

MEDICAL POLICY



SUBJECT: IMPLANTABLE CARDIAC HEMODYNAMIC MONITORING FOR HEART FAILURE	EFFECTIVE DATE: 08/20/15 REVISED DATE: 10/20/16, 09/21/17, 09/20/18
POLICY NUMBER: 7.01.91 CATEGORY: Technology Assessment	PAGE: 1 OF 4
<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

Based upon our criteria and assessment of peer-reviewed literature, cardiac hemodynamic monitoring for the management of heart failure in the outpatient setting utilizing implantable direct pressure monitoring of the pulmonary artery (e.g., CardioMEMS HF system) has not been proven to be medically effective and is therefore considered **investigational**.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Patients with chronic heart failure are at risk of developing acute decompensated heart failure, often requiring hospital admission. Patients with a history of acute decompensation have the additional risk of future episodes of decompensation, and death. Reasons for the transition from a stable, chronic state to an acute, decompensated state include disease progression, as well as acute events such as coronary ischemia and dysrhythmias. While precipitating factors are frequently not identified, the most common preventable cause is noncompliance with medication and dietary regimens. Strategies for reducing decompensation, and thus the need for hospitalization, are aimed at early identification of patients at risk for imminent decompensation.

Several novel approaches have been investigated as techniques to measure cardiac hemodynamic variables in an outpatient setting. One proposed technique involves the implantation of a wireless pressure sensor in the pulmonary artery (PA) during a right heart catheterization procedure to measure pulmonary artery pressure and heart rate in individuals with heart failure. Pressure readings are transmitted wirelessly to an external monitor and database where information may be used by clinicians and clinical staff to guide treatment decisions, and monitor individuals from their home or other non-clinical setting. It is postulated that these PA pressure readings can supplement the patient's characteristic signs and symptoms and improve the clinician's ability to intervene early to prevent acute decompensation.

RATIONALE:

In May 2014, FDA approved the CardioMEMS™ Champion Heart Failure Monitoring System (CardioMEMS, now St. Jude Medical, St. Paul, MN) through the PMA process and is indicated for measuring pulmonary artery pressure and heart rate in individuals who have undergone hospitalization for New York Heart Association (NYHA) Class III heart failure in the past year. This device consists of an implantable PA sensor, which is implanted in the distal PA, a transvenous delivery system, and an electronic sensor that processes signals from the implantable PA sensor and transmits PA pressure measurements to a secure database.

Several additional devices that monitor cardiac output through measurements of pressure changes in the PA or right ventricular outflow tract have been investigated in the research setting but have not received FDA approval. These include the Chronicle® implantable continuous hemodynamic monitoring device (Medtronic Inc., Minneapolis, MN), which includes a sensor implanted in the right ventricular outflow tract and, and the ImPressure® device (Remon Medical Technologies, Caesara, Israel), which includes a sensor implanted in the PA.

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Evidence from randomized controlled trials (RCTs) for various pulmonary artery pressure monitors has demonstrated a correlation between increased pressure readings and increased heart failure event risk. One RCT (the CHAMPION trial) noted that the use of pulmonary artery pressure readings may reduce heart failure-related hospitalizations, but this study was subject to a number of potential biases. Therefore, the evidence is insufficient to form conclusions that the CardioMEMS device is associated with improvements in health outcomes. Studies of other implantable direct pulmonary artery pressure measurement devices have not demonstrated significantly improved outcomes (Adamson, et al. 2011; Bourge, et al. 2008).

CardioMEMS Device

The CHAMPION (Cardiomems Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Patients) Trial Study was a prospective, single-blind, randomized controlled trial (RCT) conducted at 64 centers in the United States. This trial was designed to evaluate the safety and efficacy of an implanted, passive, wireless, pulmonary artery pressure monitor developed by CardioMEMS for the ambulatory management of heart failure patients. The CardioMEMS device is implanted using a heart catheter system fed through the femoral vein and requires patients have an overnight hospital admission for observation after implantation. The CHAMPION study enrolled 550 patients who had at least 1 previous hospitalization for heart failure in the past 12 months and were classified as having NYHA Class III heart failure for at least 3 months. Left ventricular ejection fraction (LVEF) was not a criterion for participation, but patients were required to be on medication and stabilized for 1 month before participating in the study if LVEF was reduced. All enrolled patients received implantation of the CardioMEMS pulmonary artery radiofrequency pressure sensor monitor and standard of care heart failure disease management. Heart failure disease management followed American College of Cardiology and American Heart Association guidelines along with local disease management programs. Patients were randomized by computer in a 1:1 ratio to the treatment group (n=270), in which treating providers used data from the pulmonary artery pressure sensor in patient management or the control group (n=280), in which providers did not incorporate pulmonary artery pressure sensor data into patient management. All patients took daily pulmonary artery pressure readings but were masked to their treatment groups for the first 6 months. The trial's primary efficacy outcome was the rate of heart failure-related hospitalizations in the 6 months after implantation. The primary safety outcomes were device-related or system-related complications and pressure-sensor failures. The investigators reported a statistically significant reduction in readmissions for heart failure at 6 months by 30% in the treatment group (n=83) over the control group (n=120) (HR=0.70; 95% CI, 0.60 to 0.84; p<0.001). This benefit was maintained over the entire randomized follow-up (mean, 15 months) (153 vs 253 hospitalizations, respectively) (HR=0.64; 95% CI, 0.55 to 0.75; p<0.001). The primary safety outcome, freedom from device-related complications, was 98.6% with no occurrences of pressure-sensor failure. However, 15 adverse events occurred including 8 which were device-related and 7 which were procedure-related. Additionally, length of stay for these hospitalizations was significantly shorter in the treatment group compared with the control group (2.2 days vs 3.8 days, respectively, p=0.02). There was also benefit reported for other secondary outcomes. There were improvements in the secondary outcomes of mean pulmonary pressure and quality of life at 6 months. There was no difference in overall mortality, although the trial was not designed with sufficient power to evaluate mortality benefit. There were 15 deaths in the treatment group and 26 deaths in the control group at 6 months (HR=0.77; 95% CI, 0.40 to 1.51; p=0.45). During the randomized portion of the trial, the device was generally safe: freedom from device or system-related complications was 98.6%, with a 95.2% lower confidence bound of 97.3%.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT: There is no specific CPT code for implantable direct pressure monitoring of the pulmonary artery. The

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unlisted code 93799 could be used

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HCPCS:	C2624 (E/I)	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components
	C9741 (E/I)	Right heart catheterization with implantation of wireless pressure sensor in the pulmonary artery, including any type of measurement, angiography, imaging supervision, interpretation, and report
ICD10:	I50.2-I50.9	Heart failure (code range)

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* key article

KEY WORDS:

CardioMEMS HF, Heart Failure, Pulmonary artery pressure sensor, Wireless hemodynamic monitor

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon our review, the use of an implantable wireless direct pressure sensor in the pulmonary artery for monitoring heart failure is not specifically addressed in National or regional CMS coverage determinations or policies. However, Medicare does have reimbursement guidelines for the HCPCS C codes.