Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS) - Single Service

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: March 22, 2024

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS) (Single Service)

Literature review current through: 3/13/2024
Document last updated: 3/22/2024
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS)

General Guidelines

- **Units, Frequency, & Duration:** Requires mandatory physician review.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** The CardioMEMS device is implanted in a pulmonary artery branch to help manage heart failure remotely. The purpose of this device is to allow earlier intervention to reduce CHF exacerbations and hospitalizations. This guideline is based on the American College of Cardiology (ACC)/American Heart Association (AHA) Joint Committee on Clinical Practice Guidelines. [1]

  In selected adult patients with NYHA class III HF and a history of HF hospitalization in the past year or elevated natriuretic peptide levels, on maximally tolerated stable doses of GDMT with optimal device therapy, the usefulness of wireless monitoring of PA pressure by an implanted hemodynamic monitor to reduce the risk of subsequent HF hospitalizations is uncertain. Class (Strength) of Recommendation (COR): Class 2b (weak). Level (Quality) of Evidence (LOE): B-R (Moderate quality from 1 or more RCTs). The guideline also included a value statement which says: Uncertain Value (B-NR) - 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 their recommendation, it is also felt to be reasonable and necessary to incorporate the Inclusion/Exclusion criteria from two studies listed by the NIH website ClinicalTrials.gov that were sponsored by Abbott Medical Devices, the manufacturer of the CardioMEMS device, including the CardioMEMS HF System Post Approval Study (https://clinicaltrials.gov/ct2/show/NCT02279888?term=cardiomems&draw=2&rank=4)[2] and the Hemodynamic-GUIDEd Management of Heart Failure (GUIDE-HF) study (https://clinicaltrials.gov/ct2/show/NCT03387813?term=cardiomems&draw=7&rank=12)[3]. All the Inclusion Criteria should be met, and no Exclusion Criteria should be present before consideration for prior approval.
- **Exclusions:** None

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 three (3) months (See link for: Optimal guidelines); **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:

- 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 ≤ 40% and LVEF > 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

Medical Evidence

In the 2022 American Heart Association/American College of Cardiology/Heart Failure Society of America Heart Failure Guideline, 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 economic value and cost-effectiveness with use of the device are expected in the future.[1]

Abbott Medical Devices sponsored the CardioMEMS HF System Post Approval Study, completed in February of 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.[2]

An additional clinical trial sponsored by Abbott Medical Devices was the Hemodynamic-GUIDEd Management of Heart Failure (GUIDE-HF) trial taking place 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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