Implantable Hemodynamic Monitoring Devices

MEDICAL POLICY NUMBER: 416

Effective Date: 1/1/2025

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Next Annual Review: 8/2025

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Implantable Pulmonary Artery Pressure Monitoring: Guideline Note 173

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

I. Implantable pulmonary artery pressure monitoring (e.g. CardioMEMS Heart Failure System, Cordella™ Pulmonary Artery (PA) Pressure Sensor System) is considered **not medically necessary** for the treatment of any indication, including but not limited to congenital heart failure.

II. Implantable left atrial monitoring devices (e.g. HeartPOD™ System, Promote® LAP System, and V-LAP™ System) are considered **not medically necessary** for the treatment of any indication.

Link to Evidence Summary

POLICY CROSS REFERENCES

- External Ambulatory Electrocardiography, MP188
- Implantable Loop Recorders, MP76
- Transcatheter Aortic Valve Replacement (TAVR), MP77

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

New York Heart Association (NYHA) Classification

The NYHA Classification System 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.

Implantable Pulmonary Artery Pressure Monitoring

An implantable pulmonary artery pressure monitoring system is a medical device designed to continuously monitor the pressure in the pulmonary artery. This system aims to help manage heart failure, as changes in pulmonary artery pressure can be an indicator of worsening heart failure or other cardiovascular issues. The system generally consists of a small sensor that is implanted into the pulmonary artery via a minimally invasive procedure. The sensor wirelessly transmits data to an external monitoring device, allowing healthcare providers to remotely track the patient's pulmonary artery pressure. By monitoring these pressures, the device aims to aid physicians in detecting early signs of deterioration and adjust treatment plans accordingly, potentially preventing hospitalizations and improving overall patient outcomes.

CardioMEMS Implantable Hemodynamic Monitor (CM-IHM)

The CM-IHM system utilizes an implantable pulmonary artery pressure (PAP) sensor to allow patients to measure PAP remotely from home. Since elevated PAP is often an early indication of an impending HF exacerbation, data from CM-IHM can alert the patient and physician so that decisions regarding treatment can be made. Patients are instructed to obtain daily PAP readings, which are automatically uploaded to a database that can be accessed by the patient and caregivers. Physicians incorporate the PAP data into the HF treatment plan, often resulting in data-based dose changes to guideline-directed medical therapy (GDMT).

Cordella™ PA Pressure Sensor System

The Cordella™ Pulmonary Artery (PA) Pressure Sensor System (Endotronix, Inc.) is composed of a small sensor that is implanted directly into the pulmonary artery through a minimally invasive procedure. This sensor transmits real-time data on pulmonary artery pressure wirelessly to an external reader. The data collected can be accessed by healthcare providers, enabling them to monitor the patient's condition continuously and adjust treatment plans as necessary to prevent worsening of the heart failure condition.

Left Atrial Monitoring Devices

Left atrial implantable hemodynamic monitoring devices are specialized medical devices designed to monitor the hemodynamic status of the left atrium of the heart. These devices purport to provide real-time data on left atrial pressure, which is used for managing and treating conditions like heart failure. By continuously monitoring these pressures, device manufacturers claim to help healthcare providers make more informed decisions regarding patient management, by providing detailed and continuous information about the patient's cardiac status, allowing for more precise and proactive treatment adjustments. Example devices include the following, none of which are currently approved for use by the U.S. Food and Drug Administration:

- The HeartPOD™ System is an implantable device that continuously monitors left atrial pressure and transmits this information to an external device, with the goal of allowing physicians to track the patient's hemodynamic status remotely, facilitating timely interventions based on accurate, real-time data.
- The Promote® LAP System is another implantable device designed for monitoring left atrial pressure. It works similarly to the HeartPOD™ by providing continuous data on the pressures within the left atrium, which can then be used to guide therapy and manage conditions such as chronic heart failure.
- The V-LAP™ System by Vectorious is an advanced wireless implant that monitors left atrial pressure. It incorporates a miniature sensor implanted into the left atrium through a minimally invasive procedure. The V-LAP™ System transmits pressure data to an external device, enabling continuous, real-time monitoring and providing valuable insights for optimizing heart failure treatment.

Heart Failure

Heart failure (HF) is a medical condition where the heart is unable to pump blood efficiently throughout the body, leading to symptoms such as shortness of breath, coughing, and fatigue. These symptoms often worsen as the disease progresses. HF affects between 5.1 million and 6.5 million Americans, and it becomes more common with age, with hospitalization rates of 11.6 per 1000 individuals aged 55 and older each year. The condition imposes a significant burden, including frequent rehospitalizations, a diminished health-related quality of life (HRQOL), and a relatively high mortality rate.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CardioMEMS Heart Failure System

The U.S. FDA granted PMA for the CardioMEMS HF System (CardioMEMS, Inc.) in May 2014 (P100045).[1] St Jude Medical acquired CardioMEMS, Inc., in 2014, and Abbott acquired St. Jude Medical in 2017. The system includes the CM2000 implantable PA Sensor/Monitor and transvenous catheter delivery system, the CM1000 Patient Electronics System (GSM [Global System for Mobile]), the CM1010 Patient Electronics System (GSM), and CM3000 Hospital Electronics System. The most recent labeled indication for CardioMEMS reads:

> The CardioMEMS HF System is indicated for wirelessly measuring and monitoring pulmonary artery pressure and heart rate in NYHA Class II or III heart failure patients who either have been hospitalized for heart failure in the previous year and/or have elevated natriuretic peptides. The hemodynamic data are used by physicians for heart failure management with the goal of controlling pulmonary artery pressures and reducing heart failure hospitalizations.[2]

Since the original PMA, FDA approved 60 PMA supplements that pertained to device design changes, changes to the postapproval study protocol, changes in the instructions for use descriptions, and manufacturing process changes. The device received the CE mark in November 2010 for measuring PA pressure in patients with HF.

Cordella™ PA Pressure Sensor System

In June 2024, the Cordella™ PA Pressure Sensor System received FDA approval for marketing in the United States.[3] The approval indicates that the device can be used for the management of New York Heart Association (NYHA) Class III heart failure patients who are at home on diuretics and guideline-directed medical therapy (GDMT) as well as have been stable for 30 days on GDMT. The device output is meant to aid clinicians in the assessment and management of heart failure, with the goal of reducing heart failure hospitalizations.

Miscellaneous Devices

Several other devices that monitor cardiac output by measuring pressure changes in the pulmonary artery (PA) or right ventricular outflow tract have been investigated in the research setting but have not received FDA approval. They include the Chronicle Implantable Continuous Hemodynamic Monitoring Device (Medtronic), which includes a sensor implanted in the right ventricular outflow tract, and the ImPressure device (Remon Medical Technologies), which includes a sensor implanted in the PA, and the Cordella PA Pressure Sensor System (Endotronix, Inc.), which includes a sensor implanted in the PA.

Left Atrial Monitoring Devices

No left atrial implantable hemodynamic monitoring devices (HeartPOD™ System, Promote® LAP System, and V-LAP™ System) have received FDA approval for widespread clinical use in the United States as of November 2024.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of the implantable hemodynamic monitoring systems as a treatment of congenital heart failure. Below is a summary of the available evidence identified through July 2024.

Systematic Reviews

- In 2023, Hayes published an evidence review assessing the safety and efficacy of CardioMEMS Implantable Hemodynamic Monitor (Abbott) for managing patients with heart failure.[4] The literature search identified 9 eligible studies (in 10 publications) that evaluated CM-IHM for the management of HF, including two RCTs in three publications, one prospective comparative cohort study, three prospective pretest-posttest studies, two retrospective noncomparative database studies, two retrospective noncomparative database studies, and one retrospective propensity score-matched comparative database study. A low-quality body of evidence suggests that use of CM-IHM as an adjunct to standard care for managing adult patients primarily with symptomatic NYHA class III HF, benefits health outcomes by leading to a consistent reduction of HFH risk and mean PAP values with some improvements in cardiac function. However, the data on the effects of CM-IHM on mortality and HRQOL were inconclusive due to inconsistent findings, short duration of follow-up, and variability in reported outcome measures. CM-IHM appears to be safe and pose no major risks. The remaining uncertainty surrounding the efficacy of CM-IHM to reduce mortality and improve HRQOL needs to be investigated with additional large well-designed comparative studies that conduct long-term assessments extending beyond 1-year postimplantation. Authors assigned a “C” rating (potential but unproven benefit).

- In 2022, ECRI published an evidence review assessing the safety and efficacy of CardioMEMS HF System (Abbott Cardiovascular) for wireless monitoring of pulmonary artery pressure in patients with heart failure.[5] Consistent findings of a systematic review (SR) and six additional studies showed that CardioMEMS monitoring is safe and effective for reducing hospitalization risks in patients with moderate HF; however, significant limitations to data interpretation and large evidence gaps remain. Although reported outcomes have overall good statistical precision, most of the studies included in the SR and additional studies are at risk of bias from lack of randomization or independent controls. The sole study including patients with mild HF, though randomized, was affected by COVID-19. None of the other reviewed studies reported on physical function or QOL improvement, which are important treatment goals in HF, and additional low-quality studies available in the literature may not support conclusions on these outcomes. None of the studies reported on outcomes beyond one-year follow-up, which are needed to assess CardioMEMS' benefits because patients with HF typically survive for at least several years. Additional RCTs reporting on survival, physical function, and QOL over a five-year horizon are needed to optimize CardioMEMS use in HF treatment; studies that compare CardioMEMS with other HF monitoring systems, such as HeartLogic, ReDS and Audicor are also needed.

Authors wrote that evidence from a systematic review (SR) and six additional studies shows that CardioMEMS monitoring is safe and reduces hospitalizations in patients with moderate HF. However, recent reports of electric and fire hazard related to CardioMEMS interrogation devices raise safety concerns. Until these are addressed, physicians and patients should exercise caution. Authors concluded that available data are too limited in quality and quantity to determine how CardioMEMS affects mortality, physical function, and quality of life; whether CardioMEMS benefits patients with mild HF; and how CardioMEMS compares with other HF monitoring systems.

- In 2023, Iaconelli and colleagues conducted a meta-analysis of both pre-print and published RCTs (four trials in total).[6] Outcomes of interest included HF-related hospitalization and all-cause mortality. Hemodynamic monitoring resulted in only a small reduction in mean pulmonary artery pressure (< 1 mmHg as a daily average), marginally significant reductions in HF-related hospitalizations (HR 0.75; 95% CI 0.58-0.96; p=0.03) and no difference in mortality (Relative Risk [RR] 0.92; 95% CI 0.68-1.26; p=0.48). The authors conclude, "Hemodynamic monitoring for patients with heart failure may reduce the risk of hospitalization for heart failure but this has not yet translated into a reduction in mortality, perhaps because the duration of trials was too short or the reduction in pulmonary artery pressure was not sufficiently large."

Randomized Controlled Trials (RCTs)

- In 2023, Brugts and colleagues published results of an open-label RCT conducted across 25 sites throughout the Netherlands.[7] Eligible study participants had chronic, NYHA class III HF and a previous HF-related hospitalization. The study's primary endpoint was the mean difference in the Kansas City Cardiomyopathy Questionnaire (KCCQ) summary score at 12 months. Participants were randomly assigned in a 1:1 fashion to implantation and monitoring via CardioMEMS-HF (n=176) or standard care (n=172). Follow-up time-points were scheduled at 3 months, 6 months, and every 6 months thereafter, up to 48 months. Study participants median age was 69 years and median ejection fraction was 30% (range, 23-40). At 12 months, the KCCQ summary score was 7.13 (95% CI 1.51-12·75; p=0.013) between groups (+7.05 in the CardioMEMS group, p=0.001, and -0.08 in the standard care group, p=0.97). HF-related hospitalizations were significantly less likely in the CardioMEMS group (n=117) compared to the standard of care group (n=212) (HR=0.56; CI, 0.38-0.84; p=0.005). While the QOL measure and HF-related hospitalization favored the CardioMEMS group, remote monitoring did not affect cardiac-related mortality nor all-cause mortality. Freedom from device-related complications and sensor failure were 97.7% and 98.8%, respectively. In the Netherlands, individuals with moderate-to-severe heart failure hemodynamic monitoring improved individuals subjective QOL relative to those receiving routine care, however given the lack of blinding in this study design, study bias cannot be ruled out. Further investigation is warranted.

- In 2022, Cowie and colleagues conducted a prospective, multicenter, open-label, post-market study to evaluate the safety, effectiveness, and feasibility of CardioMEMS in individuals with NYHA Class III symptoms and a previous HF hospitalization (n=100).[8] The primary endpoint was HF hospitalization rates 1 year post initiation of remote HF management relative to the year prior. Safety outcomes were evaluated at 2 years post initiation of device monitoring. At 1 year post device implantation, the annualized HF hospitalization rate was 82% lower (95% CI, 72-88%) than the previous 12 months (0.27 vs. 1.52 events/subject-year, respectively, p<0.0001).

At 2 years, device/system-related complications and pressure sensor failure were 0% and 1%, respectively. Authors concluded that, "Hemodynamic-guided HF management was safe and significantly reduced hospitalization in a group of high-risk patients." Confirmation is warranted in the setting of a randomized control trial with longer-term follow-up. Participants in this study did not have a period of guideline-directed medical therapy prior to device implantation. Neither the participants nor their evaluators were blinded. It is possible that either or both factors influenced the observed difference in hospitalization rates. The design of the study does not permit reasonable conclusions about the effects of invasive monitoring relative to standard medical care.

Nonrandomized Studies

- In 2023, Heywood and colleagues published results of the previously described CardioMEMS post-approval study through 2 years of follow-up.[9] Of the 1200 participants originally enrolled with NYHA Class III symptoms, 710 (59%) completed the 2-year follow-up with 684 showing up for the final visit (57%). Individuals who completed the 2-year follow-up showed a sustained, but modest reduction in PA diastolic pressure (23.9 to 20.8 mmHg). The HF-hospitalization rate was 0.37 at 2 years, with 59% of participants free of HF-hospitalization during follow-up. Freedom from device- or system-related complications at 2 years and freedom from pressure-sensor failure at 2 years were both above 99%. The single-arm, observational design and limited follow-up period in this post-approval study, remain as significant limitations in the validity of outcomes for an implanted device.

- In 2022, Sharif and colleagues reported on the safety, accuracy, and usability of the Cordella™ Pulmonary Artery Pressure Sensor System and the comprehensive Cordella™ Heart Failure System (CHFS) in managing patients with NYHA Class III heart failure.[10] The trial was prospective, multi-center, and open-label with the primary goal of testing the system's safety and efficacy. It involved 70 patients who had previously been hospitalized for heart failure or had increased NT-proBNP levels. The main efficacy outcome was to assess the accuracy of the Cordella sensor in measuring mean PAP against standard measurements obtained by right heart catheterization at 90 days post-implant. Results showed equivalence in measurements. The device demonstrated a high safety profile with 98.6% of participants free from serious device-related complications for at least 30 days after implantation. There were no failures in the pressure sensor, and patient adherence to daily transmission of their PAP and vital signs was high at 94%. Limitations include the study's small sample size, lack of comparator groups and lack of long-term follow-up.

CLINICAL PRACTICE GUIDELINES

<u>American College of Cardiology, the American Heart Association, and the Heart Failure Society of America ACC/AHA/HFA</u>

In 2022, the ACC/AHA/HFA published an update to the heart failure management guidelines, 2 recommendations were provided regarding remote hemodynamic monitoring in heart failure.[11] Authors stated that "the usefulness of wireless monitoring of PA pressure by an implanted hemodynamic monitor to reduce the risk of subsequent HF hospitalizations is uncertain."

Heart Failure Society of America

In 2018, the Heart Failure Society of America Scientific Statements Committee published a white paper consensus statement on remote monitoring of patients with heart failure.[12] The committee concluded that "routine use of external RPM devices is not recommended. Implanted devices that monitor pulmonary arterial pressure and/or other parameters may be beneficial in selected patients or when used in structured programs, but the value of these devices in routine care requires further study."

National Institute of Health and Care Excellence (NICE)

In 2018, the NICE issued a new interventional procedures guidance regarding the use of percutaneous implantation of pulmonary artery pressure sensors for monitoring the treatment of chronic heart failure.[13] The Institute's recommendation stated that "evidence on the safety and efficacy of percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure is adequate to support using this procedure provided that standard arrangements are in place for clinical governance, consent, and audit."

EVIDENCE SUMMARY

Evidence is insufficient to support the use of implantable pulmonary artery pressure monitoring or implantable left atrial monitoring devices for managing heart failure. Findings suggest that CM-IHM reduces hospitalization risks and mean pulmonary artery pressure in NYHA class III heart failure patients when used alongside standard care. However, its impact on mortality and health-related quality of life remains uncertain due to inconsistent results and limited follow-up. Limitations include the lack of long-term outcomes and effects on mild heart failure cases. Moreover, no evidence-based clinical practice guidelines currently recommend percutaneous implantation of pulmonary artery pressure sensory monitors. Additional large randomized controlled trials with long-term follow-up are needed to validate long-term benefits and compare with other monitoring systems to optimize treatment strategies in heart failure. No implantable left atrial monitoring devices are currently approved for use by the U.S. Food and Drug Administration.

BILLING GUIDELINES AND CODING

- CPT code 33289 is for **implantation** of the wireless pulmonary artery pressure sensor system.
- CPT code 93264 code is for **remote monitoring** of the system.
- HCPCS code C2624 is for the reporting of the **device** and should be used only by facilities. This code should **not** be used on professional claims.

CODES*		
CPT	0934T	Remote monitoring of a wireless left atrial pressure sensor for up to 30 days, including data from daily uploads of left atrial pressure recordings,

		interpretation(s) and trend analysis, with adjustments to the diuretics plan, treatment paradigm thresholds, medications or lifestyle modifications, when performed, and report(s) by a physician or other qualified health care professional
	0933T	Transcatheter implantation of wireless left atrial pressure sensor for long-term left atrial pressure monitoring, including sensor calibration and deployment, right heart catheterization, transseptal puncture, imaging guidance, and radiological supervision and interpretation
	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
HCPCS	C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components
	G0555	Provision of replacement patient electronics system (e.g., system pillow, handheld reader) for home pulmonary artery pressure monitoring

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. U.S. Food and Drug Administration. Premarket Approvel - CardioMEMS HF Pressure Measurement System. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100045. Published 2014. Accessed 7/10/2024.
2. Abbot Laboratories. CarioMEMS HF System - Indications, Safety & Warnings. https://www.cardiovascular.abbott/us/en/hcp/products/heart-failure/pulmonary-pressure-monitors/cardiomems/indications-safety-warnings.html. Published 2024. Accessed 7/10/2024.
3. U.S. Food and Drug Administration. Premarket Approvel - Cordella Pulmonary Artery Sensor System (CorPASS).

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230040. Published 2024. Accessed 7/16/2024.
4. Hayes Inc. CardioMEMS Implantable Hemodynamic Monitor (Abbott) for Managing Patients With Heart Failure. https://evidence.hayesinc.com/report/htb.wireless3228. Published 2023. Accessed 7/10/2024.
5. ECRI. CardioMEMS HF System (Abbott Cardiovascular) for Wireless Monitoring of Pulmonary Artery Pressure in Patients with Heart Failure. https://www.ecri.org/components/ProductBriefs/Pages/14132.aspx. Published 2022. Accessed 7/10/2024.
6. Iaconelli A, Pellicori P, Caiazzo E, et al. Implanted haemodynamic telemonitoring devices to guide management of heart failure: a review and meta-analysis of randomised trials. *Clinical Research in Cardiology.* 2023;112(8):1007-1019.
7. Brugts JJ, Radhoe SP, Clephas PR, et al. Remote haemodynamic monitoring of pulmonary artery pressures in patients with chronic heart failure (MONITOR-HF): a randomised clinical trial. *The Lancet.* 2023;401(10394):2113-2123.
8. Cowie MR, Flett A, Cowburn P, et al. Real-world evidence in a national health service: Results of the UK CardioMEMS HF system post-market study. *ESC heart failure.* 2022;9(1):48-56.
9. Heywood JT, Zalawadiya S, Bourge RC, et al. Sustained reduction in pulmonary artery pressures and hospitalizations during 2 years of ambulatory monitoring. *Journal of cardiac failure.* 2023;29(1):56-66.
10. Sharif F, Rosenkranz S, Bartunek J, et al. Safety and efficacy of a wireless pulmonary artery pressure sensor: primary endpoint results of the SIRONA 2 clinical trial. *ESC Heart Failure.* 2022;9(5):2862-2872.
11. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: executive summary: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;145(18):e876-e894.
12. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. *Circulation.* 2017;136(6):e137-e161.
13. National Institute for Health and Care Excellence. Chronic heart failure in adults: diagnosis and management. https://www.nice.org.uk/guidance/ng106. Published 2018. Accessed 7/10/2024.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
10/2024	New policy.
1/2025	Policy title change. Q1 code set update. Added criteria for implantable left atrial monitoring devices.