Clinical Policy Title: Wireless pulmonary artery pressure monitoring devices for heart failure

Clinical Policy Number: CCP.1259

Effective Date: January 1, 2017
Initial Review Date: September 21, 2016
Most Recent Review Date: October 1, 2019
Next Review Date: February, 2021

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas’ clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy

Wireless pulmonary artery pressure monitoring devices for heart failure monitoring are investigational, and, therefore, not medically necessary.

Limitations:

None.

Alternative covered services:

- Self-contained pacemaker monitors
- Chronicle implantable hemodynamic monitors

Background

Heart failure occurs when the heart is unable to pump enough blood and oxygen to the body’s organs. About 5.7 million Americans have chronic heart failure; about half of those who develop the condition die within five years of diagnosis (U.S. Centers for Disease Control and Prevention, 2016). Persons with chronic heart failure are more likely to develop decompensated heart failure (a worsening of the condition that can
result in acute respiratory distress) which typically results in a hospital admission and sometimes death. Perhaps the most preventable cause of decompensation is lack of compliance with appropriate diet or prescribed medications.

Providers and researchers have long tried to develop methods of reducing future hospitalizations for heart failure patients. These methods have included use of biochemical markers, echocardiography, right heart catheterization, tele-monitoring, pro-B-type natriuretic peptide, chest radiograph, and cardiac implanted electronic devices such as pacemaker and defibrillator. Despite some progress, further reductions with minimum cost and difficulties with treatments are possible (Mangi, 2017).

To avoid decompensation in persons with heart failure, it is critical that pulmonary artery pressure be monitored. Traditionally, monitoring did not occur until the onset of symptoms and the patient’s encounter with the provider. Just over a decade ago, researchers created a new wireless pressure sensor for use in the pulmonary artery, implanted during a right heart catheterization procedure in heart failure patients, to monitor pulmonary artery pressure. As monitoring is done for patients in their homes, this method offered the potential to reduce avoidable admissions, as well as improved survival. Readings could be transmitted to the provider’s external monitor to help in clinical decision making while the patient remains at home. The U.S. Food and Drug Administration approved permanent implantation of wireless sensors in 2005 (Phys.org, 2005).

Champion CardioMEMSTM is a heart failure monitoring system that uses a sensor that communicates wirelessly to share information in the body. (MEMS is an abbreviation for microelectromechanical systems). The sensor is small (15 mm x 3 mm) and is implanted into the pulmonary artery to monitor cardiac output and pulmonary artery pressure. Implanting the sensor is done through the femoral vein using a Swan-Ganz catheter based system that delivers the device into the pulmonary artery. After discharge, the patient takes 20 second readings from the device. Any pressure changes are picked up by an external antenna wand and data is transmitted to a web site for provider use (Barghash, 2015).

After the CardioMEMSTM system (St. Jude Medical, St. Paul MN) was initially turned down by the Food and Drug Administration in December, 2011 (Loh, 2013), approval was granted on May 28, 2014 (U.S. Food and Drug Administration, 2014). The Administration ruled that the device is approved for patients hospitalized in the past year for New York Heart Association Class III heart failure patients. Currently, there are three existing devices that use hemodynamic monitoring sensors to detect heart failure. These include CardioMEMSTM (for pulmonary artery pressure), Chronicle (for right ventricular pressure), and Heart POD (for left atrial pressure) (Tse, 2018) Only CardioMEMSTM is approved by the Food and Drug Administration.

**Searches**

AmeriHealth Caritas searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.
The Cochrane library.

We conducted searches on August 14, 2019. Search term was: “wireless pulmonary artery pressure monitor.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews.**

- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

In 2016, the European Society of Cardiology issued a guideline on heart failure, including a statement that wireless monitoring devices may be considered for monitoring symptomatic patients with heart failure (Ponikowski, 2016). The American College of Cardiology/American Heart Association/Heart Failure Society of America 2017 update of a 2013 guideline by the group on heart failure did not mention monitoring with wireless pulmonary artery pressure monitoring, similar to the 2013 version (Yancy, 2017; Yancy, 2013). A 2013 guideline from the National Institute of Health Care and Excellence mentioned implantable monitoring pulmonary artery pressure devices have been proposed to monitor heart failure severity and to provide early detection of worsening cardiac function, but made no recommendation for its use (National Institute of Health Care and Excellence, 2013).

One systematic review/meta-analysis compared reductions in hospitalizations between tele-monitoring (61 studies, 55 randomized/controlled, n = 31,501), and hemodynamic monitoring sensors (12 studies, eight randomized/controlled articles from three studies, n = 4,831). Eight of the 12 hemodynamic monitoring studies addressed pulmonary artery pressure (CardioMEMS) devices. Patients were monitored for 11 and 13 months, respectively, for the tele-monitoring and hemodynamic monitoring groups. Both groups had significant declines in hospitalization rates ($P < .0001$ and $P < .001$). However, the hemodynamic groups had larger declines for short term under six months (45 percent versus 24 percent), long term over 12 months (37 percent to 27 percent), and overall (40 percent versus 26 percent). Of the three types of hemodynamic monitoring, pulmonary artery pressure had the most significant decline ($P < .001$) compared with left atrial ($P < .05$) and right ventricular ($P = .058$) (Tse, 2018). This last finding was consistent with a review of a few years earlier (Seifert, 2015).

A systematic review of seven studies (n = 1,912) compared the ability of types of hemodynamic monitoring to reduce future hospitalizations for heart failure patients. The study on left atrium pressure showed the highest reduction (59.0 percent) in heart failure hospitalization, followed by the pulmonary artery pressure
(CardioMEMS, 56.3 percent) and right ventricle pressure (31.0 percent). However, only one of the seven studies was of left atrium pressure, so authors caution not to conclude this method is most effective (Minhas, 2017).

The first large-scale study of wireless pulmonary artery pressure monitors aside from the initial clinical trials included 1,114 patients. The number of heart failure-related hospitalizations in the six months before and after implantation dropped dramatically from 1020 to 381. The follow-up period also included only 139 deaths, and 17 ventricular assist device implantations and/or transplants (Desai, 2017).

One study published soon after the 2005 Food and Drug Administration approval of wireless sensors determined that CardioMEMS Champion™ was equally accurate in monitoring pulmonary artery pressure as was Swan-Ganz catheterization and echocardiography in ambulatory heart failure patients (Verdejo, 2007). Another controlled study documented a 36 percent reduction in hospitalization rate, no pressure-sensor failures, and three percent system-related complications for heart failure Class III or IV patients whose providers were given information from the Chronicle® system (Bourge, 2008).

The initial large-scale study of the efficacy (and safety) of wireless sensors for heart failure has been the prospective, single-blind, randomized controlled trial CHAMPION study of the CardioMEMS system, at 64 U.S. medical centers (n = 550) of those New York Heart Association Class III patients who had at least one previous hospitalization for heart failure in the past 12 months (Abraham, 2011). Patients were randomly assigned to the treatment or control group. Of these, 347 completed the randomized access period, and also transitioned to the open access period (Abraham, 2016).

A Food and Drug Administration summary of the initial six months of the trial showed that outcomes for the treatment group (except for survival) all exceeded those of the control group (U.S. Food and Drug Administration, 2011). Table 1 summarizes these findings, a number of which were later published in peer-reviewed journals.

Table 1
Patient Outcomes, CardioMEMS Champion™ Heart Failure Monitoring System
Six Months after Initiation of Trial (Abraham, 2016)

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Treatment Group (n = 270)</th>
<th>Control Group (n = 280)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart failure-related hospitalizations per 100</td>
<td>32</td>
<td>44</td>
</tr>
<tr>
<td>Percent of subjects hospitalized</td>
<td>20.4</td>
<td>28.6</td>
</tr>
<tr>
<td>Hospitalization rates/patient-year, ejection</td>
<td>0.36</td>
<td>0.47</td>
</tr>
<tr>
<td>Hospitalization rates/patient/year, ejection</td>
<td>0.18</td>
<td>0.33</td>
</tr>
<tr>
<td>Average days hospitalized</td>
<td>2.2</td>
<td>3.8</td>
</tr>
<tr>
<td>Deaths per 100 subjects</td>
<td>5.6</td>
<td>7.1</td>
</tr>
<tr>
<td>Survival (average days alive)</td>
<td>176.6</td>
<td>175.9</td>
</tr>
</tbody>
</table>
Mean pulmonary artery pressure change, in mmHg days
-155.7 +33.1
Percent subjects with serious adverse effects
44.8 55.4
Improvement in quality of life score, using Minnesota Living with Heart Failure Q’naire
-10.6 -7.4

A subsequent, in-depth assessment of the CHAMPION study in particular and CardioMEMS studies in general described the device to be a “leading innovation” in treating heart failure. However, the small number of studies and small study sizes need to be performed to validate these results, before CardioMEMS is accepted as a preferred treatment for heart failure (Mangi, 2017).

Subsequent reports upheld the reduced number of hospital admissions over a longer period of time. One study of 245 Medicare patients from the CHAMPION group found that 30 day readmissions were 49 percent and 58 percent lower for the treatment groups for heart failure and for all causes, respectively (Adamson, 2016). In addition, providers made more changes in the diuretic and vasodilator therapies to subjects in the treatment group due to increased information (Adamson, 2014). Another study found subjects in the active monitoring group experienced a greater number of medication adjustments; significant increases of diuretics, vasodilators, and neuro-hormonal antagonists; targeted intensification of diuretics and vasodilators in patients with higher pulmonary artery pressures; and preservation of renal function despite diuretic intensification (Costanzo, 2016).

Other reports used CHAMPION data to analyze risk of 314 patients who had Stage II (World Health Organization) pulmonary hypertension, whose mortality rate was more than double that of 236 subjects without the condition. In patients with and without pulmonary hypertension, knowledge of hemodynamic data meant a reduction of 38 percent in hospitalizations (Benza, 2015). Another study documented 48.8 percent of patients with Right Heart Catheterization exhibited pulmonary hypertension, suggesting the condition may be significantly under-diagnosed in the Right Heart Catheterization population (Raina, 2015). Another recent review found that in CHAMPION patients with Chronic Obstructive Pulmonary Disease, intervention with CardioMEMS resulted in 41 percent and 62 percent reductions in hospitalizations for heart failure and respiratory disorders, respectively (Krahnke, 2015).

After the CHAMPION study, one large health network measured the pulmonary artery pressure for six months in the first 2000 patients with a CardioMEMS implant. The network’s average pulmonary artery pressure was 34.9, which compares with 31.3 for the CHAMPION subjects (Heywood, 2017).

The CardioMEMS heart failure system study significant (P < .0002) decline in hospitalizations for heart failure 27 percent greater than controls after six months continued to be significant (P < .0001) after 15 months of follow up (Leung, 2019).

A group of 1087 Medicare patients who received CardioMEMS implants from June 1, 2014 to March 31, 2016 was compared with 1087 controls, also Medicare patients who had been hospitalized for heart failure during that time. After 12 months of follow up, the treatment group had significantly fewer hospitalizations
(616 versus 784, \( P < .001 \)), deaths (241 versus 325, \( P < .001 \)) and average hospital days for heart failure (3.7 versus 4.4, \( P < .001 \)). The number of ventricular assist devices and heart transplants was also lower (13 versus 20) but not statistically significant (Leung, 2019).

**Policy updates:**

A total of two peer-reviewed references were added to, and one guideline/other and four peer-reviewed references removed from this policy in August, 2019.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**Centers for Medicare & Medicaid Services National Coverage Determinations:**

No National Coverage Determinations identified as of the writing of this policy.
Local Coverage Determinations:

L36419 Outpatient Wireless Pulmonary Artery Pressure Monitoring for Heart Failure.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>93799</td>
<td>Unlisted cardiovascular service or procedure</td>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>I50.20</td>
<td>Unspecified systolic (congestive) heart failure</td>
</tr>
<tr>
<td>I50.22</td>
<td>Chronic systolic (congestive) heart failure</td>
</tr>
<tr>
<td>I50.23</td>
<td>Acute on chronic systolic (congestive) heart failure</td>
</tr>
<tr>
<td>I50.30</td>
<td>Unspecified diastolic (congestive) heart failure</td>
</tr>
<tr>
<td>I50.32</td>
<td>Chronic diastolic (congestive) heart failure</td>
</tr>
<tr>
<td>I50.40</td>
<td>Unspecified combined systolic (congestive) and diastolic (congestive) heart failure</td>
</tr>
<tr>
<td>I50.42</td>
<td>Chronic combined systolic (congestive) and diastolic (congestive) heart failure</td>
</tr>
<tr>
<td>I50.43</td>
<td>Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure</td>
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<tr>
<td>I50.9</td>
<td>Heart failure, unspecified</td>
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</table>

<table>
<thead>
<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>C2624</td>
<td>Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components</td>
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</table>

Appendix

No additional information was identified for this section during the writing of this policy.