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

Clinical Policy Number: 04.01.08

<table>
<thead>
<tr>
<th>Effective Date:</th>
<th>January 1, 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Review Date:</td>
<td>September 21, 2016</td>
</tr>
<tr>
<td>Most Recent Review Date:</td>
<td>September 21, 2016</td>
</tr>
<tr>
<td>Next Review Date:</td>
<td>September 2017</td>
</tr>
</tbody>
</table>

Related policies:

- CP# 04.01.01 Real-time outpatient cardiac monitoring
- CP# 04.01.03 Ambulatory blood pressure monitoring
- CP# 04.01.05 Implantable cardiac loop recorder
- CP# 04.02.01 Wearable cardioverter-defibrillator
- CP# 04.02.03 External counterpulsation (ECP) therapy

ABOUT THIS POLICY: AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania’s 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 Pennsylvania 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 Pennsylvania’s 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 Pennsylvania’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania’s clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas Pennsylvania considers the use of wireless pulmonary artery pressure monitoring devices for heart failure monitoring to be investigational, and, therefore, not medically necessary.

Limitations:

Note: The following CPT/HCPCS codes are not listed in the Pennsylvania Medicaid fee schedule:

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

**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.

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 (FDA) approved permanent implantation of wireless sensors in 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. Implantiing 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.

The FDA approved the CardioMEMSTM system (St. Jude Medical, St. Paul, MN) on May 28, 2014 (U.S. Food and Drug Administration, 2014). The FDA ruled that the device is approved for patients hospitalized in the past year for New York Heart Association (NYHA) Class III heart failure patients. Other
devices that monitor pulmonary artery pressure changes have not received FDA approval. These include the Chronicle® implantable continuous hemodynamic monitoring device (Medtronic Inc., Minneapolis, MN) and the ImPressure® device (Remon Medical Technologies, Caesara, Israel), which the FDA rejected in 2007.

**Searches**

AmeriHealth Caritas Pennsylvania searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on August 1, 2016. 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**

One study published soon after the 2005 FDA approval of wireless sensors determined that CardioMEMSTM 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% reduction in hospitalization rate, no pressure-sensor failures, and 3% system-related complications for heart failure Class III or IV patients whose providers were given information from the Chronicle® system (Bourge, 2008).

To date, the largest-scale study of the efficacy (and safety) of wireless sensors for heart failure has been the prospective, single-blind, randomized controlled trial (RCT) CHAMPION study of the CardioMEMSTM system, conducted at 64 U.S. medical centers. A total of 550 subjects were included: those who had at least one previous hospitalization for heart failure in the past 12 months and were classified as having NYHA Class III heart failure for at least three months. The treatment group included 270 subjects for
which pulmonary artery pressure data from the sensor was used, and 280 subjects with no such data used.

Between September 6, 2007 and October 7, 2009, patients were randomly assigned to the treatment or control group. Of these, 347 completed the randomized access period in August 2010, and also transitioned to the open access period, which ended April 30, 2012 (Abraham, 2016).

An FDA summary of the initial six months of the trial showed that outcomes for the treatment group consistently 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

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Treatment Group (n=270)</th>
<th>Control Group (n=280)</th>
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<tbody>
<tr>
<td>Heart failure-related hospitalizations</td>
<td>0.32</td>
<td>0.44</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 fraction change &lt;40%</td>
<td>0.36</td>
<td>0.47</td>
</tr>
<tr>
<td>Hospitalization rates/patient-year, ejection fraction change &gt;40%</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>
<tr>
<td>Mean pulmonary artery pressure change, in mmHg days</td>
<td>-155.7</td>
<td>+33.1</td>
</tr>
<tr>
<td>Percent Subjects with serious adverse events</td>
<td>44.8</td>
<td>55.4</td>
</tr>
<tr>
<td>Improvement in quality of life score, using Minnesota Living with Heart Failure Q'naire</td>
<td>-10.6</td>
<td>-7.4</td>
</tr>
</tbody>
</table>

In the treatment group, hospitalization rates were consistently lower, regardless of the ejection fraction change. Average length of stay was also lower. Pulmonary artery pressure change was reduced by 155.7 mmHg days in the treatment group, and increased by 33.1 for the control group. The serious adverse event rate is lower for the treatment group, and quality of life score declined more sharply (preferable). All differences achieved statistical significance. The only measure for which there was no difference between the two groups was average days of survival (176.6 and 175.9 days), although the death rate was lower for the treatment group (5.6% vs. 7.1%), based on 15 and 20 deaths, respectively. Of the 550 subjects, there were 15 adverse events, including 8 which were device-related and 7 which were procedure-related. (Abraham, 2011).
The findings are encouraging. However, there are no meta-analyses or systematic reviews on efficacy of wireless devices, and the number of controlled trials is limited. Thus, the strength of evidence is relatively weak and more studies are needed before an evidence-based rationale exists on whether to cover wireless pulmonary artery pressure monitors (Hayes, 2015).

Subsequent reports upheld the reduced number of hospital admissions over a longer period of time (Adamson, 2014). One study of 245 Medicare patients from the CHAMPION group found that 30 day readmissions were 49% lower and 58% 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 neurohormonal 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 (PH), whose mortality rate was more than double that of 236 subjects without the condition. In patients with and without PH, knowledge of hemodynamic data meant a reduction of 38% in hospitalizations (Benza, 2015). Another study documented 48.8% of patients with Right Heart Catheterization (RHC) exhibited PH, suggesting PH may be significantly under-diagnosed in the RHC population (Raina, 2015). Another recent review found that in CHAMPION patients with Chronic Obstructive Pulmonary Disease, intervention with CardioMEMSTM resulted in a 41% and 62% reduction in hospitalizations for heart failure and respiratory disorders, respectively (Krahnke, 2015).

A recent report estimated cost savings in Germany from use of the wireless pulmonary artery monitor in the CHAMPION study, based on 37% fewer hospitalizations. The calculation of 114,000 fewer admissions from 2009-2021 means a savings of 522 euros, or $575 million (Kolominsky-Rabas, 2016). A team from Stanford University showed that despite CardioMEMSTM decreasing lifetime hospitalizations among heart failure patients (2.18 vs. 3.12 in patients with no CardioMEMSTM) average quality-adjusted life-years actually increased (2.74 vs. 2.46) as did average costs from $156,569 to $176,648 (Sahndu, 2016)).

Policy updates:

None.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
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<tbody>
<tr>
<td>Kolominsky-Rabas (2016)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
</tr>
<tr>
<td>------------------------------</td>
<td>------------------------------------</td>
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</table>
| Economic benefits of reduced hospitalizations from pressure monitoring devices for heart failure | • Used 37% reduction in hospitalizations from CHAMPION study.  
• Extrapolation calculated at 114,000 fewer admissions from 2009-2021.  
• Savings in Germany estimated at 522 euros, or $575 million, from 2009-2021. |
| Abraham (2016)               | Key points:                         |
| Updated results of pressure monitoring devices for heart failure from six months to 3-5 years | • 347 of 550 original patients in CHAMPION study followed for an additional 18 months.  
• 177 subjects in treatment group, 170 in control group.  
• Heart failure admission rate 33% lower for treatment group overall.  
• Heart failure admission rate 48% lower for treatment group after pulmonary artery pressure information made available. |
| Adamson (2016)               | Key points:                         |
| Impact of pulmonary artery pressure-guided heart failure on 30-day readmits | • 245 Medicare patients from CHAMPION study.  
• In treatment group, 30 day readmits 49% lower for heart failure, 58% lower all causes. |
| Benza (2015)                 | Key points:                         |
| Hospitalization rate changes in patients with heart failure and pulmonary hypertension via wireless monitoring | • 314 of 550 CHAMPION patients have pulmonary hypertension (PH).  
• PH patients have more than double the hospitalization rate than non-PH patients.  
• Pressure monitoring devices reduced hospitalization rates for both those with and without PH (-36% and -40%). |
| Abraham (2011)               | Key points:                         |
| Test if implantable hemodynamic monitoring systems reduce rates of hospitalization in heart failure patients | • 550 NY Heart Assn. Class III heart failure patients (270 treatment, 280 control).  
• Subjects tracked for six months after enrollment.  
• Hospitalization rate for heart failure 39% less after 15 months for study group.  
• 2.7% (8 of 270) treatment patients had device-related complications. |

**Glossary**

**CardioMEMSTM** — A wireless heart failure monitoring system that uses a sensor that communicates information in the body to providers (MEMS stands for microelectromechanical systems).

**CHAMPION study** — A study of 550 heart failure patients at 64 U.S. medical centers, comparing patients with and without a CardioMEMSTM to manage patients based on assessment of pulmonary artery pressure

**Chronic Heart Failure** — A syndrome marked by signs and symptoms that suggest the heart is impaired and cannot pump adequate amounts of blood through the body.

**Pulmonary artery pressure** — Increased pressure in the pulmonary arteries (which carry blood from the heart to the lungs), marked by shortness of breath, fatigue, chest pain, and racing heartbeat.
References

Professional society guidelines/other:


Peer-reviewed references:


Hayes Health Technology Brief. Wireless Pulmonary Artery Pressure Monitoring With CardioMEMSTM HF System (St. Jude Medical Inc.) for Management of Chronic Heart Failure. November 24, 2015. https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=33126&searchStore=%24search_type%3Dall%24icd%3D%24keywords%3Dwireless%2Cpulmonary%2Cartery%2Cmonitor%24status%3Dall%24from_date%3D%24to_date%3D%24report_type_options%3D%24technology_type_options%3D%24organ_system_options%3D%24specialty_options%3D%24order%3Da searchRelevance. Accessed August 4, 2016.


**Clinical trials:**

Searched clinicaltrials.gov on August 4, 2016, using terms “wireless pulmonary artery pressure monitoring” and “CardioMEMSTM.” | Five (5) Open Studies, two relevant.


CMS National Coverage Determinations (NCDs):

No NCDs identified as of the writing of this policy.

Local Coverage Determinations (LCDs):

L36419 Outpatient Wireless Pulmonary Artery Pressure Monitoring for Heart Failure. CMS website.

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.

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<thead>
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<th>CPT Code</th>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>I50.20</td>
<td>Unspecified systolic (congestive) heart failure</td>
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<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>
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<tr>
<td>I50.30</td>
<td>Unspecified diastolic (congestive) heart failure</td>
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<tr>
<td>I50.32</td>
<td>Chronic diastolic (congestive) heart failure</td>
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<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>
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<tr>
<td>I50.43</td>
<td>Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure</td>
</tr>
<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>
</tr>
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<tbody>
<tr>
<td>C2624</td>
<td>Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components</td>
</tr>
<tr>
<td>C9741</td>
<td>Right heart catheterization with implantation of wireless pressure Sensor in the pulmonary artery, including any type of measurement, angiography, imaging supervision, interpretation and report</td>
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