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: August 30, 2018
Next Review Date: September 2019

Related policies:

- CCP.1013 Real-time outpatient cardiac monitoring
- CCP.1108 Ambulatory blood pressure monitoring
- CCP.1150 Implantable cardiac loop recorder
- CCP.1073 Wearable cardioverter-defibrillator
- CCP.1161 External counterpulsation) therapy

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

Coverage policy

Select Health of South Carolina considers the use of wireless pulmonary artery pressure monitoring devices for heart failure monitoring to be investigational/experimental, 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 CardioMEMS™ 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 CardioMEMS 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 CardioMEMS (for pulmonary artery pressure), Chronicle (for right ventricular pressure), and Heart POD (for left atrial pressure) (Tse, 2018) Only CardioMEMS is approved by the Food and Drug Administration.

**Searches**

Select Health of South Carolina searched PubMed and the databases of:
We conducted searches on August 15, 2018. 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 hospitalizations rates ($P < .0001$ and $P < .001$). However, the hemodynamic groups had larger declines for short term under six months (45 versus 24 percent), long term over 12 months (37 to 27 percent), and overall (40 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=1912) 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) and right ventricle pressure (31.0). 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. The lower number of hospitalizations resulted in a decline of $7,433 per patient. Similar trends in costs and hospitalizations continued to 12 months after implant (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, conducted at 64 U.S. medical centers. A total of 550 subjects 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 sensor.

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).

A Food and Drug Administration 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

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Treatment Group (n=270)</th>
<th>Control Group (n=280)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Heart failure-related hospitalizations per 100
Percent of subjects hospitalized
Hospitalization rates/patient-year, ejection fraction change <40%
Hospitalization rates/patient/year, ejection fraction change >40%
Average days hospitalized
Deaths per 100 subjects
Survival (average days alive)
Mean pulmonary artery pressure change, in mmHg days
Percent subjects with serious adverse effects
Improvement in quality of life score, using Minnesota Living with Heart Failure Q’naire

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 versus 7.1 percent), based on 15 and 20 deaths, respectively. Of the 550 subjects, there were 15 adverse events, including eight which were device-related and seven which were procedure-related. (Abraham, 2016).

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 (Adamson, 2014). One study of 245 Medicare patients from the CHAMPION group found that 30 day readmissions were 49 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 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, 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 it 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 and 62 percent reductions 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 percent 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 CardioMEMS decreasing lifetime hospitalizations among heart failure patients (2.18 versus 3.12 in patients with no CardioMEMS) average quality-adjusted life-years actually increased (2.74 versus 2.46) as did average costs from $156,569 to $176,648 (Sahndu, 2016). Another study comparing heart failure patients with CardioMEMS against those undergoing standard care concluded the CardioMEMS group was cost-effective, with an incremental cost effectiveness ratio of $44,832 per quality adjusted life year (Schmier, 2017).

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).

A 2015 analysis by the Institute for Clinical and Economic Review compared CardioMEMS™ (23 references) with the drug Entresto™ for congestive heart failure patients. The panel of 10 experts concluded a greater net health benefit of Entresto versus standard care/ACE inhibitor (9 of 10 votes), than that of CardioMEMS versus usual care (6 of 10 votes). The cost per quality year was higher for CardioMEMS, $57,933 versus $47,000 (Ollendorf, 2015).

A study of 66 patients with New York Hospital Association Level III heart failure compared the 34 with implants of CardioMEMS to 32 without. Average body weight decreased after 90 days from 190 to 177 in the CardioMEMS group, with no change for the control group ($P < .0001$). The CardioMEMS group had an increase in quality of life scores three times greater than that of controls (+33 versus +11, $P < .001$). Six minute walk distances rose 250, 303, and 346 meters at the 30-, 60-, and 90-day marks after implantation compared to no change for controls ($P < .0001$) (Alam, 2016).

**Policy updates:**

A total of five guidelines/other and seven peer-reviewed references were added to, and one guideline/other and seven peer-reviewed references removed from this policy in August, 2018.

**Summary of clinical evidence:**
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
</table>
| Hse (2018)        | **Key points:**  
|                   | • Systematic review and meta-analysis.  
|                   | • Tele-monitoring group consisted of 61 studies (n=31,501), 55 were randomized controlled trials, followed an average 11 months.  
|                   | • Hemodynamic monitoring had consisted of 12 studies (n=4,831), eight based on three randomized controlled trials, followed an average of 13 months.  
|                   | • Eight of 12 hemodynamic studies were CardioMEMS.  
|                   | • Hemodynamic group had larger decline in all hospitalizations (40 versus 26 percent (%)).  
|                   | • Hemodynamic group had larger decline in short-term (< 6 months), 45 versus 24%.  
|                   | • Hemodynamic group had larger decline in long-term (>12 months), 37 versus 27%.  
|                   | • Within the hemodynamic group, pulmonary artery monitoring had most significant decline ($P <.001$), compared to left atrial pressure ($P <.05$) and right ventricular pressure ($P =.058$). |
| Seifert (2015)    | **Key points:**  
|                   | • A narrative review noted that three different hemodynamic monitoring devices have so far been investigated in clinical trials employing right ventricular pressure, left atrial pressure and pulmonary artery pressure monitoring.  
|                   | • Only one of these systems, the CardioMEMS™ HF monitoring system, demonstrated a significant reduction of hospitalization due to heart failure over six months in the CHAMPION trial.  
|                   | • The systematic adaptation of medication in the CHAMPION trial significantly differed from the usual care of the control arm over six months.  
|                   | • Further studies demonstrating a positive effect on mortality are needed before translation of this approach into guidelines.  
|                   | • Without this evidence a further implementation of pressure monitoring into currently used devices and justification of the substantial technical and personnel demands are not warranted. |
| Kolominsky-Rabas (2016) | **Key points:**  
| 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)

Test if implantable hemodynamic monitoring systems reduce rates of hospitalization in heart failure patients

Key points:
- 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.

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:**


**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>
</tr>
</thead>
<tbody>
<tr>
<td>93799</td>
<td>Unlisted cardiovascular service or procedure</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
</tr>
</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>
</tr>
<tr>
<td>I50.9</td>
<td>Heart failure, unspecified</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
</tr>
</thead>
<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>
</tr>
</tbody>
</table>