Molina Clinical Policy
Wireless Pulmonary Artery Pressure Monitoring for Congestive Heart Failure: Policy No. 393

Last Approval: 08/14/2024
Next Review Due By: August 2025

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Congestive heart failure (CHF) is a condition in which fluid accumulates in the body as the heart fills or pumps blood inefficiently. CHF is caused by conditions that weaken the heart muscle, such as coronary artery disease, myocardial infarction, cardiomyopathy, and hypertension, and is a major public health concern. Treatment of CHF is guided by treating the underlying cause, which is often a chronic systemic disease process and includes hypertension, diabetes, coronary artery disease, valvular heart disease, or myocarditis as well as lifestyle improvements (e.g., diet, exercise, smoking cessation). Despite the availability of evidence-based medical and device therapies for CHF, morbidity, mortality, and associated costs remain high. The severity of CHF is classified by a patient's functional status using the New York Heart Association (NYHA) system (CDC 2024; AHA 2023; Borlaug & Colucci 2023).

Wireless implantable hemodynamic monitoring systems are designed for use at home to reduce heart failure hospitalizations in NYHA class II and III patients (refer to 'Supplemental Information' section for description of heart failure classes). The system consists of an implantable pulmonary artery sensor that is implanted in the distal pulmonary artery via a right heart catheterization, a transvenous delivery system, and an electronic sensor that processes signals from the implantable pulmonary artery sensor and transmits pulmonary artery pressure measurements to a secure database. An electronic system transmits the generated data to a secure network where it is available for interpretation by the treating physician and clinical team, allowing for any necessary medication or treatment adjustments with the goal of reducing heart failure hospitalizations (FDA 2024; FDA 2014; Hayes 2022).

Regulatory Status

The CardioMEMS™ Champion Heart Failure Monitoring System was approved for marketing by the U.S. Food and Drug Administration (FDA) through the premarket approval process (PMA) under the product code "MOM" in May 2014 (FDA 2014). The CardioMEMS Heart Failure System was initially approved for use in NYHA Class III heart failure patients who had been hospitalized for heart failure within the previous year (FDA 2014). The FDA extended approval for the system in February 2022 for use in patients with Class II heart failure and those whose blood tests reported high levels of natriuretic peptides, indicating worsening failure (FDA 2022). The CardioMEMS Heart Failure System's expanded indication was supported by clinical data from the GUIDE-HF trial. Based on study data adjusted for the impact of COVID-19, both NYHA class II heart failure patients and patients with elevated natriuretic peptides were suggested to have better outcomes when their therapy was guided by pulmonary artery pressure monitoring, with a respective 34% and 25% reduction in heart failure hospitalizations, emergency department visits, and death (FDA 2022).

The CorPASS (Endotronix Inc.) received FDA approval on June 20, 2024. The CorPASS was approved for use in "NYHA class III heart failure patients who are at home on diuretics and guideline-directed medical therapy as well as have been stable for 30 days on guideline-directed medical therapy (FDA 2024)."

COVERAGE POLICY

Wireless pulmonary artery pressure monitoring for congestive heart failure is considered **experimental, investigational, and unproven** due to insufficient published evidence to assess the safety and/or impact on health outcomes.

SUMMARY OF MEDICAL EVIDENCE

The current peer reviewed published evidence is insufficient to support the use of ambulatory cardiac hemodynamic monitoring using an implantable pulmonary artery pressure measurement device in individuals with heart failure in an outpatient setting. Additional well-designed and high quality randomized controlled trials (RCTs) are necessary to establish whether health outcomes are significantly improved relative to standard of care for heart failure management. Furthermore, there is a lack of evidence on the device's accuracy and therapeutic value for usage in additional NYHA functional classes. A summary of the studies is provided below.

CardioMEMS

Brugts et al. (2023) completed the MONITOR-HF trial, which was an open-label, randomized trial that enrolled participants from 25 hospitals in the Netherlands. Inclusion criteria included a diagnosis of "NYHA class III chronic heart failure with a previous hospital admission for decompensated heart failure or urgent visit with the necessity of intravenous diuretics in the past 12 months, irrespective of left ventricular ejection fraction." A total of 348 participants were randomized 1:1 to guideline-directed medical therapy and diuretics (standard of care group, n = 172) or guideline-directed medical therapy and diuretics combined with hemodynamic monitoring using the CardioMEMS device (CardioMEMS group, n = 176). The primary efficacy outcome was the change in Kansas City Cardiomyopathy Questionnaire scores from baseline to 12 months and the secondary efficacy outcome was the number of heart failure-related hospitalizations and urgent visits requiring intravenous diuretics at any point during follow-up. Results showed baseline Kansas City Cardiomyopathy Questionnaire scores of 55.8 for the CardioMEMS group and 54.9 for the standard of care group. At 12-month follow-up, Kansas City Cardiomyopathy Questionnaire scores were 66.1 for the CardioMEMS group compared to 56.9 for the standard of care group. Total heart failure-related hospitalizations at 12-month follow-up were 117 for the CardioMEMS group and 212 for the standard of care group. The event rate of heart failure-related hospitalizations was 0.381 per patient year in the CardioMEMS group compared to 0.678 per patient year in the standard of care group, representing a 44% decrease in heart failure-related hospitalizations ($p = 0.0053$). The mean pulmonary artery pressure for the CardioMEMS group at baseline was 33.3±10.6 mmHg and at 12-months was 24.9±9.4 mmHg ($p < 0.0001$). The median n-terminal pro-B-type natriuretic peptide (NT-proBNP) for the CardioMEMS group at baseline was 2377 pg/mL compared to 1907 pg/mL for the standard of care group. The median NT-proBNP for the CardioMEMS group at 12-months was 1708 pg/mL ($p = 0.013$) compared to 1607 pg/mL ($p = 0.81$) for the standard of care group. The total number of medication changes was higher in the CardioMEMS group (CardioMEMS = 0.93 changes per patient-month; standard of care = 0.55 changes per patient-month). A total of four device-related or system-related complications and two sensor failures occurred in the CardioMEMS group. The frequency of daily pulmonary artery pressure measurements was 84.3%. Researchers noted that the CardioMEMS device led to quality-of-life improvements that were sustained during the 12-month follow-up period. Researchers also noted that a COVID-19 sensitivity analysis was completed prior to the last follow-up visit and the "analysis showed no interaction of COVID-19 warranting no stratified analysis or presentation of results."

Gibson et al. (2023) completed a single-center study at a Canadian hospital to evaluate the impact of pulmonary artery pressure monitoring using the CardioMEMS device on health outcomes and spending in patients with NYHA class III heart failure. There were 21 patients initially included in the study. However, one patient was not successfully implanted with the device and one patient had a successful implantation but developed dampening approximately six weeks after implementation. The dampening was associated with a small implant artery. Approximately 45% of the patients were female and the mean age was 70.6 years. Each patient's electronic medical record and paper charts were audited to determine the number of heart failure-related emergency department visits, hospitalizations, heart failure medical doctor visits, heart failure nurse clinician visits, and nurse clinician phone calls for the year prior to and year after implementation. A baseline assessment of NT-proBNP, creatinine, systolic pulmonary artery pressure, diastolic

pulmonary artery pressure, mean pulmonary artery pressure, 6-minute walk test, and NYHA class were completed prior to device implantation. Subsequent assessments of each of those parameters were completed using a combination of in-person and remote telephone visits at 3-, 6-, 9-, and 12-months following device implantation. Patients were responsible for taking readings from the device as well as obtaining a non-invasive blood pressure measurement on a daily basis. Education was provided to patients on how to obtain these values from the device. A total of 324 medication changes were made using the device data uploaded to the device server. Approximately 165 of those medication changes were made within the first 3-months following device implantation. Results showed an overall improvement in clinical laboratory values and hemodynamics as well as a reduction in the number of emergency department, physician, and nurse clinician visits and the number of hospitalizations. The mean estimated glomerular filtration rate at baseline was 49.0±17.7 mL/min/m^2 and the mean at the 12-month follow-up was 45.5±17.3 mL/min/m^2. The mean NT-proBNP at baseline was 2422±1729 pg/ml. One patient was noted to have an NT-proBNP of > 70,000 pg/mL at the 12-month follow-up due to wild-type transthyretin cardiac amyloidosis with the development of progressive ventricular dysfunction. Excluding this patient from the mean at 12-months showed a significant decline to 1462±1419 pg/mL. The mean systolic pulmonary artery pressure at baseline was 46.9±9.0 mmHg and at 12-months was 38.1±9.0 mmHg. The mean diastolic pulmonary artery pressure at baseline was 24.0±5.8 mmHg and at 12-months was 18.7±5.2 mmHg. Mean pulmonary artery pressure at baseline was 31.5±6.5 mmHg and at 12-month follow-up was 24.8±6.7 mmHg. The baseline 6-minute walk test was 364.4±169.6 meters compared to 402.8±182.6 meters at the 12-month follow-up. All patients were NYHA class III pre-transplant. Post-transplant NYHA classifications were 15% NYHA III, 65% NYHA II, and 20% NYHA I. Researchers noted an 88% reduction in the number of emergency department visits (pre-transplant=26, post-transplant=3) and an 87% reduction in hospitalizations (pre-transplant=23, post-transplant=3). There was also a 29% decrease in the number of heart failure physician visits (pre-transplant=77, post-transplant=55) and a 28% decrease in the in the number of nurse clinician visits (pre-transplant=82, post-transplant=59). There was a 178% increase in the number of nurse clinician phone calls (pre-transplant=173, post-transplant=481). The number of total hospitalization days (pre-transplant=229, post-transplant=31) and mean hospitalization days per patient (pre-transplant=11.4±9.8, post-transplant=1.55±5.7) significantly decreased. The mean cost of healthcare utilization for the year prior to transplantation was $29,813.62±30,780.65 CAD. The mean cost of healthcare utilization following implantation and including the cost of the device was $25,642±17,276.21 CAD. The mean cost of healthcare utilization following implantation and excluding the cost of the device was $7,184±17,276.21 CAD.

Curtain et al. (2023) completed a systematic review and meta-analysis of 5 major trials associated with 3 different implantable hemodynamic monitoring devices including the Chronicle, CardioMEMS, and HeartPOD. The trials included in the review and analysis were the CHAMPION, COMPASS-HF, REDUCE-HF, LAPTOP-HF, and GUIDE-HF trials, all of which are considered major trials for implantable hemodynamic monitoring devices. A total of 2710 patients were included in the meta-analysis with 628 patients having a preserved ejection fraction (EF) and 2023 patients having a reduced EF. A preserved EF was defined as an EF ≥ 50% and a reduced EF was defined as an EF < 50%. All patients had NYHA class II-IV heart failure. The primary outcomes observed were total heart failure-related hospitalizations, worsening heart failure events (heart failure hospitalization and emergency department and urgent clinic visits for intravenous heart failure therapy), all-cause mortality, combined all-cause mortality and heart failure hospitalization, and combined all-cause mortality and worsening heart failure events. Total heart failure hospitalizations for patients regardless of EF were 591 hospitalizations reported out of 1314 patients receiving implantable hemodynamic monitoring-guided care compared to 836 hospitalizations reported out of 1365 patients receiving standard care. This showed a 26% reduction in hospitalizations for implantable hemodynamic monitoring-guided care. Total worsening heart failure events regardless of EF were 650 total events for 1314 patients receiving implantable hemodynamic monitoring-guided care compared to 889 total events for 1365 patients receiving standard care. This showed a 29% reduction in heart failure events for patients receiving implantable hemodynamic monitoring-guided care. All-cause mortality for all patients regardless of EF was 110 deaths in 1103 patients receiving implantable hemodynamic monitoring-guided care compared to 121 deaths in 1121 patients receiving standard care, showing no significant difference between groups for all-cause mortality. Combined all-cause mortality and heart failure hospitalizations for all patients regardless of EF were 621 total events reported for 1103 patients receiving implantable hemodynamic monitoring-guided care compared to 802 total events reported for 1121 patients receiving standard care, representing a 22% reduction in favor of implantable hemodynamic monitoring-guided care. Combined all-cause mortality and total worsening heart failure events for all patients regardless of EF were 680 total events in 1103 patients receiving implantable hemodynamic monitoring-guided care compared to 855 total events in 1121 patients receiving standard care, representing a 20% reduction in favor of implantable hemodynamic monitoring-guided care. Available data for patients with an EF < 50% only supported calculation of the total number of worsening heart failure events.

There was a total of 497 events for those receiving implantable hemodynamic monitoring-guided care compared to 681 events for those receiving standard care, showing a 25% reduction in favor of implantable hemodynamic monitoring-guided care. A total of 231 deaths were reported across 4 trials. However, these trials had relatively short follow-up periods (≤ 1 year). Researchers noted that only 2 trials included in the meta-analysis reported on a device that had current FDA-approval. Researchers also noted that the LAPTOP-HF trial that reported outcomes for the HeartPOD device was terminated early due to periprocedural safety concerns.

Zile et al. (2022) reported on the GUIDE-HF trial, a single-blind randomized controlled trial involving 1000 participants that were randomized on a 1:1 basis to receive hemodynamically guided treatment using an implanted CardioMEMS device or a control group that receive standard care. Participants were eligible for inclusion if they were ≥ 18 years of age, were diagnosed with NYHA functional class II-IV heart failure, had a heart failure-related hospitalization within the preceding 12 months, and had a B-type natriuretic peptide (BNP) obtained within 30 days before consent. The primary goal of the trial was to measure the composite of HF-related hospitalizations, urgent HF medical visits, and all-cause mortality at 12-months following enrollment into the trial. Outcomes were assessed according to EF subgroups: (1) EF ≤ 40%, (2) EF of 41-49%, and (3) EF ≥ 50%. There were 497 participants randomized to the treatment group and 503 randomized to the control group. The trial was impacted by the COVID-19 pandemic. Data from prior to the COVID-19 pandemic was analyzed to determine outcomes. Researchers found that the overall number of events and heart failure-related hospitalizations were lower in the treatment group regardless of EF subgroup. Researchers also noted that "targeting filling pressures supersedes categories of EF as a fundamental determinant of heart failure hospitalization risk."

Brinkley et al. (2021) completed the CardioMEMS Post Approval Study, which was a prospective, multicenter, open-label trial to determine the impact of therapy guided by pulmonary artery pressure monitoring in patients with heart failure and obesity. A total of 1200 patients were included in the study. Inclusion criteria included NYHA class III heart failure, at least one prior heart failure hospitalization within the previous 12 months prior to implantation, and patients with a body mass index (BMI) > 35kg/m^2 were required to have a chest circumference < 65 inches. Patients were grouped into cohorts based on a BMI < 35kg/m^2 and ≥ 35kg/m^2. Cohorts were further stratified based on left ventricular EF of < 40% and ≥ 40%. For the purposes of this study, a preserved EF was defined as an EF ≥ 40% and a reduced EF was defined as an EF < 40%. At baseline, patients in the higher BMI cohorts had a younger mean age, a higher prevalence of diabetes, and a higher cardiac output. Baseline diastolic pulmonary artery pressures were noted to be higher in patients with a BMI ≥ 35kg/m^2 regardless of EF. The impact of monitoring on pulmonary artery pressure was restricted to 839 patients that had both 1-week and 12-month post-implantation readings available. A significant reduction was noted in all pressure artery pressure measurements from 1-week to 12-months regardless of EF or BMI. Changes were made to diuretics based on pulmonary artery pressure measurements with the most frequently changed medication being loop diuretics followed by thiazides. Loop diuretics were changed less frequently in the higher BMI cohort with reduced EF but more frequently in the higher BMI cohort with preserved EF. Thiazides were changed more frequently in the higher BMI cohort regardless of EF. Mineralocorticoid antagonists were changed more frequently in the higher BMI cohort with reduced EF. Researchers noted a > 50% reduction in the annualized risk of heart failure-related hospitalizations from 1-year pre-implantation to 1-year post-implantation regardless of BMI or EF. Researchers also noted a > 20% reduction in all-cause hospitalizations from 1-year pre-implantation to 1-year post-implantation regardless of BMI or EF.

CorPASS/SIRONA 2 Trial

Sharif et al. (2022) assessed the safety and effectiveness of the CorPASS device in the SIRONA 2 prospective, multi-center, open-label, single-arm clinical trial. Inclusion criteria included: 1) age > 18 years, 2) diagnosis of NYHA class III heart failure with reduced or preserved EF for at least 6 months (participants also had to be treated for a minimum of 3 months and stable for a minimum of 1 month prior to enrollment), 3) participants had to have at least one heart failure-related hospitalization, treatment in a hospital day-care setting, or an unplanned outpatient heart failure clinic visit within 12 months prior to consent, and/or 4) an increased NT-proBNP or BNP at time of screening (defined as an NT-proBNP ≥ 1000pg/mL or BNP ≥ 250 pg/mL for participants with a left ventricular EF [LVEF] ≤ 40% and NT-proBNP ≥ 700 pg/mL or BNP ≥ 175 pg/mL for participants with an LVEF > 40%). A total of 75 participants were initially included in the study but only 70 participants were successfully implanted with the CorPASS system due to three participants withdrawing consent, two meeting exclusion criteria while awaiting implant, and one withdrawn by a physician. "The primary safety endpoint was freedom from adverse events associated with use of the [CorPASS] through 30 days post-sensor implant…[and] the primary efficacy endpoint was the accuracy of the [pulmonary artery] sensor mean

[pulmonary artery pressure] measurements relative to standard-of-care fluid-filled catheter mean [pulmonary artery pressure] measurements obtained by standard [right heart catheterization] at 90 days post-sensor implant." Participants will be followed for a total of 48 months with follow-up visits at 1, 3, 6, 12, 18, 24, 36, and 48 months (or until study termination) and "assessments performed at follow-up visits include physical examinations, concomitant medication assessment, clinical laboratory assessments, vital signs, review of [CorPASS] readings, NYHA functional classification, [Kansas City Cardiomyopathy Questionnaire], [6-minute walk test], and [adverse event] assessment." *This study reported results up to the 6-month follow-up visit.* Results showed a mean age of 71.0±10.0 years and a mean BMI of 28.7±5.8 kg/m^2. A total of 27 participants had an LVEF > 40% and 43 participants had an LVEF ≤ 40%. Baseline mean 6-minute walk test scores were 287.3±133.4m overall (LVEF > 40% = 252.1±155.1m, LVEF ≤ 40% = 311.7±111.7m) and baseline mean Kansas City Cardiomyopathy Questionnaire scores were 55.75±24.4 points (LVEF > 40% = 52.0±23.0 points, LVEF ≤ 40% = 58.1±25.2 points). Baseline mean NT-proBNP measurements were 2316.9±3907.2 pg/mL overall (LVEF > 40% = 1239.5±1096.7 pg/mL, LVEF ≤ 40% = 3055.7±4883.4 pg/mL). Mean baseline values for pulmonary artery pressures were 41.1±19.5 mmHg (LVEF > 40% = 52.8±22.7 mmHg, LVEF ≤ 40% = 38.1±13.3 mmHg) systolic, 16.4±10.7 mmHg (LVEF > 40% = 18.6±7.5 mmHg, LVEF ≤ 40% = 13.2±7.5 mmHg) diastolic, and 24.7±14.4 mmHg (LVEF > 40% = 30.7±11.9 mmHg, LVEF ≤ 40% = 22.6±9.1 mmHg) mean. A total of 58 participants underwent the 90-day right heart catheterization to assess efficacy (eight participants were unable to undergo catheterization due to COVID-19, two refused to undergo catheterization, and two were canceled due to serious adverse events). Results for the primary efficacy endpoint showed a mean difference between CorPASS pulmonary artery pressure sensor and right heart catheterization measurements of 1.4±6.7 mmHg for the mean pulmonary artery pressure, -0.3±7.4 mmHg for systolic pulmonary artery pressure, and 2.3±7.7 mmHg for diastolic pulmonary artery pressure ($p < 0.001$ for all measurements). A total of eight participants required hospitalization due to heart failure during the 90-day follow-up and 11 participants requiring hospitalization during the 6 months after implantation. There was a total of three deaths during the 6-month follow-up period. There were no significant changes in Kansas Cardiomyopathy Questionnaire and 6-minute walk test scores at 90 days compared to baseline. Patient compliance with transmitting measurements was 95% at 1 month, 94% at 3 months, and 93% at 6 months. Researchers noted that the COVID-19 pandemic began 9 months into study enrollment and heart failure-related "events were reduced in the general heart failure population during the COVID-19 pandemic."

Sharif et al. (2024) reported the 12-month follow-up results of the SIRONA 2 trial. A total of 48 of the original 70 participants were assessed at 12-months post-CorPASS implantation to assess the efficacy of the CorPASS sensor measurements. Of the 22 not undergoing 12-month assessment, five participants had died, two withdrew from the study, two participants canceled due to patient condition, three refused to undergo catheterization, two participants had a left ventricular assist device, and faulty cath lab equipment resulted in the exclusion of one participant's data. Seven of the 22 participants excluded from the 12-month assessment underwent right heart catheterization; however, six were excluded due to pressure readings being impacted by electromagnetic interference from cath lab equipment and one participant did not have concurrent CorPASS measurements for comparison. Results showed that the pulmonary artery pressure readings continued to strongly correlate with average differences of 2.9±7.3 mmHg in the mean pulmonary artery pressures, 3.2±8.1 mmHg in the systolic pulmonary artery pressures, and 3.0±6.8 mmHg in the diastolic pulmonary artery pressures ($p < 0.0001$ for all measurements). Average monthly medication changes were 0.29 for diuretics, 0.12 for beta-blockers, 0.10 for mineralocorticoid receptor antagonists and angiotensin receptor–neprilysin inhibitors, 0.04 for angiotensin-converting enzyme inhibitors, and 0.03 for angiotensin II receptor blockers and sodium–glucose cotransporter 2 inhibitors. A total of 18 heart failure-related hospitalizations occurred amongst 14 participants and a total of five deaths occurred post-implantation. While the rate of heart-failure related hospitalizations was not a predefined outcome measurement for the study, researchers noted the number of hospitalizations had decreased by 78.6% post-implantation. Significant improvements were noted in the 6-minute walk test scores compared to baseline (301.2±140.3m vs 324.7±116.1m, $p = 0.005$). No significant changes between baseline and 12-month follow-up were noted in Kansas Cardiomyopathy Questionnaire scores. Patient compliance with transmitting measurements was 95% at 12-months. Researchers noted this is the first study to report the long-term efficacy of an implantable pulmonary artery pressure monitoring system compared to right heart catheterization. Researchers also noted "the SIRONA 2 clinical trial did not include a consistent medication management guideline based on [pulmonary artery pressures] to guide remote adjustment of guideline-directed medical therapy…and the rate of monthly [heart failure] medication changes is slightly lower than a contemporary report deploying similar technology."

National and Specialty Organizations

The **American College of Cardiology (ACC)** published an expert consensus decision pathway in 2023 for the management of heart failure with preserved EF (Kittleson et al. 2023). Pulmonary artery pressure monitoring is discussed, with the CardioMEMS device specifically referenced in the decision pathway. The ACC references the CHAMPION trial that provided initial evaluation of the CardioMEMS device, stating the primary concern with the CHAMPION trial "was that it was nonblinded, with differential contact of study personnel with individuals in the treatment arm, raising methodological concerns about the opportunity for bias to have influenced its results." The ACC also references the GUIDE-HF trial and states that, while it was a blinded study, "it did not result in a lower…rate of mortality and total heart failure events compared with the control group." The ACC states that this therapy may be most beneficial for "individuals with heart failure with preserved EF] who:

- Experience ≥ 1 hospitalization for heart failure and continue to experience NYHA functional class III symptoms despite optimal guideline-directed medical therapy.
- Experience significant lability in volume status despite close ambulatory monitoring.
- Have cardiorenal syndrome.
- Have comorbidities such as obesity or chronic lung disease, for which differentiation of heart failure from other causes of dyspnea is difficult."

The **American Heart Association (AHA), ACC,** and **Heart Failure Society of America (HFSA)** published updated guidelines for the management of heart failure in 2022 (Heidenreich et al. 2022). The guidelines state that wireless monitoring of pulmonary artery pressures provides uncertain value. The AHA/ACC/HFSA assigned a class of recommendation rating of "2b (weak)" with a level of evidence rating of "B-R (moderate-quality evidence from 1 or more RCTs or a meta-analysis of moderate-quality RCTs)."

The **European Society of Cardiology (ESC)** published guidelines in 2021 for the diagnosis and treatment of acute and chronic heart failure (McDonagh et al. 2021). The recommendations for wireless pulmonary artery pressure monitoring in symptomatic patients with heart failure are class IIb (may be considered) and level B (data derived from a single RCT or large non-randomized studies).

The **National Institute for Health and Care Excellence (NICE)** published guidance for the percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of CHF (NICE 2021). The recommendations indicate that evidence "is adequate to support using this procedure provided that standard arrangements are in place for clinical governance, consent, and audit. Patient selection, continuing monitoring, and management should be done by a multidisciplinary team."

The **National Heart Foundation of Australia (NHFA)** and the **Cardiac Society of Australia and New Zealand (CSANZ)** published guidelines for the prevention, detection, and management of heart failure in 2018 with a weak recommendation for implantable pulmonary artery pressure monitoring based on a low quality of evidence (Atherton et al. 2018). The guidelines state "implantable pulmonary artery pressure monitoring systems may be considered for individuals with a history of heart failure-related hospitalizations with a reduced or preserved left ventricular EF and "have persistent moderate heart failure symptoms despite optimal care to decrease hospitalization for heart failure." The rationale for this recommendation is that a "change in pulmonary artery pressure is considered a marker of change in volume status and perhaps an early predictor of hospitalization for heart failure."

SUPPLEMENTAL INFORMATION

NYHA classification has served as a vital tool for risk stratification of HF and for determining clinical trial eligibility and medication and device candidate eligibility (AHA 2023).

- 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.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

Code	Description
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.
93799	Unlisted cardiovascular service or procedure [when specified as implantation of a wireless pressure sensor in the pulmonary artery]

HCPCS (Healthcare Common Procedure Coding System) Code

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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

08/14/2024	Policy reviewed, no changes to criteria. "CardioMEMS" removed from policy title.
08/09/2023	Policy reviewed, no changes to criteria. Updated Overview, Summary of Medical Evidence, and References. Grammatical edits to Disclaimer section and Documentation Requirements disclaimer. IRO Peer Review on July 20, 2023, by a practicing, board-certified physician with a specialty in Cardiovascular Disease. IRO Peer Review on July 27, 2023, by a practicing, board-certified physician with a specialty in Cardiology.
08/10/2022	Policy reviewed and updated. No changes in coverage position. Updated references. Updated policy from 'Wireless Pulmonary Artery Pressure Monitoring' to: 'Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS) for Congestive Heart Failure'
02/08/2021	New policy.
12/17/2020	Policy reviewed on December 17, 2020, by a board-certified, practicing physician in the areas of Cardiovascular Disease, Interventional Cardiology, and Internal Medicine.

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