Clinical Policy: Implantable Wireless Pulmonary Artery Pressure Monitoring

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Effective Date: 06/18
Last Review Date: 10/19

Coding Implications
Revision Log

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 PA Health & Wellness® (PHW) that *implantable wireless pulmonary artery pressure monitoring* is **not medically necessary** for all indications, including management of heart failure.

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 that is 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 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 are 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.

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"

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 2018, 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
93799	Unlisted cardiovascular service or procedure

HCPCS Codes	Description
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components
C9741	Right heart catheterization with implantation of wireless pressure sensor in the pulmonary artery, including any type of measurement, angiography, imaging supervision, interpretation, and report

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	Date	Approval Date
Policy developed	05/18	
Updated background information. References and codes reviewed and updated. Specialist reviewed.	10/19	

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