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

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OVERVIEW

Heart failure (HF) is a condition in which fluid accumulates in the body as the heart fills or pumps blood inefficiently. HF 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 HF 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 HF, morbidity, mortality, and associated costs remain high. The severity of HF is classified by a patient's functional status using the New York Heart Association (NYHA) system (CDC 2024; AHA 2025; Borlaug & Colucci 2025).

Wireless implantable hemodynamic monitoring systems are designed for use to reduce heart failure hospitalizations in NYHA class II and III patients. The system consists of a wireless pulmonary artery sensor that is implanted in the distal pulmonary artery via a right heart catheterization. Patient and/or hospital electronic systems process signals from the sensor and transmit pulmonary artery pressure measurements to a secure database where it is available for interpretation by the treating physician and clinical team. This allows for any necessary medication or treatment adjustments with the goal of reducing heart failure hospitalizations (FDA 2024; FDA 2014; Abbott 2023; Hayes 2026).

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 under the product code MOM in May 2014 (FDA 2014). The CardioMEMS Heart Failure System was initially approved for use in NYHA Class III HF patients who had been hospitalized for HF within the previous year (FDA 2014). The FDA extended approval for the system in February 2022 for use in patients with NYHA Class II HF and those whose blood tests reported high levels of natriuretic peptides, indicating worsening failure (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

The implantation of a wireless pulmonary artery pressure monitoring sensor (e.g., CardioMEMS or CorPASS*) for heart failure may be **considered medically necessary** when ALL the following are met:

1. Diagnosis of NYHA class II or III heart failure for at least 3 months prior to implantation
   **NOTE: The CardioMEMS is approved for use in individuals with NYHA class II or III heart failure. The Cordella CorPASS is approved for use in individuals with NYHA class III heart failure.*

2. Member has been on optimal or maximally tolerated guideline-directed medical therapy for at least 3 months prior to implantation

3. Member meets at least ONE of the following:
   a. One or more hospitalizations for heart failure within the previous 12 months
   b. One or more outpatient or urgent visits (e.g., emergency department) requiring intravenous diuretic therapy within the previous 12 months
   c. Elevated natriuretic peptides
   d. Heart failure with preserved ejection fraction and cardiorenal syndrome
   e. Heart failure with preserved ejection fraction and a comorbidity (e.g., severe obesity, chronic lung disease) causing dyspnea that requires differentiation from heart failure

4. Member has not had a major cardiovascular event (e.g., myocardial infarction, open heart surgery) within the preceding 3 months prior to device implantation

5. Member does not have a history of recurrent pulmonary embolism or deep vein thrombosis

DOCUMENTATION REQUIREMENTS: Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

The current peer-reviewed published evidence is sufficient to support the use of ambulatory cardiac hemodynamic monitoring using an implantable pulmonary artery pressure (PAP) measurement device in individuals with NYHA class II or III heart failure (HF). Initial FDA approval for the CardioMEMS was based on results from the CHAMPION trial and the indication approved was for use in individuals with NYHA class III HF (FDA 2014). An expanded indication was granted for use in individuals with NYHA class II HF who have been hospitalized for HF in the previous year and/or have elevated natriuretic peptides in the previous 30 days. The CardioMEMS Heart Failure System's expanded indication was supported by clinical data from the GUIDE-HF trial (FDA 2022). Based on GUIDE-HF study data adjusted for the impact of COVID-19, both NYHA class II HF patients and patients with elevated natriuretic peptides were suggested to have better outcomes when their therapy was guided by PAP monitoring, with a respective 34% and 25% reduction in heart failure hospitalizations (HFHs), emergency department visits, and death (FDA 2022). Systematic reviews and meta-analyses have been published that show a reduction in HFHs and mortality with pooled data. Additional studies to assess the safety and efficacy of the Cordella CorPASS in individuals with NYHA class II and III HF, wireless PAP monitoring in individuals with left ventricular assist devices, and the use of the CardioMEMS device for hemodynamic monitoring in individuals with cardiorenal syndrome ([1-3]ClinicalTrials.gov 2026). A summary of relevant studies is provided below.

CardioMEMS

Randomized Controlled Trials

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 (GDMT) and diuretics (standard of care group, n = 172) or GDMT 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 (KCCQ) scores from baseline to 12 months and the secondary efficacy outcome was the number of HFHs and urgent visits requiring intravenous diuretics at any point during follow-up. Results showed baseline KCCQ scores of 55.8 for the CardioMEMS group and 54.9 for the standard of care group. At 12-month follow-up, KCCQ scores were 66.1 for the CardioMEMS group compared to 56.9 for the standard of care group. Total HFHs at 12-month follow-up were 117 for the CardioMEMS group and 212 for the standard of care group. The event rate of HFHs was 0.381 per patient year in the

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CardioMEMS group compared to 0.678 per patient year in the standard of care group, representing a 44% decrease in HFHs (p = 0.0053). The mean PAP 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. 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."

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 received standard care. Participants were eligible for inclusion if they were ≥ 18 years of age, were diagnosed with NYHA class II-IV HF, had a HFH 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 HFHs, 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 HFHs 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".

Abraham et al. (2011) published the results of the CHAMPION trial, the pivotal study evaluating the effectiveness of the implantable hemodynamic monitoring system. CHAMPION was a multicenter, randomized, single-blind trial conducted at 64 U.S. sites. A total of 550 participants with NYHA Class III HF and a history of hospitalization within the prior year were enrolled and implanted with the CardioMEMS HF System. Prior to hospital discharge, they were randomized 1:1 into a treatment arm (n=270) or a control arm (n=280). Participants in the treatment group had their PAP data made available to clinicians to guide therapy, while those in the control arm received standard care without access to pressure data. To maintain blinding, all participants were instructed to perform daily blood pressure measurements, and both groups had scheduled clinical visits at 1-, 3-, and 6-months, followed by visits every 6 months thereafter. Each site was required to balance the number of control and experimental patient visits. Eligible participants had a HF diagnosis for at least three months and were on optimized GDMT. Exclusion criteria included recurrent thromboembolic disease, advanced chronic kidney disease (Stages IV/V), recent cardiovascular events, or known hypersensitivity to aspirin or clopidogrel. The primary efficacy endpoint was the rate of HFHs at six months. The treatment group experienced 83 events (0.31 events per patient per 6 months), compared to 120 events in the control group (0.44 events per patient per 6 months), representing a 30% relative risk reduction (hazard ratio [HR] 0.70; 95% CI 0.60–0.84; p < 0.0001). Over the full follow-up period (mean 15 months), the treatment group had 153 hospitalizations versus 253 in the control group, corresponding to a 39% reduction in HFHs (HR 0.64; 95% CI 0.55–0.75; p < 0.0001). Safety outcomes were favorable. There were no pressure sensor failures, and freedom from device-related complications was 98.6% (95% CI 97.3–99.4), surpassing the prespecified threshold of 80% (p < 0.0001). A total of 15 device-related complications occurred, including four bleeding events, three related to anticoagulation therapy, two exacerbations of atrial arrhythmias, two febrile illnesses, one in-situ pulmonary thrombus, one cardiogenic shock, one episode of atypical chest pain, and one delivery-system failure requiring retrieval. Long-term analyses confirmed the benefit of PAP-guided therapy. At 18 months, HFH rates were lower in the treatment group (46%) than in the control group (68%). During a 13-month open-access period when former control participants began receiving PAP-guided care, hospitalization rates improved from 68% during the control phase to 36%, illustrating the potential of hemodynamic monitoring in a real-world setting. Limitations of the study include its design not being powered for mortality endpoints, lack of baseline quality-of-life data, and FDA-raised concerns regarding potential sponsor influence during patient randomization and management.

Systematic Reviews and Meta-Analyses

Lindenfeld et al. (2024) completed a patient level pooled meta-analysis that evaluated the impact of implantable

hemodynamic monitors on mortality and HFHs in patients with HF with reduced ejection fraction (HFrEF). The study pooled data from three randomized clinical trials (GUIDE-HF, CHAMPION, and LAPTOP-HF) and included 1,350 patients with recent HFHs or elevated natriuretic peptide levels, most of whom had NYHA Class III symptoms. Over a median follow-up of 12.2 months (IQR 7.8–21.8 months), patients managed with implantable hemodynamic monitoring-guided therapy experienced a 25% reduction in overall mortality (HR = 0.75, 95% CI 0.57–0.99, p = 0.043) and a 36% reduction in HFHs (HR = 0.64, 95% CI 0.55–0.76, p < 0.0001). The study population was well-optimized on GDMT, with 78% receiving ACE inhibitors/ARBs/ARNIs, 95% on beta-blockers, and 52% on mineralocorticoid antagonists. Previous studies evaluating implantable hemodynamic monitors have generally demonstrated reductions in HFHs but not overall mortality, with limitations such as small sample sizes, short follow-up durations, and inclusion of a broad range of HF patients potentially affecting mortality outcomes. To address these concerns, the authors conducted a pooled meta-analysis using patient-level data with long-term follow-up, specifically focusing on HFrEF patients. The results confirmed the previously observed benefit in reducing HFHs while also demonstrating a significant reduction in overall mortality. Despite some limitations, including variability in trial design and blinding, early trial stoppage, and lower use of ARNI and SGLT2 inhibitors, the findings suggest that implantable hemodynamic monitors provide tangible benefits for selected HF patients, reinforcing their role in ambulatory HF monitoring and management.

Urban et al. (2024) conducted a meta-analysis and systematically reviewed five randomized controlled trials (RCTs) involving 2,572 participants to assess the efficacy of PAP monitoring devices, specifically CardioMEMS and Chronicle (not an FDA approved device), in reducing adverse HF outcomes. The findings indicated a 28% reduction in HFHs (RR 0.72, 95% CI 0.6–0.87, p = 0.0006) and a 14% reduction in HF events (RR 0.86, 95% CI 0.75–0.99, p = 0.03), with no statistically significant impact on all-cause or cardiovascular mortality. Subgroup analyses revealed that CardioMEMS was more effective than Chronicle, and blinded studies produced more consistent benefits. Furthermore, longer follow-up periods correlated with greater reductions in HFHs, suggesting that extended monitoring may enhance outcomes. Despite these promising results, the certainty of evidence ranged from low to moderate, and the risk of bias was generally high. While PAP monitoring shows potential for improving HF management by reducing hospitalizations and HF events, further research incorporating diverse patient populations, extended follow-up, and optimized intervention strategies is necessary to clarify its broader clinical role.

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 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 HFHs, worsening HF events (HFH and emergency department and urgent clinic visits for intravenous HF therapy), all-cause mortality, combined all-cause mortality and HFH, and combined all-cause mortality and worsening HF events. Total HFHs 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 HF 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 HF 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 HFHs 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 HF 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 HF 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

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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.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Zile et al. (2025) conducted retrospective analyses of data from the CHAMPION, GUIDE-HF, US PAS, and MEMS-HF trials with the goal of determining if systolic, diastolic, or mean PAPs predict all-cause mortality (at baseline and change from baseline to 6 months) and if PAPs predict mortality across the EF spectrum. A total of 4342 subjects were included across all studies with 323 being excluded from analysis due to no usable readings (n = 23), no baseline readings (n = 12), and nonphysiological readings (n = 288). Baseline PAPs (systolic, diastolic, and mean) were defined as the average of the first 14 days of outpatient PAP readings following device implant. The 6-month PAPs were defined as the average over the previous 14 days preceding the 6-month time point after device implantation. Data from all subjects were combined regardless of study treatment arm (control vs. intervention) and subjects were placed into HFrEF (EF < 50%, n = 2562) and HFpEF (EF ≥ 50%, n = 1454) groups for analysis. Mean follow-up across all subjects was 1.2±0.6 years (median 1.0, IQR 0.9-1.7, range 0-3 years). Mortality prediction was limited to 2 years to account for differences in follow-up between studies. A total of 682 deaths occurred across all studies in the 2-year analysis period. Baseline hemodynamics were similar between the HFpEF and HFrEF groups with significant exceptions including mean age (71.7±10.0 vs. 66.9±12.2), ischemic cause (23.5% vs. 53.0%), previous myocardial infarction (18.1% vs. 41.8%), atrial flutter of fibrillation (65.0% vs. 55.5%), estimated glomerular filtration rate (49.9±19.7 vs. 55.6±22.7), BNP (295.6±377.3 vs. 764.3±919.4), NT-proBNP (1905±3065 vs. 3850±6496), previous CRT (11.4% vs. 35.4%), previous implantation of defibrillator (8.7% vs. 57.4%), ACE inhibitor/ARB/ARNi (42.5% vs. 71.9%), and ARNi (3.6% vs. 26.3%). Higher baseline PAPs were associated with a higher probability of all-cause death and lower baseline PAPs were associated with a decreased probability of all-cause death. The mortality rate for the HFpEF group was 25.1% (n = 202) and 28.0% (n = 479) for the HFrEF group at 2 years. Each 1 mmHg increase in systolic, diastolic, and mean PAP from baseline to 6-months was associated with a 2%, 4%, and 3% increase in mortality, respectively (HR 1.02 [CI 1.02-1.03], 1.04 [CI 1.03-1.05], 1.03 [CI 1.02-1.04], respectively with all having p < 0.0001). When quantified as a categorical variable, a decrease (defined as a change of ≥ 2 mmHg) in diastolic PAP from baseline to 6-months was associated with a 14.7% decrease in all-cause mortality while an increase (also defined as a change of ≥ 2 mmHg) from baseline to 6-months was associated with a 26.7% increase in all-cause mortality relative to subjects with no change in pressure (p = 0.0237). When quantified as a categorical variable, a decrease (defined as a change of ≥ 3 mmHg) in systolic PAP from baseline to 6-months was associated with a 14.2% decrease in all-cause mortality while an increase (also defined as a change of ≥ 3 mmHg) from baseline to 6-months was associated with a 23.8% increase in all-cause mortality relative to subjects with no change in pressure (p = 0.0198). The increases and decreases in all-cause mortality associated with diastolic and systolic PAPs (as continuous and categorical variables) were noted to be the same in both the HFpEF and HFrEF groups, suggesting that changes in PAPs were independent predictors and had no association with EF for all-cause mortality. Limitations of this study included the study being a retrospective analysis with limited variables and the significant variation in the design and length of follow-up of the studies included. Researchers suggested additional analyses that include events and measurements that may affect PAPs.

Ali et al. (2025) conducted a single-center retrospective review of 28 consecutive patients with cancer undergoing CardioMEMS implantation for the clinical management of HF. The authors noted that cancer patients have traditionally been excluded from previous studies and note that “due to complex pathology, increased frailty and reduced resilience to treatment challenges, patients with cancer are at an increased risk of heart failure hospitalizations.” All participants received maximally tolerated GDMT therapy and diuretics were adjusted weekly based on available CardioMEMS data. Of the 28 participants, 60% had hematologic malignancies, 14% had solid tumors, and 14% had overlapping solid/hematologic malignancies. Regarding comorbidity history, 22 participants had a history of hypertension, 10 had diabetes mellitus type II, 15 had coronary artery disease, 16 had chronic kidney disease, and 11 had atrial fibrillation or flutter. In terms of HF, 10 had HFrEF and 18 had HF with preserved ejection fraction (HFpEF). CardioMEMS placement occurred due to amyloidosis (n = 8), HFpEF (n = 5), HFrEF (n = 8), and radiation-induced heart disease (n = 6). Baseline medications included ACE inhibitors/ARBs/ARNIs (n = 12), beta blockers (n = 21), loop diuretics (n = 26), anticoagulants (n = 12), and antiplatelet therapies (n = 13). Mean baseline laboratory values consisted of creatinine (1.8±1.1 mg/dL), platelet count (222.0±87.0 k/uL), NT-proBNP (3065 pg/mL, IQR [617-11131]), and troponin T (49 ng/L, IQR [34.5-84.5]). Mean baseline echocardiographic parameters included left ventricular ejection fraction (LVEF) 54.4% (35.2-61.5%), mean PAP of 35.1±10.0 mmHg, mean systolic PAP of 50.6±11.5 mmHg, mean diastolic PAP of 25.0±8.3 mmHg, and a mean pulmonary capillary wedge pressure of 22.5±7.9 mmHg. HFH rates were reported in rates per person-year, and the pre-implantation rate was 1.22 compared to 0.88 post-implantation. Participants with

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mean PAPs > 20 mmHg prior to device implantation experienced a much greater decline in mean PAP post-implantation when compared to those with mean PAP < 20 mmHg pre-implantation. There was also a greater reduction in mean diastolic PAP in those with a baseline pressure > 18 mmHg. Decreases in rates of HFH were noted for amyloidosis, HFpEF, and HFrEF. No reduction in HFH was noted in radiation-induced HF. Based on Cox regression modeling, researchers noted that a "higher number of prior HFH, elevated [systolic PAP], and [diastolic PAP] were associated with higher risk of HFH." Additionally, "prior HFH and abnormally elevated [diastolic PAP] were most strongly associated with increased risk of HFH after device placement." There was 1 device complication that the authors attributed to their early experience with device implantation. Seven participants experienced death unrelated to the device with one death being cardiac-related. Limitations of the study included the study being a single-center retrospective analysis with a small sample size and a short follow-up period (median 8.8 months) and the presence of a significant selection bias as treating clinicians carefully identified individuals for CardioMEMS implantation.

Gibson et al. (2023) completed a single-center study at a Canadian hospital to evaluate the impact of PAP monitoring using the CardioMEMS device on health outcomes and spending in patients with NYHA class III HF. 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 HF-related emergency department visits, hospitalizations, heart failure medical doctor visits, HF 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 PAP, diastolic PAP, mean PAP, 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. 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 PAP at baseline was 46.9±9.0 mmHg and at 12-months was 38.1±9.0 mmHg. The mean diastolic PAP at baseline was 24.0±5.8 mmHg and at 12-months was 18.7±5.2 mmHg. Mean PAP 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-transplantation 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 HF physician visits (pre-transplant=77, post-transplant=55) and a 28% decrease in the number of nurse clinician visits (pre-transplant=82, post-transplant=59). 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.

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 PAP monitoring in patients with HF and obesity. A total of 1200 patients were included in the study. Inclusion criteria included NYHA class III HF at least one prior HFH within the previous 12 months prior to implantation, and patients with a 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 PAPs were noted to be higher in patients with a BMI ≥ 35kg/m^2 regardless of EF. The impact of monitoring on PAP was restricted to 839 patients that had both 1-week and 12-month post-implantation readings available. A significant reduction was noted in all PAP measurements from 1-week to 12-months regardless of EF or BMI. Changes were made to diuretics based on PAP 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

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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 HFHs 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

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Guichard et al. (2024) published the results of the PROACTIVE-HF trial that assessed the safety, efficacy, and effect of the Cordella CorPASS. The trial was initially a randomized trial that was later changed to a single arm trial. Inclusion criteria for newly recruited participants included: age > 18 years of age, diagnosis and treatment of NYHA class III HF (regardless of LVEF) for ≥ 3 months at time of screening, history of at least 1 HFH or HF treatment in outpatient or urgent setting in preceding 12 months and/or elevated NT-proBNP, and optimally titrated GDMT for ≥ 30 days at time of screening. The primary cohort (n = 456) consisted of the former treatment arm in the randomized trial (n = 88) and newly enrolled single-arm participants (n = 368). The former control arm (n = 72) was managed identically to the treatment arm, but the control arm was not included in the safety and effectiveness analyses. Participants were treated to a target trend seated mean PAP of 5-20 mmHg using a trial-specific GDMT guideline. Researchers defined the trend seated mean PAP as 7-day moving average of daily mean PAP readings. Follow-up visits for clinical assessment occurred at 1 and 6 months and a telemonitoring visit occurred at 3 months. Researchers noted that the PROACTIVE-HF trial participants were generally younger with a higher BMI, higher proportion with LVEF > 40%, lower NT-pro-BNP, and higher utilization of baseline sodium glucose co-transporter 2 inhibitors compared to similar trials. The 6-month incidence of HFHs or all-cause mortality was 0.15 events per participant (95% CI 0.12-0.20) with no difference noted between the primary cohort and the former treatment arm (0.16 events per participant, 95% CI 0.09-0.26, p = 0.89). The event rate of the former control arm was significantly higher than both the former treatment arm and new single arm (0.28 vs 0.16 p = 0.08 and 0.28 vs 0.15 p = 0.03, respectively). A total of 14 participants required 17 outpatient intravenous diuretic visits (0.04 events, 95% CI 0.02-0.06). The combined 6-month event rate for outpatient intravenous diuretic visits, HFHs, and mortality was 0.19 (95% CI 0.16-0.24) and the 6-month cumulative hazard rate was 0.20. The 6-month pre-implant HFH per patient rate was 0.6±0.7 compared to 0.1±0.4 6-months post-implant. The overall change in NT-proBNP from baseline (1731.4±3012.4 pg/mL) to 6-month follow-up (1632.5±2742.4 pg/mL) was not statistically significant (p = 0.06); however, participants with a baseline NT-proBNP > 1,500 pg/mL (n = 146) were noted to have a significant decrease at 6-months (4118.4±4364.5 pg/mL vs. 3565.6±4011.0 pg/mL, p = 0.003). There was a higher number of medication increases per participant per month compared to decreases (0.6±0.8 vs 0.5±0.7, p = 0.04) with the number of changes (increase or decrease) declining over time. The overall freedom from device and sensor-related complications was 99.2% with 4 participants experiencing a device failure and 1 participant experiencing a sensor failure (99.8% freedom from sensor failure). Longer-term follow-up visits will be completed at 12, 18, 24, 36, 48, and 60 months. Limitations include the open-label, single-arm design and the absence of a control arm. Researchers noted that “the endpoint assessment was blinded and performed by an independent endpoint adjudication committee.”

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 HF 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 HFH, treatment in a hospital day-care setting, or an unplanned outpatient HF 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 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 PAP measurements relative to standard-of-care fluid-filled catheter mean PAP 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, KCCQ, [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 KCCQ 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 PAPs 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 PAP sensor and right heart catheterization measurements of 1.4±6.7 mmHg for the mean PAP, -0.3±7.4 mmHg for systolic PAP, and 2.3±7.7 mmHg for diastolic PAP ($p < 0.001$ for all measurements). A total of eight participants required hospitalization due to HF during the 90-day follow-up and 11 participants required 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 KCCQ 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 HF-related "events were reduced in the general HF 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 PAP readings continued to strongly correlate with average differences of 2.9±7.3 mmHg in the mean PAPs 3.2±8.1 mmHg in the systolic PAPs, and 3.0±6.8 mmHg in the diastolic PAPs ($p < 0.0001$ 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 HFHs occurred amongst 14 participants and a total of five deaths occurred post-implantation. While the rate of HFHs 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 KCCQ 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 PAP 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 PAPs to guide remote adjustment of guideline-directed medical therapy…and the rate of monthly HF 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 HFpEF (Kittleson et al. 2023). PAP 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

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- 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 HF in 2022 (Heidenreich et al. 2022). The guidelines state that wireless monitoring of PAPs 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 **ACC** published an expert consensus decision pathway for the treatment of HFrEF that states "chronic ambulatory PAP monitoring may be considered in patients with hospitalizations in the past year who have persistent symptoms with minimal exertion (Maddox et al. 2024)."

The **European Society of Cardiology (ESC)** published a clinical consensus statement for remote PAP-guided management of patients with HF (Bayes-Genis et al. 2025). The consensus statement notes that the ESC 2021 and 2023 guidelines were finalized before the publication of major trials. Indications for patient selection include NYHA class II or III HF and one HFH or HF event in the preceding year and/or elevated natriuretic peptides. Additional considerations include difficulty managing or assessing fluid volumes, challenging physical assessment (e.g., COPD), compliance with HF medical care, HF management using GDMT, and individuals that will benefit from remote monitoring (e.g., those who live far from clinics). The committee updated the strength of their recommendations to "clinical advice, based on robust published evidence." The ESC also published guidelines in 2021 for the diagnosis and treatment of acute and chronic HF (McDonagh et al. 2021). The recommendations for wireless PAP monitoring in symptomatic patients with HF 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 PAP technologies for remote monitoring of chronic HF (NICE 2026) that state the "CardioMEMS HF System can be used as an option for remote monitoring of New York Heart Association (NYHA) class 3 chronic heart failure in adults at risk of hospitalisation who are able to use the technology (with the help of a carer if necessary) and willing to adjust medication as directed." The guidance also states that "more research is needed on the Cordella Pulmonary Artery Sensor System and the Cordella Heart Failure System for remote monitoring of NYHA class 3 chronic heart failure before it can be funded by the NHS."

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 2025).

- Class I: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation or shortness of breath.
- Class II: Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, shortness of breath or chest pain.
- Class III: Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or chest pain.
- Class IV: Symptoms of heart failure at rest. Any physical activity causes further discomfort.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

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	Description
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 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

08/12/2026	Policy revised. Coverage changed from E/I/U to medically necessary. IRO Peer Reviewed on July 14, 2026 by a practicing physician board certified in Internal Medicine and Cardiovascular Disease.
08/13/2025	Policy reviewed. No changes to coverage criteria. Removed 'Congestive' from title.
08/14/2024	Policy reviewed. No changes to coverage criteria. "CardioMEMS" removed from policy title.
08/09/2023	Policy reviewed. No changes to coverage criteria. Updated Overview, 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. No changes in coverage position. Updated policy from 'Wireless Pulmonary Artery Pressure Monitoring' to "Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS) for Congestive Heart Failure"
02/08/2021	New policy. IRO Peer 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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