NO. 91610

IMPLANTABLE HEART FAILURE MONITORS

Effective: 06/01/2026
Committee review: 05/13/2026
Last Updated: 05/13/2026

Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This policy addresses implantable hemodynamic monitors (e.g., CardioMEMS™ HF System, Cordella Pulmonary Artery Sensor System (CorPASS)) for heart failure.

Related policies: None identified

I. MEDICAL NECESSITY CRITERIA

A. Implantable hemodynamic monitors (e.g., CardioMEMS™ HF System, Cordella Pulmonary Artery Sensor System (CorPASS)) for heart failure may be considered medically necessary when both (A&B) of the following are met:
   1. Clinical Indications, both a & b:
      a. All of the following:
         i. Diagnosis of NYHA class III within 14 days of implanting procedure
         ii. At least one heart failure hospitalization in previous 12 months
         iii. Reduced ejection fraction (EF) and prescribed guideline-directed medical therapy (e.g., AHA/ACC/HFSA guidelines)
         iv. If BMI is greater than or equal to 35, then chest circumference at axillary level must be less than 165cm

v. Pulmonary artery branch diameter is greater than or equal to 7mm – assessed during the right heart catheterization procedure
vi. Provider attests that the patient is in a stable condition and able to tolerate the procedure
vii. Provider attests that the patient has an advanced care plan and Durable Power of Attorney for Healthcare (DPOAHC)

b. None of the following:
i. Active infection
ii. History of recurrent pulmonary embolism or deep vein thrombosis
iii. Major cardiovascular event within previous 2 months
iv. Cardiac resynchronization therapy (CRT) likely in next 3 months or within the previous 3 months
v. Congenital heart disease or mechanical right heart valve that is contraindicated for right heart catheterization
vi. Likely to undergo evaluation for heart transplant or VAD implantation within the next 6 months
vii. Known coagulation disorders
viii. Hypersensitivity or allergy to aspirin, and/or clopidogrel

2. Clinic, Provider and Program Requirements - all of the following:
a. Physician medical director who:
i. devotes more than 40% of their practice in managing advanced heart failure patients
ii. is board certified or eligible in advanced heart failure management consistent with the ABIM subspecialty requirements.
b. 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.
c. The treating provider and the member have access to a reliable internet connection that allows remote heart failure monitoring.
d. The data collected from the CardioMEMS device is monitored regularly.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
Electrocardiographic Services 20.15 Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management 20.36	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified
First Coast Service Options, Inc.	Ambulatory Electrocardiograph (AECG) Monitoring L39492 A59270
National Government Services, Inc.	None identified
Noridian Healthcare Solutions	None identified
Novitas Solutions, Inc.	Ambulatory Electrocardiograph (AECG) Monitoring L39490 A59268
Palmetto GBA	*Billing and Coding: Independent Diagnostic Testing Facilities (IDTF) A58559
WPS Insurance Corporation	*Independent Diagnostic Testing Facilities-physician supervision and technician requirements A54953

*Not an LCD reference article

Effective for services performed on or after January 13, 2025, the **Centers for Medicare & Medicaid Services (CMS)** has determined that the evidence is sufficient to cover **implantable pulmonary artery pressure sensors (IPAPS)** for **heart failure (HF)** management under Coverage with Evidence Development (CED) when furnished according to a **Food and Drug Administration (FDA)** market-authorized indication and all of the conditions specified in NCD *Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management 20.36* are met.

III. BACKGROUND

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).

American Heart Association (AHA) – HF [Heart Failure] and Your Ejection Fraction Explained

- The ejection fraction compares the amount of blood in the heart to the amount of blood pumped out. The fraction or percentage helps describe how well the heart is pumping blood to the body.
    - **NORMAL Ejection Fraction**: between 50–70% is pumped out during each contraction (Usually comfortable during activity.)
    - **MILDLY REDUCED (BORDERLINE) Ejection Fraction**: between 41–49% is pumped out during each contraction (Symptoms may become noticeable during activity.)
    - **REDUCED Ejection Fraction**: less than or equal to 40% is pumped out during each contraction (Symptoms may become noticeable even during rest.)

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
European Society of Cardiology (ESC)	Remote Pulmonary Artery Pressure-Guided Management of Patients with Heart Failure: A Clinical Consensus Statement of the Heart Failure Association (HFA) of the ESC (Bayes-Genis A et al., 2025) 2023 Focused Update of the 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure (Authors/Task Force Members McDonagh et al, 2023) (Correction) 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: Developed by the Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC) With the special contribution of the Heart Failure Association (HFA) of the ESC

	(Authors/Task Force Members McDonagh TA et al., 2021) (Corrigendum)
Heart Rhythm Society (HRS) European Heart Rhythm Association (EHRA) Asia Pacific Heart Rhythm Society (APHRS) Latin American Heart Rhythm Society (LAHRS) International Society for Holter and Noninvasive Electrocardiology (ISHNE)	2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic (Ferrick AM et al., 2023) 2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry (Steinberg JS et al., 2017) 2015 HRS Expert Consensus Statement on Remote Interrogation and Monitoring for Cardiovascular Electronic Implantable Devices (Slotwiner D et al., 2015) ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs) (Dubner S et al., 2012) HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations (Wilkoff BL et al., 2008)
American Heart Association (AHA) American College of Cardiology (ACC) 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 (Heidenreich PA et al., 2022)
National Institute for Health and Care Excellence (NICE)	Percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure Interventional procedures guidance IPG711 (NICE, 2021)
Heart Failure Society of America (HFSA)	Remote Monitoring of Patients With Heart Failure: A White Paper From the Heart Failure Society of America Scientific Statements Committee (Dickinson MG et al., 2018)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Decision date
Product Code MOM – System, Hemodynamic, Implantable		
Cordella Pulmonary Artery Sensor System (CorPASS) (Endotronix, Inc.; acquired by Edwards Lifesciences)	P230040	06/20/2024
CardioMEMS™ HF System (ABBOTT MEDICAL)	P100045	05/28/2014

Note: These medical devices may have supplements. A supplement may have changed the device description/function or indication from that approved in the original premarket approval (PMA).

VI. CODING

See also *Priority Health Medical Policy No. 91636 - Category III Current Procedural Terminology (CPT®) Codes ("T" codes)*

ICD-10 Codes that may support medical necessity

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) heartfailure
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

C1740 Leadless electrode, transmitter, battery (all implantable), for sequential left ventricular pacing

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 Medically Necessary

C1833 Monitor, cardiac, including intracardiac lead and all system components (implantable)

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, 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, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the 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); 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. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, 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.

IX. REFERENCES

Guidelines and Position Statements

1. Authors/Task Force Members:; McDonagh TA, Metra M, Adamo M, Gardner RS, Baumbach A, Böhm M, Burri H, Butler J, Čelutkienė J, Chioncel O, Cleland JGF, Crespo-Leiro MG, Farmakis D, Gilard M, Heymans S, Hoes AW, Jaarsma T, Jankowska EA, Lainscak M, Lam CSP, Lyon AR, McMurray JJV, Mebazaa A, Mindham R, Muneretto C, Francesco Piepoli M, Price S, Rosano GMC, Ruschitzka F, Skibelund AK; ESC Scientific Document Group. 2023 Focused Update of the 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: Developed by the task force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC) With the special contribution of the Heart Failure Association (HFA) of the ESC. Eur J Heart Fail. 2024 Jan;26(1):5-17. doi: 10.1002/ejhf.3024. Epub 2024 Jan 3. PMID: 38169072.
2. Authors/Task Force Members:; McDonagh TA, Metra M, Adamo M, Gardner RS, Baumbach A, Böhm M, Burri H, Butler J, Čelutkienė J, Chioncel O, Cleland JGF, Coats AJS, Crespo-Leiro MG, Farmakis D, Gilard M, Heymans S, Hoes AW, Jaarsma T, Jankowska EA, Lainscak M, Lam CSP, Lyon AR, McMurray JJV, Mebazaa A, Mindham R, Muneretto C, Francesco Piepoli M, Price S, Rosano GMC, Ruschitzka F, Kathrine Skibelund A; ESC Scientific Document Group. 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: Developed by the Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC). With the special contribution of the Heart Failure Association (HFA) of the ESC. Eur J Heart Fail. 2022 Jan;24(1):4-131. doi: 10.1002/ejhf.2333. PMID: 35083827.
3. Bayes-Genis A, Pagnesi M, Codina P, Abraham WT, Amir O, de Boer RA, Brugts JJ, Chioncel O, Gustafsson F, Lindenfeld J, Mullens W, Petrie MC, Rosano G, Metra M. Remote pulmonary artery pressure-guided management of patients with heart failure: A clinical consensus statement of the Heart Failure Association (HFA) of the ESC. Eur J Heart Fail. 2025 Sep;27(9):1644-1657. doi: 10.1002/ejhf.3619. Epub 2025 Apr 27. PMID: 40288763; PMCID: PMC12502462.
4. Correction to: 2023 Focused Update of the 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: Developed by the task force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC) With the special contribution of the Heart Failure Association (HFA) of the ESC. Eur Heart J. 2024 Jan 1;45(1):53. doi: 10.1093/eurheartj/ehad613. Erratum for: Eur Heart J. 2023 Oct 1;44(37):3627-3639. doi: 10.1093/eurheartj/ehad195. PMID: 37995350.

5. Dickinson MG, Allen LA, Albert NA, DiSalvo T, Ewald GA, Vest AR, Whellan DJ, Zile MR, Givertz MM. Remote Monitoring of Patients With Heart Failure: A White Paper From the Heart Failure Society of America Scientific Statements Committee. J Card Fail. 2018 Oct;24(10):682-694. doi: 10.1016/j.cardfail.2018.08.011. Epub 2018 Oct 9. PMID: 30308242.
6. Dubner S, Auricchio A, Steinberg JS, Vardas P, Stone P, Brugada J, Piotrowicz R, Hayes DL, Kirchhof P, Breithardt G, Zareba W, Schuger C, Aktas MK, Chudzik M, Mittal S, Varma N. ISHNE/EHRA expert consensus on remote monitoring of cardiovascular implantable electronic devices (CIEDs). Europace. 2012 Feb;14(2):278-93. doi: 10.1093/europace/eur303. Epub 2012 Jan 9. PMID: 22232544.
7. Ferrick AM, Raj SR, Deneke T, Kojodjojo P, Lopez-Cabanillas N, Abe H, Boveda S, Chew DS, Choi JI, Dagres N, Dalal AS, Dechert BE, Frazier-Mills CG, Gilbert O, Han JK, Hewit S, Kneeland C, DeEllen Mirza S, Mittal S, Ricci RP, Runte M, Sinclair S, Alkmim-Teixeira R, Vandenberk B, Varma N. 2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic. Heart Rhythm. 2023 Sep;20(9):e92-e144. doi: 10.1016/j.hrthm.2023.03.1525. Epub 2023 May 19. PMID: 37211145.
8. Heidenreich PA, Bozkurt B, Aguilar D, Allen LA, Byun JJ, Colvin MM, Deswal A, Drazner MH, Dunlay SM, Evers LR, Fang JC, Fedson SE, Fonarow GC, Hayek SS, Hernandez AF, Khazanie P, Kittleson MM, Lee CS, Link MS, Milano CA, Nnacheta LC, Sandhu AT, Stevenson LW, Vardeny O, Vest AR, Yancy CW; ACC/AHA Joint Committee Members. 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):e895-e1032. doi: 10.1161/CIR.0000000000001063. Epub 2022 Apr 1. Erratum in: Circulation. 2022 May 3;145(18):e1033. doi: 10.1161/CIR.0000000000001073. Erratum in: Circulation. 2022 Sep 27;146(13):e185. doi: 10.1161/CIR.0000000000001097. Erratum in: Circulation. 2023 Apr 4;147(14):e674. doi: 10.1161/CIR.0000000000001142. PMID: 35363499.
9. McDonagh TA, Metra M, Adamo M, Gardner RS, Baumbach A, Böhm M, Burri H, Butler J, Čelutkienė J, Chioncel O, Cleland JGF, Coats AJS, Crespo-Leiro MG, Farmakis D, Gilard M, Heymans S, Hoes AW, Jaarsma T, Jankowska EA, Lainscak M, Lam CSP, Lyon AR, McMurray JJV, Mebazaa A, Mindham R, Muneretto C, Francesco Piepoli M, Price S, Rosano GMC, Ruschitzka F, Kathrine Skibelund A. Corrigendum to: 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: Developed by the Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC) With the special contribution of the Heart Failure Association (HFA) of the ESC. Eur Heart J. 2021 Dec 21;42(48):4901. doi: 10.1093/eurheartj/ehab670. Erratum for: Eur Heart J. 2021 Sep 21;42(36):3599-3726. doi: 10.1093/eurheartj/ehab368. PMID: 34649282.
10. 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

11. Slotwiner D, Varma N, Akar JG, Annas G, Beardsall M, Fogel RI, Galizio NO, Glotzer TV, Leahy RA, Love CJ, McLean RC, Mittal S, Morichelli L, Patton KK, Raitt MH, Ricci RP, Rickard J, Schoenfeld MH, Serwer GA, Shea J, Varosy P, Verma A, Yu CM. HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. Heart Rhythm. 2015 Jul;12(7):e69-100. doi: 10.1016/j.hrthm.2015.05.008. Epub 2015 May 14. PMID: 25981148.
12. Steinberg JS, Varma N, Cygankiewicz I, Aziz P, Balsam P, Baranchuk A, Cantillon DJ, Dilaveris P, Dubner SJ, El-Sherif N, Krol J, Kurpesa M, La Rovere MT, Lobodzinski SS, Locati ET, Mittal S, Olshansky B, Piotrowicz E, Saxon L, Stone PH, Tereshchenko L, Turitto G, Wimmer NJ, Verrier RL, Zareba W, Piotrowicz R. 2017 ISHNE-HRS expert consensus statement on ambulatory ECG and external cardiac monitoring/telemetry. Heart Rhythm. 2017 Jul;14(7):e55-e96. doi: 10.1016/j.hrthm.2017.03.038. Epub 2017 May 8. Erratum in: Heart Rhythm. 2018 May;15(5):789. doi: 10.1016/j.hrthm.2018.03.036. Erratum in: Heart Rhythm. 2018 Aug;15(8):1276. doi: 10.1016/j.hrthm.2018.06.033. PMID: 28495301.

Additional references

13. Abraham WT, 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. doi: 10.1016/S0140-6736(11)60101-3. Erratum in: Lancet. 2012 Feb 4;379(9814):412. PMID: 21315441.
14. American Heart Association (AHA). HF [Heart Failure] and Your Ejection Fraction Explained. January 2025.
15. Brugts JJ, Radhoe SP, Clephas PRD, Aydin D, van Gent MWF, Szymanski MK, Rienstra M, van den Heuvel MH, da Fonseca CA, Linssen GCM, Borleffs CJW, Boersma E, Asselbergs FW, Mosterd A, Brunner-La Rocca HP, de Boer RA; MONITOR-HF investigators. 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. PMID: 37220768.
16. Centers for Medicare & Medicaid Services (CMS). National Coverage Analysis (NCA) CAG-00466N. Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management.
17. Hayes, Inc. Health Technology Assessment. CardioMEMS Implantable Hemodynamic Monitor (Abbott) For Managing Patients With Heart Failure. Hayes, Inc. July 28, 2022. Annual Review July 23, 2025.
18. Lindenfeld J, Zile MR, Desai AS, Bhatt K, Ducharme A, Horstmanshof D, Krim SR, Maisel A, Mehra MR, Paul S, Sears SF, Sauer AJ, Smart F, Zughaib M, Castaneda P, Kelly J, Johnson N, Sood P, Ginn G, Henderson J, Adamson PB, Costanzo MR. 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. PMID: 34461042.
19. 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. doi: 10.1016/j.jacc.2012.08.1035. Epub 2013 Jan 23. PMID: 23352783.
20. 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); 2016 Oct. Report from the Norwegian Institute of Public Health No. 2016-04. PMID: 29553639.

SUMMARY OF CHANGES

No changes to medical necessity criteria.

Past committee review dates: 05/2015, 05/2016, 05/2017, 08/2017, 05/2018, 05/2019, 05/2020, 05/2021, 05/2022, 05/2023, 05/2024, 11/2024, 05/2025