospitalization in the past year; **OR**
  - Elevated brain natriuretic peptide (BNP or NT-proBNP) levels within the last 30 days are defined as **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); **Note:** For patients over BMI of 25, weight adjustments for BNP values must be made. Weight-adjusted BNP table can be found here: NT-proBNP and BNP Thresholds According to Ejection Fraction and BMI[4]; **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) **Note**: For patients over BMI of 25, weight adjustments for BNP values must be made. Weight-adjusted BNP table can be found here: NT-proBNP and BNP Thresholds According to Ejection Fraction and BMI[4]; **AND**

- **ANY** of the following:
    - Optimal cardiac resynchronization device (CRT) implanted greater than or equal to 3 months (See link for: Optimal guidelines)[1]; **OR**
    - Patient not a candidate for cardiac resynchronization therapy; **AND**
- **ANY** of the following:
    - BMI greater than 35 kg/m2 chest circumference must measure less than 65 inches; **OR**
    - BMI less than or equal to 35; **AND**
- **ANY** of the following based on guideline-directed medical therapy (GDMT) per the 2022 ACC/AHA/HFSA CHF guidelines[1]:
    - For EF less than or equal to 40% on BB for three (3) months, on diuretics, SGLT2i, MRA, ACE-I/ARB/ARNI for more than one month or none if intolerant (reference section **7.3. Pharmacological Treatment for HFrEF**); **OR**
    - For EF 41-49% on diuretic, SGLT2i, MRA, ARNI/ACE-I/ARB, BB for more than one month or none if intolerant (reference section **7.6.1. HF With Mildly Reduced Ejection Fraction (HFmrEF)**); **OR**
    - For EF greater than or equal to 50% on diuretic, SGLT2i, MRA, ARNI/ACEi/ARB for more than one month or none if intolerant (reference section **7.7.1. HF With Preserved Ejection Fraction**).

*Thresholds for NT-proBNP and BNP (for both LVEF less than or equal to 40% and LVEF greater than 40%) will be corrected for body mass index (BMI) using a 4% reduction per BMI unit over 25 kg/m2

Non-Indications

- ➔ **Wireless pulmonary artery pressure monitoring (CardioMEMS)** is NOT considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ An active, ongoing infection, defined as being febrile, an elevated white blood cell count, on intravenous antibiotics, or positive cultures (blood, sputum, or urine); **OR**
  - ◆ History of current or recurrent (greater than 1) pulmonary emboli or deep vein thrombosis; **OR**
  - ◆ Inability to tolerate a right heart catheterization; **OR**
  - ◆ A major cardiovascular event (e.g., unstable angina, PCI, myocardial infarction, open heart surgery, stroke, etc.) within the previous 3 months; **OR**
  - ◆ Glomerular filtration rate (GFR) less than 25 ml/min (obtained within 2 weeks of implant) who are non-responsive to diuretic therapy or who are on chronic renal dialysis; **OR**
  - ◆ Known coagulation disorders; **OR**
  - ◆ Patient with an inability to take dual antiplatelet or anticoagulants for one 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 six (6) months; **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**
  - ◆ Congenital heart disease that would prevent implantation of the CardioMEMS PA sensor; **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**

- Implanted with cardiac resynchronization therapy (CRT)-pacemaker (CRT-P) or CRT-defibrillator (CRT-D) for less than 90 days; **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 CardioMEMSTM 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: S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

In 2022, the American Heart Association, American College of Cardiology, and Heart Failure Society of America published a guideline on heart failure. Heidenreich et al. (2022) gave an uncertain value (COR-2b, LOE B-R) recommendation for implanted wireless pulmonary artery pressure monitoring. This recommendation is extended to selected patients with NYHA class III HF with a hospitalization within the last year or elevated natriuretic peptide levels on guideline-directed medical therapy. The authors cited the unblinded CHAMPION trial, with a 28% reduction of HF-related hospitalizations after six months post-device implant. Additional data regarding the economic value and cost-effectiveness of the device are expected.[1-2]

Abbott Medical Devices sponsored the *CardioMEMS HF System Post Approval Study*, completed in February 2020. This condition of approval prospective observational cohort study included 1200 enrollees with NYHA class III heart failure. Study results have not yet been posted on the Clinical Trials website.[4]

An additional clinical trial sponsored by Abbott Medical Devices was the *Hemodynamic-GUIDEd Management of Heart Failure (GUIDE-HF)* trial from 2018 to 2023 with an enrollment of 2358 individuals. There were a number of inclusion criteria, including NYHA class II or higher, left ventricular ejection fraction levels greater than or equal to 18 years of age, chest circumference, etc. Exclusion criteria included unrepaired severe valvular disease, pregnancy, history of recurrent pulmonary emboli, end-stage renal disease, mechanical heart valves, etc. The study included both a single arm and a randomized arm. The study results have not currently been posted.[3]

References

1. American College of Cardiology (ACC)/American Heart Association (AHA) Joint Committee on Clinical Practice Guidelines. 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. https://www.ahajournals.org. Published May 2022.
2. CardioMEMS HF System post approval study. ClinicalTrials.gov identifier: NCT02279888. Updated February 3, 2020. Accessed March 6, 2024. https://clinicaltrials.gov/study/NCT02279888#contacts-and-locations.
3. Hemodynamic-GUIDEd management of heart failure (GUIDE-HF). ClinicalTrials.gov identifier: NCT03387813. Updated August 9, 2023. Accessed March 6, 2024. https://clinicaltrials.gov/study/NCT03387813.
4. Abbott Laboratories. CardioMEMS HF System. Patient candidate considerations. 2022. https://www.cardiovascular.abbott/content/dam/cv/cardiovascular/hcp/products/heart-failure/cardiomems/documents/hf-cardiomems-patient-candidate-considerations-tool.pdf.

Clinical Guideline Revision History/Information

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