| **Priority Health** | **MEDICAL POLICY** |
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| | **No. 91610-R3** |

## IMPLANTABLE HEART FAILURE MONITORS

| **Effective Date:** December 1, 2024 | **Review Dates:** 5/15, 5/16, 5/17, 8/17, 5/18, 5/19, 5/20, 5/21, 5/22, 5/23, 5/24, 11/24 |
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| **Date Of Origin:** May 13, 2015 | **Status:** Current |

**Summary of Changes**

Changes:
- I. B. 4. Annual reporting of specified outcome measures is no longer required. Rather, requirement is that the data collected from the CardioMEMS device is monitored regularly.

Clarifications:
- I. B. 3. The treating provider and the member have access to a reliable internet connection that allows remote heart failure monitoring.

I. **POLICY/CRITERIA**

Implantable hemodynamic monitors (e.g., CardioMEMS™ HF System) for heart failure may be considered medically necessary when **both (A&B)** of the following are met:

A. Clinical Indications, **both 1 & 2:**

1. **All** of the following:
   a. Diagnosis of NYHA class III within 14 days of implanting procedure
   b. At least one heart failure hospitalization in previous 12 months
   c. Reduced EF patients are/have received beta blocker for 3 months and an ACE-I or ARB for one month unless patient is intolerant to medication therapy
   d. If BMI is greater than or equal to 35, then chest circumference at axillary level must be less than 165cm
   e. Pulmonary artery branch diameter is greater than or equal to 7mm – assessed during the right heart catheterization procedure
   f. Must be able to tolerate right heart catheterization procedure
   g. Documented Advance Care Planning discussion including the designation of a Durable Power of Attorney for Healthcare (DPOAHC)/Patient Advocate

   **AND**

2. **None** of the following:
   a. Active infection
   b. History of recurrent pulmonary embolism or deep vein thrombosis

    c. Major cardiovascular event within previous 2 months

    d. Cardiac resynchronization therapy (CRT) likely in next 3 months or within the previous 3 months

    e. Congenital heart disease or mechanical right heart valve that is contraindicated for right heart catheterization

    f. Likely to undergo evaluation for heart transplant or VAD implantation within the next 6 months

    g. Known coagulation disorders

    h. Hypersensitivity or allergy to aspirin, and/or clopidogrel

B. Clinic, Provider and Program Requirements - **all** of the following:

    1. Physician medical director who:

        a. devotes more than 40% of their practice in managing advanced heart failure patients

        **AND**

        b. is board certified or eligible in advanced heart failure management consistent with the ABIM subspecialty requirements.

    2. A multi-disciplinary team of professionals dedicated to the management of heart failure patients, including but not limited to a clinical pharmacist and social worker.

    3. The treating provider and the member have access to a reliable internet connection that allows remote heart failure monitoring.

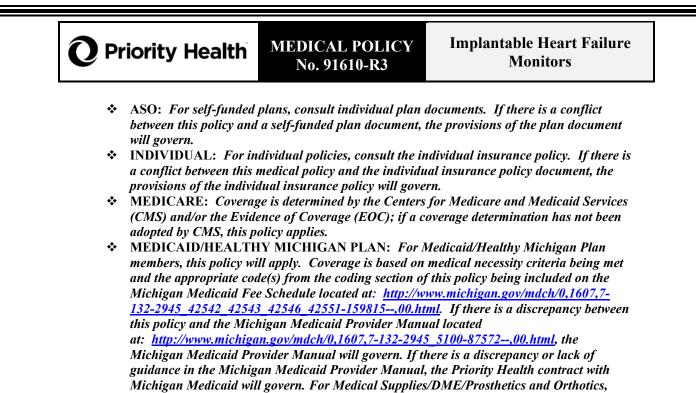    4. The data collected from the CardioMEMS device is monitored regularly.

## II.   MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

## III.   APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
❖ **POS:** *This policy applies to insured POS plans.*
❖ **PPO:** *This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.*

- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.*
- ❖ **MEDICAID/HEALTHY MICHIGAN PLAN:** *For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at:* [http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html). *If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at:* [http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html), *the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.*

## IV. DESCRIPTION

An implantable heart failure monitor (e.g. CardioMEMS HF System) is a permanently implantable sensor that wirelessly monitors pulmonary artery pressures and other hemodynamic parameters, and transmits data to clinicians managing patients with heart failure.

The best available published evidence for the CardioMEMS HF System is limited to the FDA pivotal CHAMPION trial (Abraham et al., 2011). CHAMPION was a manufacturer-sponsored randomized controlled trial that enrolled patients from 64 U.S. centers with HF management experience. The sponsor monitored, collected, and maintained trial data.

The CHAMPION trial (NCT00531661) enrolled patients with NYHA Class III HF who had been hospitalized for HF within the previous 12 months. The majority of patients were white (73%) and male (~73%). All patients were implanted with the CardioMEMS HF device and then randomly allocated to either the treatment group (n=270) or the control group (n=280). Patients in both groups transmitted data from the monitoring system to the clinician accessible CardioMEMS database. Transmissions to clinicians from control group patients were turned off. Changes in patient management were based on CardioMEMS data in the treatment group, and on patient-reported signs and symptoms in the control group. The primary efficacy endpoint was rate of HF-related hospitalizations during 6 months after sensor insertion, which was significantly lower in the treatment group versus the control group (31% versus 44%). Length of hospital stay for HF-related admissions was significantly shorter in the

treatment group versus the control group (2.2 days versus 3.8 days). Significantly more changes were made in HF drug management for patients in the treatment group than for those in the control group (9.1 and 3.8 mean changes per patient, respectively). The 2 primary safety endpoints were device- or system-related complications. Both were met. The CHAMPION trial has been criticized for both conduct and methodological flaws that may have biased published and unpublished outcomes in favor of the treatment group (Loh et al.).

**FDA response to criticism of the CHAMPION trial:**
In the CHAMPION clinical trial, provision of PA pressures to physicians for patients in the Treatment group led physicians to intensify the use of medications for heart failure (particularly diuretics and nitrates) in these patients far more frequently than in the patients in the Control group. In the Control group, the doses of medications for heart failure were altered 1061 times, based on changes in signs and symptoms of heart failure. In contrast, in the Treatment group, the doses of medications for heart failure were altered 2517 times, based not only on changes in signs and symptoms of heart failure, but also directed by knowledge of PA pressures outside the normal range.

This marked difference in the use of medications for heart failure was accompanied by a highly significant effect on the primary endpoint of the trial: the rate of hospitalizations for heart failure during the first 6 months of the trial. There were 84 hospitalizations for heart failure in the Treatment group, as compared with 120 hospitalizations for heart failure in the Control group. This 28% lower rate of hospitalization for heart failure was highly significant (p=0.0002). All pre-specified secondary endpoints were also achieved, and the device fulfilled all pre-specified safety and performance assessments.

During the entire Randomized Access period (Part 1) (mean 17.6 months), there were 182 hospitalizations for heart failure in the Treatment group, as compared with 279 hospitalizations for heart failure in the Control group. This 33% lower rate of hospitalization for heart failure was highly significant (p=0.0002), indicating the durability of the treatment effect.

The preliminary finding of a treatment-by-gender interaction for the effect of the device on the rate of hospitalizations for heart failure appears to have been related to (1) the play of chance as a result of the small number of events in women; and (2) the competing risk of an excess of early deaths in women in the Control group. When these limitations were addressed by an analysis of the combined risk of death or hospitalization for heart failure for the entire Randomized Access period, there was neither a qualitative nor quantitative treatment-by-gender interaction, and there was evidence for a treatment effect independent of gender.

The CHAMPION trial was characterized by very frequent and active intervention in the treatment arm of the trial. Principle investigators in the trial consisted of

experienced advanced heart failure cardiologists who were quite involved in helping to assure that these interventions were performed. This therefore suggests that achievement of these benefits will require a similar degree of intensive monitoring, frequent contact with the patients and guidance by clinicians experienced in the management of patients with complex heart failure syndromes.

**Other Evidence**
The hemodynamic-GUIDEed management of Heart Failure (GUIDE-HF) trial was a multicenter, single-blind study at 118 centers in the USA and Canada. Following successful implantation of a pulmonary artery pressure monitor, patients with all ejection fractions, NYHA functional class II–IV chronic heart failure, and either a recent heart failure hospitalization or elevated natriuretic peptides were randomly assigned (1:1) to either hemodynamic-guided heart failure management based on pulmonary artery pressure or a usual care control group. Patients were masked to their study group assignment. Investigators were aware of treatment assignment but did not have access to pulmonary artery pressure data for control patients. The primary endpoint was a composite of all-cause mortality and total heart failure events (heart failure hospitalisations and urgent heart failure hospital visits) at 12 months assessed in all randomly assigned patients. Safety was assessed in all patients. 1022 patients were enrolled, with 1000 patients implanted successfully. There were 253 primary endpoint events (0.563 per patient-year) among 497 patients in the hemodynamic-guided management group (treatment group) and 289 (0.640 per patient-year) in 503 patients in the control group (hazard ratio [HR] 0.88, 95% CI 0.74–1.05; p=0.16). A prespecified COVID-19 sensitivity analysis using a time-dependent variable to compare events before COVID-19 and during the pandemic suggested a treatment interaction (p interaction=0.11) due to a change in the primary endpoint event rate during the pandemic phase of the trial, warranting a pre-COVID-19 impact analysis. In the pre-COVID-19 impact analysis, there were 177 primary events (0.553 per patient-year) in the intervention group and 224 events (0.682 per patient-year) in the control group (HR 0.81, 95% CI 0.66–1.00; p=0.049). This difference in primary events almost disappeared during COVID-19, with a 21% decrease in the control group (0.536 per patient-year) relative to pre-COVID-19, virtually no change in the treatment group (0.597 per patient-year), and no difference between groups (HR 1.11, 95% CI 0.80–1.55; p=0·53). The cumulative incidence of heart failure events was not reduced by hemodynamic-guided management (0.85, 0.70–1.03; p=0.096) in the overall study analysis but was significantly decreased in the pre-COVID-19 impact analysis (0.76, 0.61–0.95; p=0.014). 1014 (99%) of 1022 patients had freedom from device or system-related complications (Lindenfeld et al, 2021)

MONITOR-HF was an open-label, randomized trial, done in 25 centers in the Netherlands. Eligible patients had chronic heart failure of New York Heart Association class III and a previous heart failure hospitalization, irrespective of ejection fraction. Patients were randomly assigned (1:1) to hemodynamic

monitoring or standard care. All patients were scheduled to be seen by their clinician at 3 months and 6 months, and every 6 months thereafter, up to 48 months. The primary endpoint was the mean difference in the Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary score at 12 months. 348 patients were randomly assigned to either the CardioMEMS-HF group (n=176 [51%]) or the control group (n=172 [49%]). The median age was 69 years (IQR 61–75) and median ejection fraction was 30% (23–40). The difference in mean change in KCCQ overall summary score at 12 months was 7·13 (95% CI 1·51–12·75; p=0·013) between groups (+7·05 in the CardioMEMS group, p=0·0014, and –0·08 in the standard care group, p=0·97). In the responder analysis, the odds ratio (OR) of an improvement of at least 5 points in KCCQ overall summary score was OR 1·69 (95% CI 1·01–2·83; p=0·046) and the OR of a deterioration of at least 5 points was 0·45 (0·26–0·77; p=0·0035) in the CardioMEMS-HF group compared with in the standard care group. The freedom of device-related or system-related complications and sensor failure were 97·7% and 98·8%, respectively. (Brugts et al., 2023)

In a meta-analysis by Curtain and colleagues, five trials comparing IHM-guided care with standard care alone were identified and included 2,710 patients across ejection fraction (EF) ranges. Data were available for 628 patients (23.2%) with heart failure with preserved ejection fraction (HFpEF) (EF ≥50%) and 2023 patients (74.6%) with heart failure with a reduced ejection fraction (HFrEF) (EF <50%). Chronicle, CardioMEMS and HeartPOD IHMs were used. In all patients, regardless of EF, IHM-guided care reduced total HF hospitalizations (HR 0.74, 95% CI 0.66 to 0.82) and total worsening HF events (HR 0.74, 95% CI 0.66 to 0.84). In patients with HFrEF, IHM-guided care reduced total worsening HF events (HR 0.75, 95% CI 0.66 to 0.86). The effect of IHM-guided care on total worsening HF events in patients with HFpEF was uncertain (fixed-effect model: HR 0.72, 95% CI 0.59 to 0.88; random-effects model: HR 0.60, 95% CI 0.32 to 1.14). IHM-guided care did not reduce mortality (HR 0.92, 95% CI 0.71 to 1.20). IHM-guided care reduced all-cause mortality and total worsening HF events (HR 0.80, 95% CI 0.72 to 0.88). The authors concluded that IHM-guided care reduced total HF hospitalizations and worsening HF events, and that this benefit was consistent in patients with HFrEF but not consistent in HFpEF. (Curtain et al., 2023)

**Guidelines and Position Statements**
**American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Failure Society of America (HFSA) -** 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines
- "CM-IHM monitoring among patients with New York Heart Association (NYHA) class III HF with HF-related hospitalization (HFH) in the past year or elevated natriuretic peptide levels and on the maximum tolerated

doses of guideline-directed medical therapy (GDMT) with optimal device therapy is uncertain to reduce the risk of subsequent HFH events" (strength, 2b [weak]; level of evidence, B-R) (p. e916).

- "CM-IHM monitoring in patients with NYHA class III HF with HFH within the prior year provides uncertain cost-benefit value" (level of evidence, B-NR) (p. e916) (Heidenreich PA, et al. 2022)

**European Society of Cardiology (ESC) -** 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

- "This 2021 ESC guideline is focused on making evidence-based recommendations specific to the diagnosis and treatment of HF. The ESC working group determined that pulmonary artery pressure (PAP) monitoring with a wireless system (e.g., CM-IHM) may be considered to improve clinical outcomes in patients with symptomatic HF" (strength, IIb; level of evidence, B) (McDonagh et al., 2021)

**National Institute for Health and Care Excellence (NICE) -** Interventional procedures guidance: Percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure (2021)

- NICE released a 2021 interventional procedures guidance (IPG) evaluating the safety and efficacy of percutaneously implanted PAP sensors for monitoring HF. Eight of the 9 studies that factored into the NICE assessment evaluated CM-IHM, while the ninth appraised the Cordella PAP sensor (Endotronix). Based on data from these 9 studies, the NICE found that the evidence base is adequate to support the use of percutaneously implanted PAP sensors for managing chronic HF (NICE, 2021).

**Norwegian Institute of Public Health (NIPH)**

- The NIPH conducted a single technology assessment (STA) of CM-IHM for the management of patients with NYHA class III HF in 2016. In assessing the available published evidence, the NIPH determined that CM-IHM likely reduces the rate of HFH compared with standard care and it appears to be a safe intervention. However, the NIPH report also acknowledges the reliance on the CHAMPION trial for reliable data and suggests these observations may change with increased publications from other trials (Pike et al., 2016).

## V.    CODING INFORMATION

**ICD-10 Codes** that may apply:
I50.1      Left ventricular failure

I50.20    Unspecified systolic (congestive) heart failure
I50.22    Chronic systolic (congestive) heart failure
I50.23    Acute on chronic systolic (congestive) heart failure
I50.30    Unspecified diastolic (congestive) heart failure
I50.32    Chronic diastolic (congestive) heart failure
I50.40    Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.42    Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43    Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.9     Heart failure, unspecified

**CPT/HCPCS CODES:**
33289   Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term 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
93297   Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional
93298   Interrogation device evaluation(s), (remote) up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional
C2624   Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components (*OP facility only*)
G0555   Provision of replacement patient electronics system (e.g., system pillow, handheld reader) for home pulmonary artery pressure monitoring *(Not Covered for Medicaid)*

**NOT COVERED**
C1833   Monitor, cardiac, including intracardiac lead and all system components (implantable)

## VI.   REFERENCES

Abraham WT(1), Adamson PB, Bourge RC, Aaron MF, Costanzo MR, Stevenson LW,Strickland W, Neelagaru S, Raval N, Krueger S, Weiner S, Shavelle D, Jeffries B, Yadav JS; CHAMPION Trial Study Group. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. Lancet. 2011 Feb 19; 377(9766):658-66.

CardioMEMS Champion HF Monitoring System PMA Amendment P100045 FDA and CardioMEMS Panel Package Prepared for the October 9, 2013 Circulatory System Devices Panel Meeting

Loh JP, Barbash IM, Waksman R. Overview of the 2011 Food and Drug Administration Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting on the CardioMEMS Champion Heart Failure Monitoring System. J Am Coll Cardiol. 2013 Apr 16;61(15):1571-6.

Hauptman, P. J., et. al. The Heart Failure clinic: A consensus statement of the Heart Failure Society of America, Journal of Cardiac Failure Vol. 14, No. 10, 2008

Hayes, Inc. CardioMEMS HF System Prognosis Overview, August 2014

Hayes, Inc. Wireless Pulmonary Artery Pressure Monitoring with CardioMEMS HF System (St. Jude Medical Inc.) for Management of Chronic Heart Failure, November 22, 2016 and annual reviews.

Hayes, Inc. CardioMEMS Implantable Hemodynamic Monitor (Abbott) For Managing Patients With Heart Failure. Health Technology Assessment.December 27, 2018.

Lindenfeld J, et al. Haemodynamic-guided management of heart failure (GUIDE-HF): a randomised controlled trial. Lancet. 2021 Sep 11;398(10304):991-1001. doi: 10.1016/S0140-6736(21)01754-2. Epub 2021 Aug 27. Curtain JP, et al. Efficacy of implantable haemodynamic monitoring in heart failure across ranges of ejection fraction: a systematic review and meta-analysis. Heart. 2023 May 15;109(11):823-831. doi: 10.1136/heartjnl-2022-321885.

Brugts JJ, et al. Remote haemodynamic monitoring of pulmonary artery pressures in patients with chronic heart failure (MONITOR-HF): a randomised clinical trial. Lancet. 2023 Jun 24;401(10394):2113-2123. doi: 10.1016/S0140-6736(23)00923-6. Epub 2023 May 20. Erratum in: Lancet. 2023 Jun 24;401(10394):2112. doi: 10.1016/S0140-6736(23)01256-4.

Heidenreich PA, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022 May 3;145(18)

McDonagh TA, et al. 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur Heart J. 2021 Sep 21;42(36):3599-3726. doi: 10.1093/eurheartj/ehab368. Erratum in: Eur Heart J. 2021 Dec 21;42(48):4901. doi: 10.1093/eurheartj/ehab670.

Pike E, Bjerkan AM, Fagerlund BC, Hamidi V, Harboe I, Klemp M. *Continuous Monitoring of Pulmonary Artery Pressure Via an Implanted Leadless and Battery Less Pressure Sensor for the Management of Patients with Moderate to Severe Heart Failure (New York Heart Association Class III)* [Internet]. Oslo, Norway: Knowledge Centre for the Health Services at the Norwegian Institute of Public Health (NIPH); October 2016. PMID: 29553639.

NICE. (2021). *Percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure* [Interventional procedures guidance [IPG711]]. https://www.nice.org.uk/guidance/ipg711

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