

Clinical Policy: Implantable Wireless Pulmonary Artery Pressure Monitoring

Reference Number: CP.MP.160

Date of Last Revision: 02/22

[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 pressure monitoring (e.g. CardioMEMS®). The implanted device measures and monitors daily pulmonary artery (PA) pressure. The data is used by physicians for heart failure management with the goal of reducing heart failure hospitalizations. Although other devices that monitor cardiac output through measurements of pressure changes in the pulmonary artery or right ventricular outflow tract are under investigation (e.g., Chronicle®, ImPressure®), currently, only CardioMEMS has FDA approval.

Policy/Criteria

- I. It is the policy of 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.

Note: As long as CardioMEMS is classified as Investigational Device Exemption Category B (IDE No. G170258), CMS requires enrollment in a registered clinical trial for it to be considered medically necessary for Medicare members/enrollees.^{18, 19}

Background

HF is one of the most common causes of hospitalization and readmission. According to the CDC, about 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. The cardinal 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.¹ The classification system most commonly used to quantify the degree of functional limitation imposed by HF is the New York Heart Association Functional Classification system (NYHA). This system assigns patients to one of four functional classes, depending on the degree of effort needed to elicit symptoms.²

Accurate monitoring of HF patients for exacerbations is important in an effort to reduce recurrent hospitalizations and its associated complications. Strategies to reduce hospitalizations in patients with HF include optimization of evidence-based drug and device therapies, addressing causes of HF, treating comorbidities, and improved management of care.³ It is proposed that monitoring changes in pulmonary artery 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.

The CardioMEMS HF System (St. Jude Medical) is Food and Drug Administration (FDA) approved for wirelessly measuring and monitoring pulmonary artery (PA) pressure and heart rate

CLINICAL POLICY

Implantable Wireless Pulmonary Artery Pressure Monitoring

in NYHA Class III heart failure patients who have been hospitalized for heart failure in the previous year. The hemodynamic data are used by physicians for heart failure management and with the goal of reducing heart failure hospitalizations.

The system provides daily PA pressure measurements including systolic, diastolic, and mean PA pressures. 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. 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. The CardioMEMS HF System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

The largest randomized single-blind trial, sponsored by the manufacturer, the Champion Trial (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes In NYHA Class III Heart Failure Patients), reported that transmission of pulmonary artery pressure data from the device reduced HF-related hospitalizations at six months (31 versus 44 percent).^{4,5} 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 percent).⁶ During a subsequent open access period (mean duration 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 percent). The rate of device- or system-related complications was 1 percent and the rate of procedure-related adverse events was 1 percent. However, concerns were raised by the FDA regarding potential influence of the sponsor during the randomization period in this study.^{7,8} 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.⁷

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) 2013 Guidelines for the Diagnosis and 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. In addition, invasive hemodynamic monitoring can be useful for carefully selected patients with acute HF with persistent symptoms and/or when hemodynamics are uncertain.

CLINICAL POLICY

Implantable Wireless Pulmonary Artery Pressure Monitoring

The ACC/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.”

European Society of Cardiology

Monitoring of pulmonary artery pressures using a wireless implantable haemodynamic 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. (Class IIb, level B recommendation (i.e., usefulness/efficacy is less well established by evidence/opinion. Data derived from a single randomized clinical trial or large non-randomized studies).¹⁶

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 2020, 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

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

+ Indicates a code requiring an additional character

ICD-10-CM Code	Description
I50.1-I50.9	Heart Failure

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed	04/18	04/18
Updated background information. References and codes reviewed and updated. Specialist reviewed.	04/19	04/19
Revised policy statement from “not medically necessary” to “investigational.” References reviewed and updated.	03/20	04/20
“Experimental/investigational” verbiage replaced in policy statement with descriptive language. All instances of “member” changed to member/enrollee. References reviewed and updated.	03/21	04/21
Added note regarding CMS guidance on IDE B devices and clinical trials. Updated references. Changed “Review Date” in header to “Date of Last Revision” and “Date” in revision log header to “Revision Date.”	02/22	02/22

References

1. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. 2013 Oct 15;62(16):e147-239. doi: 10.1016/j.jacc.2013.05.019. Epub 2013 Jun 5. Available at: <https://www.ahajournals.org/doi/10.1161/cir.0b013e31829e8776> Accessed March 24, 2021.
2. Colluci WS. Determining the etiology and severity of heart failure or cardiomyopathy. In: UpToDate, Gottlieb SS(Ed), UpToDate, Waltham, MA, 2017. Accessed March 24, 2021.
3. Gheorghide M, Braunwald E. Hospitalizations for heart failure in the United States--a sign of hope. *JAMA* 2011; 306:1705.
4. Abraham WT, Adamson PB, Bourge RC, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. *Lancet* 2011; 377:658.
5. Colluci WS. Investigational and emerging strategies for management of heart failure. In: UpToDate, Gottlieb SS (Ed), UpToDate, Waltham, MA. Accessed March 24, 2021.
6. 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; 387:453.
7. Hayes Health Technology Brief. CardioMEMS Implantable Hemodynamic Monitor (Abbott) for Managing Patients with Heart Failure. Jan 2019. Accessed March 24, 2021.
8. 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; 61:1571.

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

9. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. *J Card Fail*. 2017 Aug;23(8):628-651. doi: 10.1016/j.cardfail.2017.04.014. Epub 2017 Apr 28
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 Mar;161(3):558-66. doi: 10.1016/j.ahj.2010.10.041. Epub 2011 Jan 31.
11. Jermyn R, Alam A, Kvasic J, et al. 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 Mar;40(3):170-176. doi: 10.1002/clc.22643. Epub 2016 Nov 23.
12. Adamson PB, Abraham WT, Stevenson LW, et al. Pulmonary Artery Pressure-Guided Heart Failure Management Reduces 30-Day Readmissions. *Circ Heart Fail*. 2016 Jun;9(6)
13. 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 Nov;7(6):935-44.
14. 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 Oct 10;70(15):1875-1886
15. U.S.FDA. CardioMems HF Pressure Measurement System. Premarket approval. 5/28/14. Available at:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100045>.
16. Ponikowski P, Voors AA, Anker SD, et al. 2016 ESC Guidelines for the Diagnosis and Treatment of Acute and Chronic Heart Failure. *Rev Esp Cardiol (Engl Ed)*. 2016 Dec; 69(12):1167. doi: 10.1016/j.rec.2016.11.005
17. National Institute for Health and Care Excellence. Insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure. Interventional procedures guidance [IPG463] Published date: August 2013.
18. Centers for Medicare and Medicare Services. Medicare Managed Care Manual: Payment for Investigational Device Exemption (IDE) Studies. Chapter 4, §10.7.2. CMS.gov. [100-16 | CMS](#). Accessed February 7, 2022.
19. Centers for Medicare and Medicare Services. Approved IDE Studies: Hemodynamic-GUIDEd Management of Heart Failure. CMS.gov.
<https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies-Items/G170258-NCT03387813>. Accessed February 7, 2022.

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

CLINICAL POLICY

Implantable Wireless Pulmonary Artery Pressure Monitoring

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.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable

CLINICAL POLICY

Implantable Wireless Pulmonary Artery Pressure Monitoring

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.