Clinical Policy: Implantable Wireless Pulmonary Artery Pressure Monitoring

Reference Number: LA.CP.MP.160
Date of Last Revision: 7/22

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 (PA) pressure monitoring (e.g. CardioMEMS®). 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]

Policy/Criteria

I. It is the policy of Louisiana Healthcare Connections that the long-term safety and effectiveness of implantable wireless pulmonary artery pressure monitoring has not been proven for any indication, including 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]

Accurate monitoring of HF patients for exacerbations is important in an effort to reduce recurrent hospitalizations and its associated complications.[5,8] 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.[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 heart failure hospitalizations.[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- 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) 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 beneficial in certain patients with acute HF with persistent symptoms and/or when hemodynamics are uncertain. [6]

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" [6(p167)]

European Society of Cardiology
According to the European Society of Cardiology (ESC), 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. [17] This recommendation from ESC is considered a Class IIb, level B recommendation (i.e., usefulness/efficacy is less well established by evidence/opinion anddata 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 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 and may not support medical necessity. Inclusion or exclusion of any codes does not guarantee coverage and may not support medical necessity. 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
Converted corporate to local policy.	08/15/2020	
"Experimental/investigational" verbiage replaced in policy statement with descriptive language. References reviewed and updated.	5/2021	
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." Added "and may not support medical necessity in the coded implications section	5/22	
Description and background updated with no impact on criteria. References reviewed and updated. Added "and my not support medical necessity" to coding implications. Specialist reviewed.	7/22	9/26/22

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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. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing

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