Coverage with Evidence Development Approval Letter
CardioMEMS™ HF System

The following document may be submitted to Medicare or Medicare Advantage Plans for:

- Prior authorization
- Prior authorization appeals, or
- Post-service denials, when appropriate.

Abbott has a team of skilled specialists to answer your CardioMEMS reimbursement questions. Please reach out to them directly by emailing heartfailureeconomics@abbott.com.

Do not include this instruction page in your submission.

Important Safety Information

CardioMEMS™ HF System

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

CardioMEMS™ HF System Indications and Usage: The CardioMEMS HF System is indicated for wirelessly measuring and monitoring pulmonary artery pressure and heart rate in NYHA Class II or III heart failure patients who either have been hospitalized for heart failure in the previous year and/or have elevated natriuretic peptides. The hemodynamic data are used by physicians for heart failure management with the goal of controlling pulmonary artery pressures and reducing heart failure hospitalizations.

Contraindications: The CardioMEMS™ HF System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

CardioMEMS™ HF System Potential Adverse Events: Potential adverse events associated with the implantation procedure include, but are not limited to, the following: air embolism, allergic reaction, infection, delayed wound healing, arrhythmias, bleeding, hemoptysis, hematoma, nausea, cerebrovascular accident, thrombus, cardiovascular injury, myocardial infarction, death, embolization, thermal burn, cardiac perforation, pneumothorax, thoracic duct injury and hemothorax.

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality
Coverage and Analysis Group

James Hasegawa
Sr. Director, Health Economics & Reimbursement
Vascular and Heart Failure
Abbott
3200 Lakeside Drive, Santa Clara, CA 95054

February 7, 2025

Dear Mr. Hasegawa:

Thank you for your study protocol submission and request for coverage under Coverage with Evidence Development (CED) for Implantable Pulmonary Artery Pressure Sensors (IPAPS) for Heart Failure Management. After careful review by our multidisciplinary team of your proposed CED study, "CardioMEMS HF System Coverage with Evidence Development Study" (NCT06779552), the Centers for Medicare & Medicaid Services (CMS) has determined that it fulfills the requirements of the IPAPS National Coverage Determination (NCD).

You must notify us of any substantial changes to the protocol, such as sample size revisions or modifications of the analysis methodology. The ClinicalTrials.gov website must be kept up to date. Please remember that the results of your research should be published in peer-reviewed journals. We may use these results in future coverage decisions.

To facilitate the Medicare payment process, you should provide your study sites with appropriate billing instructions. These include entering the National Clinical Trial (NCT) identifier from the ClinicalTrials.gov website on Medicare claims along with the other codes and modifiers provided in the NCD claims processing instructions.

We appreciate your commitment to research and evidentiary development to improve care for Medicare beneficiaries. Please direct any questions to Linda Gousis at Linda.Gousis@cms.hhs.gov.

Sincerely,

Tamara S. Jensen -S

Digitally signed by Tamara S. Jensen -S
Date: 2025.02.07 14:21:36 -05'00'

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group