Implantable Left Atrial Hemodynamic Monitor

**Policy**

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

Aetna considers implantable left atrial hemodynamic monitors (e.g., the HeartPOD System and the Promote LAP System) experimental and investigational due to insufficient evidence in the peer-reviewed literature.

**Background**

The Heart Failure Society of America (2010) defines heart failure as "a syndrome caused by cardiac dysfunction, generally resulting from myocardial muscle dysfunction or loss and characterized by either left ventricular (LV) dilation or hypertrophy or both." Heart failure is a major public health problem that affects nearly 6 million Americans each year (Roger et al, 2011). Heart failure (HF) is the cause for 12 to 15 million office visits and 6.5 million hospital days per year and can result from any structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood (Hunt et al, 2009). Morbidity and mortality from HF remains high despite advances in evaluation and management with rehospitalization rates of 20% at one month and nearly 50% at 6 months (Ritzema et al, 2010). Bui et al (2012) state that the majority of these HF hospitalizations result from worsening congestion in patients previously diagnosed with HF. Arenja et al (2011) prospectively enrolled 610 consecutive patients presenting to the emergency department with acute HF and followed them for 1 year to
determine risk stratification for mortality; a total of 201 patients (33%) died within 360 days and the investigators’ analysis identified blood urea nitrogen and age as the best single predictors of 1-year mortality.

Kommuri et al (2012) studied the impact of prior HF hospitalizations on long-term mortality in 2,221 HF patients in a prospective cohort study. They found that in otherwise "low-risk" HF inpatients, a history of 2 or more HF hospitalizations within the prior 12 months markedly increases 1-year mortality risk. Bui et al (2012) report that "earlier identification and treatment of congestion together with improved care coordination, management of comorbid conditions, and enhanced patient self-management may help to prevent hospitalizations in patients with chronic HF. Such home monitoring extends from the promotion of self-care and home visitations to telemedicine and remote monitoring of external or implantable devices."

Giordano et al (2011) enrolled 358 HF patients in a 6 month home-based telemanagement (HBT) program and observed that on re-evaluation after 6 months (238 patients) there was a general improvement in clinical, functional, and quality of life (QoL) status and a significant increase in the mean daily dosage of beta-blockers prescribed. Although Giordano et al (2011) concluded that HBT for patients with congestive HF is associated with favorable effects on hospital readmission for cardiovascular reasons and on QoL, they also noted that a more comprehensive multidisciplinary approach would probably be required to obtain favorable effects on total morbidity.

Recent research has focused on the use of ambulatory hemodynamic monitoring in chronic HF patients and continuous implantable hemodynamic monitoring devices have been introduced as a potential means to improve outcomes in these patients. The American College of Cardiology/American Heart Association Guidelines for the Diagnosis and Management of Heart Failure in Adults state that implantable hemodynamic monitors used for the chronic, remote, outpatient monitoring of ventricular filling pressures and other hemodynamic and clinical variables in HF patients are hypothesized to be of benefit as changes in therapy to optimize LV filling pressure may improve outcomes in HF patients (Hunt et al, 2009). One such device used to measure left atrial pressure (LAP) is the HeartPod® system (St Jude Medical, CRMD, Sylmar, CA), which consists of an implantable sensor lead and coil antenna; the sensor module is affixed to the atrial septum by proximal and distal folding nitinol. The implantation procedure is conducted through performing a right heart catheterization with a Swan Ganz catheter. After removing the delivery sheath, the proximal lead connector is affixed to the antenna and placed in a subcutaneous pocket anchors (Troughton et al, 2010). Troughton et al. (2010) state that the handheld Patient Advisor Module device, which is used to interrogate the sensor by placing the module in proximity to the device, uses a standard algorithm to compute mean LAP.
The first reported study of an implantable left atrial hemodynamic monitor was conducted by Ritzema et al (2007) in eight male patients with established heart failure and at least 1 heart failure hospitalization or unplanned outpatient visit for parenteral therapy during the previous 12 months. The 8 subjects from this single center were enrolled in a prospective, multi-center, nonrandomized, open-label feasibility clinical trial called the Hemodynamically Guided Home Self-Therapy in Severe Heart Failure Patients (HOMEOSTASIS I). The LAP hemodynamic monitor device (HeartPOD®) was implanted in all patients without device related complications or systemic emboli. The device consisted of an implantable sensor lead coupled with a subcutaneous antenna coil, a patient advisory module (PAM), and the clinician’s personal computer software. The sensor system was implanted into the atrial septum oriented to the left atrium. Twelve-weeks post-implantation 87 % of device LAP measurements were within +/- 5 mm Hg of simultaneous pulmonary capillary wedge pressure readings over a wide range of pressures (1.6 to 71 mm Hg). Net drift corrected by calibration was -0.2 +/- 1.9 mm Hg. The authors concluded that although ambulatory monitoring of direct LAP was well tolerated, feasible, and accurate at a short-term follow-up, further follow-up and investigation were warranted to evaluate the clinical utility of LAP monitoring in patients with heart failure.

The COMPASS-HF (Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure) study was conducted by Bourge et al (2008). COMPASS-HF was a prospective, multi-center, randomized, single-blind, parallel-controlled trial of 274 New York Heart Association (NYHA) functional class III or IV HF patients who received an implantable continuous hemodynamic monitor. Patients were randomized to a Chronicle implantable continuous hemodynamic monitoring device (Medtronic Inc., Minneapolis, MN) (n = 134) or a control group (n = 140). The investigators concluded that, compared with control patients, the Chronicle group had a nonsignificant 21 % reduction (p = 0.33) in the rate of all HF-related events and a 36 % reduction (p = 0.03) in the relative risk of a first HF-related hospitalization. The investigators therefore recommended that additional trials be conducted to establish the clinical benefit of implantable continuous hemodynamic monitor–guided care in patients with advanced HF.

Ritzema et al (2010) conducted a physician-directed patient self-management of left atrial pressure in advanced chronic HF study in 40 patients with reduced or preserved left ventricular ejection fraction (LVEF) and acute decompensation. All enrolled patients were implanted with an investigational left atrial pressure monitor. Event-free survival was determined over a median follow-up period of 25 months. Survival without decompensation was 1 % at 3 years and events decreased in frequency at the first 3 months following implantation (p < 0.012). Mean daily left arterial pressure fell from 17.6 mm Hg during the first 3 months to 14.8 mm during pressure-guided therapy (p = 0.003). There were statistically significant improvements in NYHA class (p < 0.001) and LVEF (p < 0.001). The authors concluded that physician-directed patient self-
management of left atrial pressure has the potential to improve hemodynamic, symptoms, and outcomes in advanced HF. The authors also acknowledged, however, that this was a small observational study and that these results suggest that outpatient hemodynamic monitoring linked to a self-management therapeutic strategy could change current management of advanced heart failure and potentially facilitate more optimal therapy and improved outcomes.

Troughton et al (2010) evaluated the HeartPOD® left atrial hemodynamic monitoring system in 84 advanced HF patients. The investigators conducted a prospective, multicenter, observational open-label registry study the results of which showed that comparisons of LAP with pulmonary capillary wedge pressure (PCWP) generally showed a high degree of concordance. The implanted left atrial monitor measurement of LAP differed from PCWP by > 5 mmHg in 20% of readings. However, the authors stated that these disagreements were likely miscalibration of the Swan Ganz catheter, the implanted LAP sensor, or both. Freedom from device failure was 95% at 2 years and 88% at 4 years. There were no instances of device failure or anomaly associated with clinical worsening. The authors concluded that high-fidelity LAP measurements were accurate and closely predicted PCWP over a 12-month period.

St Jude Medical is currently sponsoring a Phase III randomized, open label trial of the HeartPOD™ System or Promote® LAP System. This trial is currently recruiting participants and the primary outcome measures will be safety and efficacy. Safety will be demonstrated by evaluating the freedom from study-related major adverse cardiovascular and neurological events (MACNE) following twelve months of treatment. Effectiveness will be determined by evaluating the reduction in the relative risk of Heart Failure MACNE between the Treatment and Control groups (St. Jude Medical, 2011). The HeartPOD® and Promote® LAP System have not to date received approval for use in the United States by the Food and Drug Administration.

Walton and Krum (2005) stated that congestive HF (CHF) has been described as the new epidemic. Despite recent improvements in drug therapy, a 2-year mortality of up to 50 % persists. There are limitations to the current drug treatments and cardiac resynchronization devices. The treatment of diastolic dysfunction can be suboptimal. The Savacor Company developed the HeartPOD device to directly measure LAP in patients with CHF via an implantable device. The patient can in real time, download their intra-cardiac pressure measurements to a hand-held device. With this information, they can titrate their own treatment in a very precise manner.

The HeartPOD System (Savacor Inc., Los Angeles, CA) is used for patients with ischemic or non-ischemic cardiomyopathy with systolic or diastolic dysfunction for at least 6 months or HF classified by NYHA class III. The HeartPOD system is a standalone device for use in patients not requiring implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy.
defibrillator (CRT-D) therapy, or who already received ICD or CRT-D therapy. The system monitors LAP with a permanently implantable sensory sensor used in ambulatory patients with HF. These implanted intra-cardiac sensors allow the patient to directly monitor LAP, the intra-cardiac electrogram, and core body temperature. The implant's readings are communicated with a hand-held computer. The information is used to adjust medications on a dose-by-dose basis according to the physician's prescriptive instructions. The HeartPOD System is not available for commercial use in the United States.

The Promote LAP System (St. Jude Medical, Inc., St. Paul, MN) is used for patients with ischemic or non-ischemic cardiomyopathy and class III HF. It is a combinational device for patients who require ICD or CRT-D therapy in addition to LAP monitoring. This device is not available for commercial use in the United States.

There is currently a clinical trial on “Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy (LAPTOP-HF)” that is currently recruiting subjects (estimated enrollment = 730; study start date was April 2010). Devices used are the HeartPOD System or the Promote LAP System (last verified May 2016).

Abraham (2013) stated that HF represents a major public health concern, associated with high rates of morbidity and mortality. A particular focus of contemporary HF management is reduction of hospital admission and re-admission rates. While optimal medical therapy favorably impacts the natural history of the disease, devices such as CRT devices and ICDs have added incremental value in improving HF outcomes. These devices also enable remote patient monitoring via device-based diagnostics. Device-based measurement of physiological parameters, such as intra-thoracic impedance and heart rate variability, provide a means to assess risk of worsening HF and the possibility of future hospitalization. Beyond this capability, implantable hemodynamic monitors have the potential to direct day-to-day management of HF patients to significantly reduce hospitalization rates. The use of a pulmonary artery pressure measurement system has been shown to significantly reduce the risk of HF hospitalization in a large randomized controlled study, the CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients (CHAMPION) trial. Observations from a pilot study also supported the potential use of a left atrial pressure monitoring system and physician-directed patient self-management paradigm; these observations are under further investigation in the ongoing LAPTOP-HF trial.

Maurer and colleagues (2015) noted that daily measurements of LAP may be useful for guiding adjustments in medical therapy that prevent clinical decompensation in patients with severe HF. LAPTOP-HF is a prospective, multi-center, randomized, controlled clinical trial in ambulatory patients with advanced HF in which the safety and clinical effectiveness of a physician-directed
patient self-management therapeutic strategy based on LAP measured twice-daily by means of an implantable sensor will be compared with a control group receiving optimal medical therapy. The trial will enroll up to 730 patients with NYHA functional class III symptoms and either a hospitalization for HF during the previous 12 months or an elevated B-type natriuretic peptide level, regardless of LVEF, at up to 75 investigational centers. Randomization to the treatment group or control group will be at a 1:1 ratio in 3 strata based on the LVEF greater than or less than or equal to 35 % and the presence of a de-novo CRT device indication. The authors stated that the LAPTOP-HF Trial will provide essential information regarding the role of implantable LAP monitoring in conjunction with a new HF treatment paradigm across the spectrum of HF patients.

Mooney and associates (2015) stated that HF is a challenging and highly prevalent medical condition. Hospitalization for acute decompensation is associated with high morbidity and mortality. Despite application of evidence-based medical therapies and technologies, HF remains a formidable challenge for virtually all healthcare systems. Repeat hospitalizations for acute decompensated HF (ADHF) can have major financial impact on institutions and resources. Early and accurate identification of impending ADHF is of paramount importance yet there is limited high quality evidence or infra-structure to guide management in the out-patient setting. Historically, ADHF was identified by physical examination or invasive hemodynamic monitoring during a hospital admission; however, advances in medical microelectronics and the advent of device-based diagnostics have enabled long-term ambulatory monitoring of HF patients in the out-patient setting. These monitors have evolved from piggybacking on cardiac implantable electrophysiological devices to stand-alone implantable hemodynamic monitors that transduce left atrial or pulmonary artery pressures as surrogate measures of left ventricular filling pressure. As technology evolves, devices will likely continue to miniaturize while their capabilities grow. The authors concluded that an important, persistent challenge that remains is developing systems to translate the large volumes of real-time data, particularly data trends, into actionable information that leads to appropriate, safe and timely interventions without overwhelming out-patient cardiology and general medical practices. They stated that future directions for implantable hemodynamic monitors beyond their utility in HF may include management of other major chronic diseases such as pulmonary hypertension, end stage renal disease and portal hypertension.

Abraham (2017) noted that HF is associated with high rates of hospitalization and re-hospitalization, resulting in substantial clinical and economic burden. Current approaches to monitoring patients with HF have done little to reduce these high rates of HF hospitalization. Implantable hemodynamic monitors have been developed to remotely provide direct measurement of intra-cardiac and pulmonary artery pressures (PAP) in ambulatory patients with
HF. The authors stated that these devices have the potential to direct day-to-day management of patients with HF to reduce hospitalization rates.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+".

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<thead>
<tr>
<th>Code</th>
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<td>ICD-10 codes not covered for indications listed in the CPB</td>
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<td>I50.1 - I50.9</td>
<td>Heart failure</td>
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The above policy is based on the following references:


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Amendment to
Aetna Clinical Policy Bulletin Number: 0832
Implantable Left Atrial Hemodynamic Monitor

There are no amendments for Medicaid.

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annual 11/01/2019