Clinical Review Criteria

Implantable Pulmonary Artery Pressure Monitoring Device for Patients with Heart Failure

- CardioMEMS

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Criteria

For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
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<tr>
<td>National Coverage Determinations (NCD)</td>
<td>None</td>
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<tr>
<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
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<tr>
<td>Local Coverage Article</td>
<td>None</td>
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<tr>
<td>KPWA Medical Policy</td>
<td>Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, &quot;Implantable Pulmonary Artery Pressure Monitoring Device for Patients with Heart Failure,&quot; for medical necessity determinations. Use the Non-Medicare criteria below.</td>
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</table>

For Non-Medicare Members

Kaiser Interregional New Technologies Committee

There is insufficient evidence to determine whether CardioMEMS is a medically appropriate option for patients with NYHA functional class III heart failure. The existing evidence is of insufficient quantity and quality. Potential candidates should be part of an IRB trial with a well-designed protocol, appropriate informed consent, and structured follow-up.

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Heart failure (HF) is a major public health problem in the United States and worldwide. According to the Centers for Disease Control and Prevention, about 6 million people in the US have clinically manifest HF, and the prevalence continues to rise. Hospitalization for patients with chronic HF is also on the rise despite the major advances in medical and device therapy. Statistics show that HF is the primary diagnosis in over one million hospitalizations annually. The most frequent cause of hospitalization in these patients is recurrent episodes of decompensation resulting from volume overload or changes in ventricular function. Studies show that over 90% of hospitalizations for worsening HF are due to signs and symptoms of congestion leading to the decompensated state. Patients hospitalized for HF are at high risk for all-cause rehospitalization with a 1-month readmission rate of 25%. The prognosis of patients hospitalized with HF is suboptimal especially for those with serial readmission (Hoppe 2009, Adamson 2011, Go 2013, and Yancy 2013).

Treatment strategies for patients with decompensated HF are limited and it is important to detect impending acute decompensated heart failure (ADHF) early and accurately. Historically, clinical symptoms and signs of dyspnea, orthopnea, weight gain, and leg edema, were used as indicators of congestion and volume overload, but these are
not sensitive to the early changes in volume that increase the risks of decompensation. Investigators found that pressure increase is the cause of clinical congestion and that persistent increases are apparent several days or weeks before the onset of worsening signs and symptoms. It is thus suggested that the increase in intracardiac and pulmonary artery pressures are more accurate measures than volume status in determining whether the patient’s condition is worsening. Some researchers also found that successful treatment of acutely decompensated HF patients is associated with a decrease in diastolic pressures to values equivalent or below those present at baseline, and that continuous monitoring pressure during treatment may allow the clinicians to tailor the treatment more accurately. Based on these observations, it is hypothesized that ambulatory implantable hemodynamic monitoring (IHM) may provide information that would help avoid discharging patients from the hospital before decreasing the pressure sufficiently and returning the patient to a chronic compensated state. Continuous hemodynamic monitoring after the hospital discharge is also believed to proactively detect signs of congestion and reduce the risk of hospitalization (Zile 2008, Hoppe 2009, Abraham 2011, Adamson 2011, Mooney 2015).

Recent research has thus focused on ambulatory hemodynamic monitoring in chronic HF as a surrogate marker to optimize the patients’ medical therapy in the ambulatory setting before the onset of acute hemodynamic decompensation. The concept of remote device monitoring is referred to as telemonitoring. Several implantable systems have been developed to measure various cardiac pressures and tailor medical therapy accordingly “pressure guided therapy”. Among these devices is the CardioMEMS HF System, the focus of the current review.

The CardioMEMS HF System (St Jude Medical, Inc, USA) is a permanently implantable pressure measurement system designed to directly measure systolic, diastolic and mean pulmonary artery pressure (PAP) to help guide heart failure management in an outpatient setting. It is a miniaturized wireless electromechanical sensor implanted in conjunction with a right heart catheterization procedure via transvenous access. Its design is based on the microelectromechanical principles of resonance whereby an external antenna wand emitting radiofrequency energy can cause varying degrees of oscillations in the sensor depending on the ambient pressure. The CardioMEMS HF system comprises: 1. A battery free, leadless sensor (15mm x 3mm) that consists of a coil and capacitor encased in silicone, with a nitinol wire loop at each end of the sensor, 2. A transverse delivery system designed to deploy the implantable sensor in the distal PA; and 3. The Champion Electronics System (CardioMEMS) which acquires and processes signals from the implantable sensor and wirelessly transfers PA pressure measurements to a secure database to be reviewed and evaluated by the treating physician (Loh 2013, Adamson 2011, Mooney 2015, FDA webpages).