Clinical Policy: Implantable Wireless Pulmonary Artery Pressure Monitoring

Reference Number: MC.CP.MP.160 Coding Implications
Date of Last Revision: 02/25 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Various cardiac hemodynamic monitoring techniques have been investigated as a means to remotely guide outpatient heart failure (HF) therapy, including implantable wireless pulmonary artery (PA) pressure monitoring (e.g., CardioMEMS®).[1] The implanted device measures and monitors daily PA pressure. The data is used by physicians for heart failure management with the goal of reducing heart failure hospitalizations.[2] Currently, only CardioMEMS has FDA approval, and other devices (e.g. Chronicle®, ImPressure®) that monitor cardiac output through measurements of pressure changes in the pulmonary artery or right ventricular outflow tract are not supported by current evidence.[3]

In February 2018, CMS approved the IDE study, Hemodynamic-GUIDEd Management of Heart Failure (NCT03387813). The balance of benefits and risks of harm have been determined by CMS to be favorable only if the member is enrolled in the Medicare-approved Category B IDE study.[18]

Additionally, in October 2024, CMS issued a National Coverage Analysis (NCA) with a Proposed Decision Memo proposing coverage for implantable pulmonary artery pressure sensor(s) (IIPAPS) for HF management under coverage with evidence (CED)[19].

Note: For criteria applicable to non-Medicare plans, please see CP.MP.160 Implantable Wireless Pulmonary Artery Pressure Monitoring.

Policy/Criteria

I. It is the policy of Medicare health plans affiliated with Centene Corporation® that implantable wireless pulmonary artery (PA) pressure monitoring (e.g., CardioMEMS®) is **medically necessary** when meeting all the following:

A. Member is enrolled in the CMS-approved coverage with evidence development (CED) study;
B. Diagnosis of chronic HF of at least three months duration and in New York Heart Association (NYHA) functional Class II or III within the past 30 days, prior to PAPS implantation, regardless of left ventricular ejection fraction (LVEF);
C. History of HF hospitalization or urgent HF visit (emergency room or other outpatient visit requiring intravenous diuretic therapy) within the past 12 months, or elevated natriuretic peptides within the past 30 days;
D. On maximally tolerated guideline-directed medical therapy (GDMT) for at least three months prior to PAPS implantation;
E. Evaluated for, and received if appropriate, an implantable cardioverter defibrillator (ICD), cardiac resynchronization therapy (CRT)-Pacemaker (CRT-P), or CRT-Defibrillator (CRT-D). Implantation of the device must occur at least three months prior to PAPS implantation;

F. No major cardiovascular event (e.g., unstable angina, myocardial infarction, percutaneous coronary intervention, open heart surgery, or stroke) within the last three months prior to PAPS implantation;
G. Possessing adequate technology to ensure reliable remote connectivity to the IPAPS device;
H. Must not have PAPS implantation occur during a hospital admission for an acute HF episode[19].

Background

Heart failure (HF) is one of the most common causes of hospitalization and readmission.[2,4] According to the Centers for Disease Control, an estimated 5.7 million adults in the United States have HF. HF is a complex clinical syndrome that results from any structural or functional impairment of ventricular filling or ejection of blood.[5] The primary manifestations of HF are dyspnea and fatigue, which may limit exercise tolerance, and fluid retention, which may lead to pulmonary and/or splanchnic congestion and/or peripheral edema.[6-7] The classification system most commonly used to quantify the degree of functional limitation caused by HF is the New York Heart Association Functional Classification system (NYHA).[7] This system assigns patients to one of four functional classes, depending on the degree of effort needed to elicit symptoms.[7]

Accurate monitoring of HF patients for exacerbations is important in an effort to reduce recurrent hospitalizations and associated complications.[5,8] Strategies to reduce hospitalizations in patients with HF include optimizing evidence-based drug and device therapies, addressing causes of HF, treating comorbidities, and improving management of care.[9] It is proposed that monitoring changes in pulmonary artery (PA) pressure (i.e., pressure the heart must exert to pump blood from the heart through the arteries of the lungs) may provide a way to monitor changes in HF resulting in improved HF management.[2]

The CardioMEMS HF System (St. Jude Medical) is Food and Drug Administration (FDA) approved for wirelessly measuring and monitoring pulmonary artery pressure and heart rate in NYHA Class III heart failure patients who have been hospitalized for heart failure in the previous year.[2-3] The hemodynamic data is used by physicians for heart failure management with the goal of reducing hospitalizations related to heart failure.[8]

The CardioMEMS HF system provides daily PA pressure measurements, including systolic, diastolic, and mean PA pressures.[1] The system includes a dime sized PA sensor that is permanently implanted in the pulmonary artery via fluoroscopy-guided right-heart catheterization, a transvenous catheter delivery system, a patient home monitoring electronic system, and a secure internet-accessible database that allows clinicians to access patient data.[8,10] The home monitoring components include a pillow containing the antenna to capture the sensor reading, a bedside monitoring unit to which the pillow is connected via a cable, and a remote button. Each reading captures 18 seconds of pressure data that is wirelessly transmitted to a secure database. The patient's physician can use this information to optimize medical management and potentially reduce the need for HF-related hospitalizations.[2] The CardioMEMS HF System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

Sponsored by the manufacturer, the largest randomized single-blind trial, the Champion Trial (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes In NYHA Class III Heart Failure Patients), reported that transmission of PA pressure data from the device reduced HF-related hospitalizations at six months (31% versus 44%).[2,11-12] A later analysis reported sustained reduction in HF-related hospitalization in the device-guided management group compared with the control at 18-month average follow-up (46% versus 68%).[14] During a subsequent open access period with a mean duration of 13 months, pulmonary artery pressure information was made available to guide therapy in the former control group. The rate of admission was reduced compared with that in the control group during the randomized access period (36% versus 68%). The rate of device-related or system-related complications was 1%, which was also the rate of procedure-related adverse events. However, concerns were raised by the FDA regarding potential influence of the sponsor during the randomization period in this study.[12,15-16] In addition, study limitations include the lack of power to perform mortality analyses, lack of baseline quality-of-life data, and potential for sponsor to influence patient management.[15]

At this time, the current evidence is insufficient to support the use of ambulatory cardiac hemodynamic monitoring using an implantable pulmonary artery pressure measurement device in individuals with heart failure in an outpatient setting. Data on long-term health benefits (including survival), safety issues, and quality of life are lacking. In addition, there is a lack of evidence on the accuracy and clinical utility of the device for use in other NYHA functional classifications.

American College of Cardiology Foundation
The American College of Cardiology Foundation/American Heart Association (ACCF/AHA) 2022 Guideline for the Management of Heart Failure in Adults recommend monitoring with a pulmonary artery catheter in patients with respiratory distress or impaired systemic perfusion when clinical assessment is inadequate.[6] In addition, invasive hemodynamic monitoring can be beneficial in certain patients with acute HF with persistent symptoms and/or when hemodynamics are uncertain.[6]

The ACCF/AHA guidelines do not specifically address outpatient wireless implantable pulmonary artery pressure monitoring; however, they note, “There has been no established role for routine or periodic invasive hemodynamic measurements in the management of HF. Most drugs used for the treatment of HF are prescribed on the basis of their ability to improve symptoms or survival rather than their effect on hemodynamic variables. The initial and target doses of these drugs are generally selected on the basis of controlled trial experience rather than changes produced in cardiac output or pulmonary capillary wedge pressure.”[6]

European Society of Cardiology
According to the European Society of Cardiology (ESC), monitoring of pulmonary artery pressures using a wireless implantable hemodynamic monitoring system (CardioMEMS) may be considered in symptomatic patients with HF with previous HF hospitalization in order to reduce the risk of recurrent HF hospitalization.[17] This recommendation from ESC is considered a Class IIB, level B recommendation (i.e., usefulness/efficacy is less well established by

evidence/opinion, and data has been derived from a single randomized clinical trial or large non-randomized studies).[17]

National Institute for Health and Care Excellence (NICE)
Current evidence on the safety and efficacy of the insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure is limited in both quality and quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.[17]

Centers for Medicare and Medicaid Services (CMS)
In October 2024, CMS issued a NCA proposing coverage for IPAPS for members enrolled in a CMS-approved coverage with evidence development (CED) study. Physician-related criteria include that the managing providers must be cardiologists with experience in advanced HF management and must have advanced training and experience in pulmonary arterial catheterization and intervention. CED study criteria includes that the IPAPS items and services are furnished in the context of a CMS-approved CED study under the CMS-approved CED protocols[19].

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2024, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	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
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

HCPCS Codes	Description
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed.	08/23	08/23
Annual review. Description updated with no impact to criteria. References reviewed and updated. Reviewed by external specialist.	04/24	04/24
Annual review. Added medically necessary indications to criteria I. Description and Backgroup updated with no impact on criteria. References reviewed and updated.	02/25	02/25

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.