HEALTH PLANS
UNIVERSITY OF UTAH

Medical Policy

Implantable Hemodynamic Monitor for Managing Patients with Heart Failure (e.g. CardioMEMS)

Policy MP-035

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Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.

Description:

According to the AHA (American Heart Association), heart failure (HF) is a chronic, progressive condition where the body is not receiving enough oxygen because the heart muscle is unable to pump enough blood throughout the body to meet its need of oxygen from the blood stream. Signs and symptoms of HF described by the National Heart, Lung, and Blood Institute (NHLBI) are trouble breathing or shortness of breath, fatigue, and swelling in the hands, feet, abdomen, legs and veins in the neck and the symptoms worsen as the disease progresses. Which with reduced blood flow to the kidneys, they start to retain sodium and cause the body to build up fluid. When the body starts to build up excess fluid other symptoms such as weight gain, frequent urination. A cough may also develop, from fluid buildup in the lungs, and if it is associated with HF could be pulmonary edema, which would require emergency treatment.

The New York Heart Association (NYHA) categorizes HF by their functional classification system that is based on physical activity limits and the symptomatic status of HF (*see* Table A). The American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) categorize HF based on the development and progression of HF (*see* Table B).

Approximately 5.7 million people in America will be effected with HF and about half of those will die around 5 years after they are diagnosed. There is no cure, it effects children and adults, generally adults 65 and older. The cost to treat HF is estimated around $30 billion a year when you include all health related expenses including: lost work days, healthcare services, and pharmacological treatment associated with HF management (CDC, 2016).

Standard management of HF is to regularly monitor the signs and symptoms such as weight gain, swelling, fatigue, shortness of breath. CardioMEMS (Abbott [acquired from St. Jude Medical Inc. in 2017]) is a minimally invasive, wireless implantable hemodynamic monitoring

device that provides continuous monitoring of pulmonary artery pressure (PAP) for use at home in patients with HF. This device offers an aid for early detection and prevention of HF decompensation with a PAP sensor, a transvenous catheter delivery system, a patient home-monitoring electronic system, and a secure Internet-accessible database that allows clinicians to access patient data. CardioMEMS provides measurement of the systolic, diastolic, and mean PAP, intending to allow for adjustment of HF medical therapy based on pressure trends and specified pressure goals. Once implanted, the patient will take pressure data measurements once daily at home, then the reading is transmitted to the physician to review and make adjustments to the HF treatment if needed.

Policy Statement and Criteria

1. Commercial Plans

U of U Health Plans does NOT cover implantable hemodynamic monitors (e.g. CardioMEMS) for the management of patients with NYHA* Class III heart failure as the safety and efficacy of this device has not been established.

***Table A** - NYHA Heart Failure Functional Classification

NYHA Class	Limitations on Physical Activity	Impact on Physical Activity
I	No limitations	Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea
II	Slight limitation	Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, or dyspnea.
III	Marked limitation	Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
IV	Unable to carry on any physical activity without discomfort	Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

Table B – ACCF and AHA Heart Failure Class System

Class	Symptoms
Class A	No objective evidence of cardiovascular disease. No symptoms and no limitation in ordinary physical activity.
Class B	Objective evidence of minimal cardiovascular disease. Mild symptoms and slight limitation during ordinary activity. Comfortable at rest.
Class C	Objective evidence of moderately severe cardiovascular disease. Marked limitation in activity due to symptoms, even during less-than-ordinary activity. Comfortable only at rest.
Class D	Objective evidence of severe cardiovascular disease. Severe limitations. Experiences symptoms even while at rest.

2. **Medicaid Plans**
   Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

3. **Medicare Plans**
   Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, U of U Health Plans' commercial policies would apply. For the most up-to-date Medicare policies and coverage, please visit their search website at: http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website.

Clinical Rationale

The CHAMPION trial, a 2011 single-blind trial (Abraham et al) found that the CardioMEMS implantable hemodynamic monitoring system reduced the rate of hospital admissions. Sixty-four centers in the U.S were enrolled with patients that had a previous hospital admission for heart failure (HF) and were diagnosed with NYHA class III heart failure, irrespective of the left ventricular ejection fraction. Patients were randomly assigned to their group and masked as to which group they belonged. The treatment group were managed with a wireless implantable hemodynamic monitoring (W-IHM) system and the clinicians used daily measurement of pulmonary artery pressures in addition to standard of care. The control group experienced standard of care alone, both groups were treated for at least 6 months. The primary efficacy end-point was the rate of heart-failure-related hospitalizations at 6 months. The safety end-points assessed at 6 months were freedom from device-related or system-related complications (DSRC) and freedom from pressure-sensor failures. All analyses were by intention to treat. In 6 months, 83 heart-failure-related hospitalizations were reported in the treatment group (n = 270) compared with 120 in the control group (n = 280; rate 0.31 versus 0.44, hazard ratio [HR] 0.70, 95% CI: 0.60 to 0.84, p < 0·0001). During the entire follow-up (mean 15 months [SD 7]), the treatment group had a 39% reduction in heart-failure-related hospitalization compared with the control group (153 versus 253, HR 0.64, 95% CI: 0.55 to 0.75; p < 0.0001). Eight patients had DSRC and overall freedom from DSRC was 98.6% (97.3 to 99.4) compared with a pre-specified performance criterion of 80% (p < 0.0001); and overall freedom from pressure-sensor failures was 100% (99.3 to 100.0).

A 2015 retrospective analysis (Benza et al) of the CHAMPION trial examined the implantable hemodynamic monitor (IHM) in 550 NYHA Functional Class III HF patients, regardless of left ventricular ejection fraction (LVEF) or HF etiology. Evaluations of clinical variables, changes in medical therapy, HF hospitalization rates and survival in patients with and without World Health Organization (WHO) Group II pulmonary hypertension (PH) were conducted. Data were obtained for 314 patients (59%) who had WHO Group II PH. Patients without PH were at significantly lower risk for mortality than PH patients (hazard ratio [HR] 0.31, 95% CI: 0.19 to 0.52, p < 0.0001). Pulmonary hypertension patients had higher HF hospitalization rates than non-PH patients (0.77/year versus 0.37/year; HR 0.49, 95% CI: 0.39 to 0.61, p < 0.001). In patients with and without PH, ongoing knowledge of hemodynamic data resulted in a reduction in HF hospitalization for PH patients (HR 0.64, 95% CI: 0.51 to 0.81, p = 0.002) and for non-PH

patients (HR 0.60, 95% CI: 0.41 to 0.89, p = 0.01). Among PH patients, there was a reduction in the composite end-point of death and HF hospitalization with ongoing knowledge of hemodynamics (HR 0.74, 95% CI: 0.55 to 0.99, p = 0.04), but no difference in survival (HR 0.78, 95% CI: 0.50 to 1.22, p = 0.28). In conclusion WHO Group II PH associated with left heart disease is quite prevalent and identifies HF patients at risk for adverse outcomes. Ongoing knowledge of hemodynamic variables at frequent time intervals from the patient's home, which cannot practically be provided by right heart catheterization (RHC), may allow for more effective treatment strategies to reduce the morbidity of this disease.

Within the CHAMPION trial, a 2016 subgroup analysis by Costanzo et al, compared medical therapy in patients who were managed with CardioMEMS implantable hemodynamic monitors (CM-IHM) and those who received standard management only. In patients managed with CM-IHM for HF (Heart Failure)-related hospitalizations, there was a reduction of stay, the subgroup did an analysis to determine what medical interventions appeared to produce these reductions. Baseline medical therapy was similar among patient groups; however, patients managed with CM-IHM had a significantly higher frequency of medication adjustments, particularly in the number of diuretic (1547 for CM-IHM versus 585 for SM; P<0.001) and vasodilator (293 for CM-IHM versus 104 for SM; P<0.05) dose changes. These findings suggest an inverse relationship between increased medication management and HF rates among patients whose treatment was managed by CM-IHM data.

In a 2017 retrospective cohort study (Desai et al) of 1935 Medicare enrollees who underwent implantation of the CM-IHM following FDA approval, 1114 individuals were continuously enrolled and had evaluable Medicare administrative claims data for at least 6 months before and following implantation to use for the study. A subset of 480 enrollees had complete data for 12 months before and after implantation. The cumulative incidence of HF−related hospitalizations were significantly lower in the post-implantation period than in the preimplantation period at both 6- and 12-month follow-ups. Limitations of this pre-post retrospective study include lack of data on medical history, ejection fraction, indication for implantation and possible confounding due to amplified touchpoints with the health care system necessitated by the device's implantation.

In 2018, Kilic and colleagues examined if there is definitive criteria to establish patient selection for monitoring HF in patients with a CM-IHM. Clinical trials such as the CHAMPION RCT suggest that patients with moderate HF on optimal medical therapy with difficult-to-control volume status and frequent hospitalizations for decompensated HF appear to achieve the most benefit from pressure-guided HF monitoring. Factors such as ejection fraction, PH, or COPD do not seem to suggest an impact of the benefit from CM-IHM on reducing HF-related hospitalization according to a subgroup analyses using data from the CHAMPION RCT. Findings in patients with HF who were not part of a clinical trial, who were included in a large registry analysis, suggested that the benefits of CM-IHM may extend to the general population of patients with HF. Results of another registry analysis (n=430 pts) demonstrated that patients monitored with CM-IHM who subsequently had a LVAD implanted had higher mean PAP levels in the months leading up to LVAD placement compared with patients who did not receive LVAD placement, suggesting that CM-IHM may aid in clinical decision making about the timing of LVAD implant and the management of LVAD patients. In conclusion, the authors found that further studies are needed to establish definitive patients' selection criteria for the monitoring HF with CM-IHM, as currently there is not enough data to determine this criteria.

The Food and Drug Administration (FDA) approved the CardioMEMS heart failure (HF) Pressure Measurement System on May 28, 2014 (P100045). This system is indicated for patients with New York Heart Association class III HF who have been hospitalized for HF in the previous year, to wirelessly

measure and monitor PAP and heart rate. However, On June 14, 2018, Abbott Laboratories initiated a recall which remains open as of December 13, 2018. The manufacturer noted that "A small number of CardioMEMS Hospital Electronic Systems (Model CM3000) and Patient Electronics Systems (Model CM1100) may deliver a system error. While the error message is intended to present if the electronics system exceeds a certain temperature, these units may deliver a false error message due to an incorrectly configured component within the device electronics. The firm is requesting return of the units." (Recall number Z-2522-2018).

The CardioMems is a sensor percutaneously placed into the pulmonary artery and is utilized for continuous hemodynamic monitoring of those being managed for CHF (Yancy et al, 2017). It has been developed as a means to assist in the treatment of such individuals. Evaluation of this device has consisted of single-blinded trials, as well as some retrospective and sub- group analyses. These assessments have essentially demonstrated that the device may decrease hospitalizations for those with congestive heart failure. Specifically, those with more severe CHF (NYHA class III) and/or those who have been hospitalized more frequently experienced a lower hospitalization rate. A sub-group analysis of the CHAMPION Trial demonstrated that those with the device had a higher frequency of medication adjustments, which possibly lead to a lower hospitalization rate. However, as these were basically retrospective, single-blinded, and sub- group analyses a benefit of the device towards overall improved cardiac outcomes has not been definitively established. Additionally, a mortality benefit or long-term quality of life benefit has also not been established. Thus, there is no definitive evidence that the monitor, compared to conventional medical management and clinical monitoring, has been established as standard of care towards improved overall CHF or cardiac outcomes (morbidity and mortality). As such the plan criteria appropriately does not cover the device for the management of patients with NYHA class III heart failure as the safety and efficacy of this device is not been established.

Hayes published a health technology brief on the CardioMEMS implantable hemodynamic monitor for managing patients with heart failure in Jan 2019. They found a very-low-quality body of evidence that was insufficient to draw conclusions regarding the safety and efficacy of the CM-IHM in adults with NYHA class III HF. Limited evidence suggested management of HF patients with CM-IHM in addition to standard care, reduced the incidence of HF-related hospitalization. In conclusion, the authors found that substantial uncertainty remains about the comparative effectiveness of CM-IHM with standard monitoring and the impact of CM-IHM on long-term patient's safety, mortality, survival, and quality of life. Further studies are needed to provide comparative evidence for the long-term benefits and harms of CM-IHM.

Applicable Coding

CPT Codes

93701 Bioimpedance-derived physiologic cardiovascular analysis

93799 Unlisted cardiovascular service or procedure

HCPCS Codes

No applicable codes

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