Subject: Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS) for Congestive Heart Failure		Original Effective Date: 2/8/2021
Policy Number: MCP-393	Revision Date(s):	
MCPC Approval Date: 2/8/2021	Review Date:	

Contents

DISCLAIMER

This Molina clinical policy is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina clinical policy document and provide the directive for all Medicare members.[1]

POSITION STATEMENT RECOMMENDATION

The Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS) for Congestive Heart Failure is considered experimental, investigational and unproven due to insufficient published evidence to assess the safety and/or impact on health outcomes.

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

CardioMEMS Implantable Hemodynamic Monitor

The CardioMEMS™ Heart Failure (HF) System [Abbott] is a wireless pulmonary artery (PA) monitor for use at home to reduce heart failure hospital admissions in New York Heart Association (NYHA) class III patients.* This system is permanently implanted in the pulmonary artery using a right-heart catheterization procedure and may be performed by a cardiac surgeon in the out-patient setting. Patient-initiated sensor readings are then wirelessly transmitted on a daily basis to an electronics unit and stored in a secure website for the physician and clinical team to access and review and make any necessary treatment adjustments with the goal of reducing heart failure hospitalizations.

Congestive Heart Failure

Congestive heart failure (CHF) describes the condition of fluid build-up in the body as the heart inefficiently fills with or pumps out blood. CHF results from conditions that weaken the heart muscle including coronary artery disease, myocardial infarction, cardiomyopathy, and hypertension, and is a major public health concern. Management of CHF is guided by treating the underlying cause which is often a chronic systemic disease process and includes hypertension, diabetes, coronary artery disease, valvular heart disease, or myocarditis and lifestyle improvements (e.g., diet, exercise, smoking cessation). The morbidity, mortality, and costs associated with the condition remain high despite the fact that a variety of evidence-based medical and device therapies for CHF are available. The severity of CHF is often classified according to the New York Heart Association (NYHA) system of classification by patient functional status. These classes commonly appear in treatment guidelines and as enrollment criteria for CHF clinical trials:

- Class I - individuals with cardiac disease but without resulting limitation of physical activity; ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain; symptoms only occur on severe exertion.
- Class II - individuals with cardiac disease resulting in slight limitation of physical activity; they are comfortable at rest; ordinary physical activity (e.g., moderate physical exertion such as carrying shopping bags up several flights of stairs) results in fatigue, palpitation, dyspnea, or anginal pain.
- *Class III - individuals with cardiac disease resulting in marked limitation of physical activity; they are comfortable at rest; less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.
- Class IV - individuals with cardiac disease resulting in inability to carry on any physical activity without discomfort; symptoms of heart failure or the anginal syndrome may be present even at rest; if any physical activity is undertaken, discomfort is increased

FDA

The CardioMEMS Heart Failure Pressure Measurement System received Premarket Approval (PMA) on May 28, 2014 (P100045). The system is approved for wirelessly measuring and monitoring pulmonary artery (PA) pressure and heart rate in New York Heart Association (NYHA) Class III heart failure patients who have been hospitalized for heart failure in the previous year.

CONTINUATION OF THERAPY

N/A

LIMITATIONS

Contraindications for wireless PA monitoring include but are not limited to all of the following:

- ❑ Absolute:
  - Inability to take dual antiplatelet or anticoagulants for 1 month postimplant.
- ❑ Relative:
  - Active infection, coagulation disorders, congenital heart disease, mechanical heart valves, hypersensitivity or allergy to aspirin or clopidogrel.
  - History of recurrent pulmonary embolism or deep vein thrombosis (> 1).
  - Body mass index > 35 and axillary level chest circumference > 165 centimeters.
  - Implanted cardiac resynchronization device within the past 3 months.
  - Glomerular filtration rate < 25 milliliters per minute and nonresponsive to diuretic therapy or on chronic renal dialysis.

SUMMARY OF MEDICAL EVIDENCE [5-26]

The current peer reviewed published evidence is insufficient to support the use of ambulatory cardiac hemodynamic monitoring using an implantable pulmonary artery pressure measurement device in individuals with heart failure in an outpatient setting. Additional well-designed and high quality RCTs are necessary to establish whether health outcomes are significantly improved relative to standard of care for heart failure management. A summary of the studies is provided below.

Abraham and colleagues (2011) evaluated individuals with New York Heart Association (NYHA) Class III heart failure, who had been hospitalized for heart failure at least once in the previous 12 months in a prospective, single-blinded, multi-center study known as the CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients) trial. After implantation of the pressure sensor, study participants (n=550) were randomized either to the treatment group that consisted of wireless pulmonary artery pressure monitoring and standard of care (n=270) or into a control group that consisted of participants who received only standard of care (n=280); the control arm's device measurements were not made available to investigators for monitoring and management. The primary outcome measure was the rate of hospitalization due to heart failure in the first 6 months following implantation with the device. Quality of life (QOL) measures were included as secondary outcomes. Additional safety outcomes included complications associated with the device or sensor, and pressure-sensor failures. Participants were trained to take daily pulmonary artery pressure measurements at home, and were blinded to their treatment group. Follow-up assessments were scheduled at 1, 3, and 6 months, and subsequently every 6 months afterward. Study results indicated a statistically significant 30% reduction in the primary outcome of hospital readmissions for heart failure at the 6-month follow-up in the treatment group compared with the control group (hazard ratio [HR]=0.72; 95% confidence interval [CI], 0.60 to 0.85; p=0.0002). Additionally, the length of hospital stay for heart failure-related admissions was significantly shorter in the treatment group compared with

the control group (2.2 days compared with 3.8 days, respectively; p=0.02). The QOL score, using the Minnesota Living with Heart Failure Questionnaire (MLHFQ) Total Score, was significantly improved in the treatment group compared with controls (p=0.02), when assessed at 6 months follow-up. A total of 15 adverse events occurred, 8 of which were considered complications related to the device or system (n=3 treatment group; n=3 control group; n=2 not enrolled). None of the 550 participants experienced sensor-related failures during the entire follow-up period (average of 15 months). [7]

In 2015, Abraham and colleagues published follow-up data to the CHAMPION trial. After completion of the initial randomized access period (average of 18 months), investigators were granted access to pulmonary artery pressure for subjects in both study arms (open access period) for an average of an additional 13 months of follow-up. Over the randomized access period, the reduction in hospital admission rates related to heart failure were sustained, and found to be 33% lower in the treatment group compared to the control group (HR=0.67, 95% CI, 0.55-0.80; p<0.0001). During the open access period, rates of hospital admission related to heart failure for the former control group were reduced by 48% (HR=0.52, 95% CI, 0.40-0.69; p<0.0001) compared to admission rates during the random access period. Heart failure-related mortality and all-cause mortality were not significantly different between the two study arms during the random access period or the open access period. No additional device-related failures were reported. [6]

Desai (2017) published a retrospective cohort study of Medicare administrative claims data for individuals who received the CardioMems device following FDA approval. Out of 1935 Medicare enrollees who underwent implantation of the device, there were 1114 who were continuously enrolled and had evaluable data for at least 6 months prior to, and following, implantation (a subset of 480 enrollees had complete data for 12 months before and after implantation). There were 1020 heart failure-related hospitalizations in the 6 months before implantation, relative to 381 hospitalizations in addition to 17 ventricular assisted device (VAD) implantations or transplants, and 139 deaths in the 6-month post implantation follow-up period. The cumulative incidence of hospital-related heart failure was significantly lower than in the 6 months prior to implantation (HR=0.55; 95% CI: 0.49-0.61; p<0.001). Similarly, amongst the 480 individuals with 12-month follow-up data, there were 696 heart failure-related hospitalization in the 12 months prior to implantation, compared to 300 heart failure-related hospitalizations following implantation. There were also 15 VAD implantations or transplants, and 106 deaths. The cumulative incidence of heart failure-related hospitalizations was also significantly lower in the 12-month post implantation cohort (HR=0.66; 95% CI: 0.57-0.76; p<0.001). Despite the trial's positive outcomes, claims data limitations include that it is not possible to rule out confounding due to medication changes/adjustments, or correlate outcomes to direct intervention based on pulmonary artery pressure data. The primary outcome, reduction in hospital-related heart failure, may be related to the device or simply the amplified touch-points with the healthcare system necessitated by the device's implantation, and the limited follow-up period in addition to the lack of a control cohort leave the safety and efficacy of the CardioMems device still uncertain. [15]

In 2017, Heywood and colleagues published retrospective data from a de-identified cohort of the first 2000 individuals who received the CardioMEMS device and had available follow-up data for a minimum of 6 months (general-use cohort). The primary outcome of interest was trends in remotely monitored pulmonary artery pressures. The mean age of the cohort enrolled was 70 years (standard deviation [SD]=12 years) and the mean follow-up period was 333 days (SD=125 days). Relative to the previously described CHAMPION clinical trial, general-use cohort in this study had a trend of a higher baseline mean arterial pressure (34.9 ± 10.2 mm Hg vs.

31.6 ± 10.7 mm Hg for the CHAMPION cohort; p<0.05). The pulmonary artery pressure reductions in the general-use cohort from this study were significantly higher compared with the CHAMPION trial treatment cohort (p-value unreported) who had an AUC of -150.1 mm Hg-days after 6 months of pressure-guided care whereas the general-use cohort had an AUC of -434 mm Hg-days after 6 months and mean pulmonary artery pressure was reduced from 34.9 ± 10.2 to 31.6 ± 10.4 mm Hg after 6 months (p<0.0001). In this 'real-world' cohort, there was a median of 1.2 days between remote pressure transmissions and > 98% weekly use of the system, demonstrating a high-level of adherence. However, similar to the limitations cited in the CHAMPION trial, safety and efficacy conclusions are precluded by the lack of mortality-related data and lack of long-term follow-up data. Further, the registry data of this study cannot rule out medication changes/adjustments as a potential confounding variable. [18]

PROFESSIONAL SOCIETY GUIDELINES [27-31]

CTAF/ICER

In December of 2015 the final report was published from the California Technology Assessment Forum (CTAF) evaluating the safety and efficacy of the CardioMEMS HF System. The report is entitled "CardioMEMS™ HF System (St. Jude Medical, Inc.) and Sacubitril/Valsartan (Entresto™, Novartis AG) for Management of Congestive Heart Failure: Effectiveness, Value, and Value-Based Price Benchmarks". The summary of the report states: "For patients with Class III CHF with either reduced or preserved ejection fraction who have been hospitalized in the prior 12 months, we judge there to be moderate certainty of a small net benefit for the CardioMEMS HF System compared with usual monitoring of patients' signs and symptoms. There is moderate certainty because while the CHAMPION trial indicated that patients had fewer hospitalizations when care was informed by the CardioMEMS HF System, the results of the CHAMPION study are limited by concerns regarding the potential confounding influence of the study nurse on the superior outcomes in the treatment arm. In addition, while post-hoc analyses have been presented illustrating reductions in cardiovascular mortality with CardioMEMS, there have been no published data from trials powered to detect mortality differences. It seems reasonable to surmise that ongoing post-marketing trials evaluating the device may demonstrate a wide variety of outcomes, from substantial net health benefit to a small likelihood of overall "negative" benefit given the potential harms associated with device placement. Therefore, we judge the current body of evidence on CardioMEMS to be "promising but inconclusive" using the ICER Evidence Rating framework." [26]

Hayes:

According to a recent Health Technology Assessment report (April, 2020) entitled "CardioMEMS Implantable Hemodynamic Monitor (Abbott) For Managing Patients With Heart Failure": "A very-low-quality body of evidence suggests that management of heart failure (HF) patients with the CardioMEMS Implantable Hemodynamic Monitor (CM-IHM) may reduce the incidence of HF related hospitalization. However, substantial uncertainty remains about the comparative effectiveness of the CM-IHM with standard monitoring and the impact of CM-IHM on long-term health benefits, including mortality, survival, overall patient management, safety, and quality of life. Additional studies are needed to provide comparative evidence for the long-term benefits and harms of CM-IHM.". A summary of the studies states that "FDA approval was based on

a multicenter randomized controlled trial (RCT) (the CHAMPION trial) that compared CardioMEMS Implantable Hemodynamic Monitor with standard monitoring practices in 550 patients with NYHA functional class III HF. The 6-month and long-term results of this trial are reported in two publications. [5 7] A series of retrospective analyses of CHAMPION trial data are reported. These studies analyzed the outcomes of heart failure monitoring with CardioMEMS Implantable Hemodynamic Monitor among various patient subgroups, including patients with left ventricular ejection fraction (LVEF) ≥ 40% and ≥ 50% [11], PH [12], COPD [21], right heart catheterization (RHC), [23] heart failure medication changes, [14] and LVEF ≤ 40%. [17] One cohort study (n=66) compared CardioMEMS Implantable Hemodynamic Monitor with standard monitoring practices,[19] and 3 retrospective registry analyses evaluated the efficacy of CardioMEMS Implantable Hemodynamic Monitor in patients with heart failure.[15 18 20] These studies suggest that monitoring with CardioMEMS Implantable Hemodynamic Monitor in addition to standard care may reduce the rate of heart failure associated hospitalization. Considerable doubt remains about the comparative effectiveness of CardioMEMS Implantable Hemodynamic Monitor with standard monitoring and the impact of CardioMEMS Implantable Hemodynamic Monitoring on long-term patient safety, mortality, and quality of life." [30]

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for longterm hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed
93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional.
93799	Unlisted cardiovascular service or procedure [when specified as implantation of a wireless pressure sensor in the pulmonary artery]

HCPCS	Description
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components

ICD-10	Description: [For dates of service on or after 10/01/2015]
150.1-150.9	Heart Failure

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REVISION/REVIEW HISTORY:

2/8/2021: New Policy

Appendix

***Definitions**

New York Heart Association (NYHA) Definitions: The NYHA classification of heart failure is a 4-tier system that categorizes subjects based on subjective impression of the degree of functional compromise. The four NYHA functional classes are as follows:

- Class I - individuals with cardiac disease but without resulting limitation of physical activity; ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain; symptoms only occur on severe exertion.
- Class II - individuals with cardiac disease resulting in slight limitation of physical activity; they are comfortable at rest; ordinary physical activity (e.g., moderate physical exertion such as carrying shopping bags up several flights of stairs) results in fatigue, palpitation, dyspnea, or anginal pain.
- Class III - individuals with cardiac disease resulting in marked limitation of physical activity; they are comfortable at rest; less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.
- Class IV - individuals with cardiac disease resulting in inability to carry on any physical activity without discomfort; symptoms of heart failure or the anginal syndrome may be present even at rest; if any physical activity is undertaken, discomfort is increased.