

Clinical Policy: Implantable Wireless Pulmonary Artery Pressure Monitoring

Reference Number: MC.CP.MP.160

Date of Last Revision: 04/24

[Coding Implications](#)

[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

Because evidence is still emerging, ongoing trial data does not yet support that the benefits of this monitor outweigh the risks at this time. Additional large, well-designed comparative studies involving long-term assessments beyond one year post-implantation are needed to evaluate the long-term safety of this device.¹⁵

Additionally, 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

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 the long-term safety and effectiveness of implantable wireless pulmonary artery pressure monitoring has not been proven for any indication, including the management of heart failure.

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

CLINICAL POLICY

Implantable Wireless Pulmonary Artery Pressure Monitoring

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

CLINICAL POLICY

Implantable Wireless Pulmonary Artery Pressure Monitoring

(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

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 2023, 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.

Implantable Wireless Pulmonary Artery Pressure Monitoring

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

References

1. Ayyadurai P, Alkhawam H, Saad M, et al. An update on the CardioMEMS pulmonary artery pressure sensor. *Ther Adv Cardiovasc Dis*. 2019;13:1753944719826826. doi:10.1177/1753944719826826
2. Givertz MM, Stevenson LW, Costanzo MR, et al. Pulmonary Artery Pressure-Guided Management of Patients With Heart Failure and Reduced Ejection Fraction. *J Am Coll Cardiol*. 2017;70(15):1875 to 1886. doi:10.1016/j.jacc.2017.08.010
3. U.S Department of Health & Human Services. Premarket approval (PMA) CardioMems HF Pressure Measurement System. Silver Spring, MD: U.S. Food and Drug Administration; 2014.
4. Adamson PB, Abraham WT, Bourge RC, et al. Wireless pulmonary artery pressure monitoring guides management to reduce decompensation in heart failure with preserved ejection fraction. *Circ Heart Fail*. 2014;7(6):935 to 944. doi:10.1161/CIRCHEARTFAILURE.113.001229
5. Jermyn R, Alam A, Kvasic J, Saeed O, Jorde U. Hemodynamic-guided heart-failure management using a wireless implantable sensor: Infrastructure, methods, and results in a community heart failure disease-management program. *Clin Cardiol*. 2017;40(3):170 to 176. doi:10.1002/clc.22643
6. 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 [published correction appears in *Circulation*. 2022 May 3;145(18):e1033] [published correction appears in *Circulation*. 2022 Sep 27;146(13):e185]. *Circulation*. 2022;145(18):e895-e1032. doi:10.1161/CIR.0000000000001063

CLINICAL POLICY**Implantable Wireless Pulmonary Artery Pressure Monitoring**

7. Coluci WS. Determining the etiology and severity of heart failure or cardiomyopathy. UpToDate. www.uptodate.com. Published February 17, 2022. Accessed March 6, 2024.
8. National Institute for Health and Care Excellence. Percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure. Interventional procedures guidance [IPG711]. <https://www.nice.org.uk/guidance/IPG711>. Published November 24, 2021. Accessed March 6, 2024.
9. Gheorghiade M, Braunwald E. Hospitalizations for heart failure in the United States--a sign of hope [published correction appears in JAMA. 2012 Feb 8;307(6):563]. *JAMA*. 2011;306(15):1705 to 1706. doi:10.1001/jama.2011.1510
10. Abraham WT, Adamson PB, Hasan A, et al. Safety and accuracy of a wireless pulmonary artery pressure monitoring system in patients with heart failure. *Am Heart J*. 2011;161(3):558 to 566. doi:10.1016/j.ahj.2010.10.041
11. Abraham WT, Adamson PB, Bourge RC, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial [published correction appears in Lancet. 2012 Feb 4;379(9814):412]. *Lancet*. 2011;377(9766):658 to 666. doi:10.1016/S0140-6736(11)60101-3
12. Coluci WS. Investigational therapies for management of heart failure. UpToDate. www.uptodate.com. Published June 29, 2022. Accessed March 6, 2024.
13. Adamson PB, Abraham WT, Stevenson LW, et al. Pulmonary Artery Pressure-Guided Heart Failure Management Reduces 30-Day Readmissions. *Circ Heart Fail*. 2016;9(6):e002600. doi:10.1161/CIRCHEARTFAILURE.115.002600
14. Abraham WT, Stevenson LW, Bourge RC, et al. Sustained efficacy of pulmonary artery pressure to guide adjustment of chronic heart failure therapy: complete follow-up results from the CHAMPION randomised trial. *Lancet*. 2016;387(10017):453 to 461. doi:10.1016/S0140-6736(15)00723-0
15. Evidence Analysis Research Brief. CardioMEMS implantable hemodynamic monitor (Abbott) for managing patients with heart failure. Hayes. www.hayesinc.com. Published July 28, 2022. Accessed March 6, 2024.
16. Loh JP, Barbash IM, Waksman R. Overview of the 2011 Food and Drug Administration Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting on the CardioMEMS Champion Heart Failure Monitoring System. *J Am Coll Cardiol*. 2013;61(15):1571 to 1576. doi:10.1016/j.jacc.2012.08.1035
17. Ponikowski P, Voors AA, Anker SD, et al. 2016 ESC Guidelines for the Diagnosis and Treatment of Acute and Chronic Heart Failure [published correction appears in Rev Esp Cardiol (Engl Ed). 2017 Apr;70(4):309 to 310]. *Rev Esp Cardiol (Engl Ed)*. 2016;69(12):1167. doi:10.1016/j.rec.2016.11.005
18. Abbott Medical Devices. Hemodynamic-GUIDEd Management of Heart Failure. clinicaltrials.gov. Published August 8, 2023. Accessed March 13, 2024. <https://clinicaltrials.gov/study/NCT03387813#study-overview>

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

CLINICAL POLICY

Implantable Wireless Pulmonary Artery Pressure Monitoring

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

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.

CLINICAL POLICY

Implantable Wireless Pulmonary Artery Pressure Monitoring



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.

©2018 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.