Anthem

Medical Policy

Subject: Outpatient Cardiac Hemodynamic Monitoring Using a Wireless Sensor for Heart Failure Management
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Description/Scope

This document addresses the use of a wireless implantable hemodynamic system for ambulatory monitoring of heart failure, specifically the Cordella™ PA Pressure Sensor System (Endotronix, Inc., Lisle, IN) and the CardioMEMS™ HF System (St. Jude Medical Inc., Atlanta, GA). These systems utilize a wireless pressure sensor that is permanently implanted via a right heart catheterization surgical procedure for the purpose of cardiac hemodynamic monitoring of individuals with heart failure in a non-clinical outpatient setting.

Note: For information regarding other technologies used for hemodynamic monitoring, see:

- SURG.00128 Implantable Left Atrial Hemodynamic Monitor

Position Statement

Investigational and Not Medically Necessary:

The implantation of a pressure sensor into the pulmonary artery for the purpose of wireless ambulatory monitoring of heart failure and all other indications is considered **investigational and not medically necessary.**

Rationale

In May 2014, the FDA initially approved the CardioMEMS HF System through the premarket approval (PMA) process. The system utilizes a pulmonary artery sensor device and is indicated for measuring pulmonary artery pressure and heart rate. The CardioMEMS HF System allows the hemodynamic data to be transmitted wirelessly to clinical staff that are monitoring and managing heart failure, with the specific intent to reduce hospitalizations due to heart failure. Initially approval was for individuals who have undergone hospitalization for NYHA Class III heart failure in the past year. In February 2022, FDA approval was expanded to include individuals with NYHA Class II (early stage) heart failure. The system is contraindicated for individuals who are unable to take antiplatelet or anticoagulants for 1 month following the implantation procedure.

Abraham and colleagues (2011) evaluated individuals with New York Heart Association (NYHA) Class III heart failure, who had been hospitalized for heart failure at least once in the previous 12 months in a prospective, single-blinded, multi-center study known as the CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients) trial. After implantation of the pressure sensor, study participants (n=550) were randomized either to the treatment group that consisted of wireless pulmonary artery pressure monitoring and standard of care (n=270) or into a control group that consisted of participants who received only standard of care (n=280); the control arm's device measurements were not made available to investigators for monitoring and management. The primary outcome measure was the rate of hospitalization due to heart failure in the first 6 months following implantation with the device. Quality of life (QOL) measures were included as secondary outcomes. Additional safety outcomes included complications associated with the device or sensor, and pressure-sensor failures. Participants were trained to take daily pulmonary artery pressure measurements at home and were blinded to their treatment group. Follow-up assessments were scheduled at 1, 3, and 6 months, and subsequently every 6 months afterward. Study results indicated a statistically significant 30% reduction in the primary outcome of hospital readmissions for heart failure at the 6-month follow-up in the treatment group compared with the control group (hazard ratio [HR]=0.72; 95% confidence interval [CI], 0.60 to 0.85; p=0.0002). Additionally, the length of hospital stay for heart failure-related admissions was significantly shorter in the treatment group compared with the control group (2.2 days compared with 3.8 days, respectively; p=0.02). The QOL score, using the Minnesota Living with Heart Failure Questionnaire (MLHFQ) Total Score, was significantly improved in the treatment group compared with controls (p=0.02), when assessed at 6 months follow-up. A total of 15 adverse events occurred, 8 of which were considered complications related to the device or system (n=3 treatment group; n=3 control group; n=2 not enrolled). None of the 550 participants experienced sensor-related failures during the entire follow-up period (average of 15 months).

In 2015, Abraham and colleagues published follow-up data to the CHAMPION trial. After completion of the initial randomized access period (average of 18 months), investigators were granted access to pulmonary artery pressure for subjects in both study arms (open access period) for an average of an additional 13 months of follow-up. Over the randomized access period, the reduction in hospital admission rates related to heart failure were sustained, and found to be 33% lower in the treatment group compared to the control group (HR=0.67, 95% CI, 0.55-0.80; p<0.0001). During the open access period, rates of hospital admission related to heart failure for the former control group were reduced by 48% (HR=0.52, 95% CI, 0.40-0.69; p<0.0001) compared to admission rates during the random access period. Heart failure-related mortality and all-cause mortality were not significantly different between the two study arms during the random access period or the open access period. No additional device-related failures were reported.

Despite the early positive results of using the outpatient wireless pressure sensor device for heart failure management, the manufacturer-sponsored randomized controlled trial (RCT) was hampered by methodological weaknesses. The safety and durability of treatment effect are unknown since the study's follow-up period was limited to an average of 31 months (2.6 years). In addition, the primary outcome of 6-month hospital admission rates, while important, is a surrogate measure for more clinically meaningful outcomes, such as mortality data, which the device monitoring reportedly did not significantly impact. Well-designed RCTs with extended follow-up periods and morbidity and mortality primary outcome measures are necessary to establish the safety and efficacy of outpatient cardiac hemodynamic monitoring using a wireless pressure sensor for the routine management of heart failure.

In December of 2015 the final report was published from the California Technology Assessment Forum (CTAF) evaluating the safety and efficacy of the CardioMEMS HF System. The CTAF concluded the following:

> …while post-hoc analyses have been presented illustrating reductions in cardiovascular mortality with CardioMEMS, there have been no published data from trials powered to detect mortality differences. It seems reasonable to surmise that ongoing post-marketing trials evaluating the device may demonstrate a wide variety of outcomes, from substantial net health benefit to

a small likelihood of overall “negative” benefit given the potential harms associated with device placement. Therefore, we judge the current body of evidence on CardioMEMS to be “promising but inconclusive” using the ICER Evidence Rating framework.

Desai (2017) published a retrospective cohort study of Medicare administrative claims data for individuals who received the CardioMEMS device following FDA approval. Out of 1935 Medicare enrollees who underwent implantation of the device, there were 1114 who were continuously enrolled and had evaluable data for at least 6 months prior to, and following, implantation (a subset of 480 enrollees had complete data for 12 months before and after implantation). There were 1020 heart failure-related hospitalizations in the 6 months before implantation, relative to 381 hospitalizations in addition to 17 ventricular assisted device (VAD) implantations or transplants, and 139 deaths in the 6-month post implantation follow-up period. The cumulative incidence of heart failure-related hospitalization was significantly lower than in the 6 months prior to implantation (HR=0.55; 95% CI: 0.49-0.61; p<0.001). Similarly, amongst the 480 individuals with 12-month follow-up data, there were 696 heart failure-related hospitalization in the 12 months prior to implantation, compared to 300 heart failure-related hospitalizations following implantation. There were also 15 VAD implantations or transplants, and 106 deaths. The cumulative incidence of heart failure-related hospitalizations was also significantly lower in the 12-month post implantation cohort (HR=0.66; 95% CI: 0.57-0.76; p<0.001). Despite the trial’s positive outcomes, claims data limitations include that it is not possible to rule out confounding due to medication changes/adjustments, or correlate outcomes to direct intervention based on pulmonary artery pressure data. The primary outcome, reduction in heart failure-related hospitalizations, may be related to the device or simply the amplified touch-points with the healthcare system necessitated by the device’s implantation, and the limited follow-up period in addition to the lack of a control cohort leave the safety and efficacy of the CardioMEMS device still uncertain.

In 2017, Heywood and colleagues published retrospective data from a de-identified cohort of the first 2000 individuals who received the CardioMEMS device and had available follow-up data for a minimum of 6 months (general-use cohort). The primary outcome of interest was trends in remotely monitored pulmonary artery pressures. The mean age of the cohort enrolled was 70 years (standard deviation [SD]=12 years) and the mean follow-up period was 333 days (SD=125 days). Relative to the previously described CHAMPION clinical trial, general-use cohort in this study had a trend of a higher baseline mean arterial pressure (34.9 ± 10.2 mm Hg vs. 31.6 ± 10.7 mm Hg for the CHAMPION cohort; p<0.05). The pulmonary artery pressure reductions in the general-use cohort from this study were significantly higher compared with the CHAMPION trial treatment cohort (p-value unreported) which had an AUC of -150.1 mm Hg-days after 6 months of pressure-guided care whereas the general-use cohort had an AUC of -434 mm Hg-days after 6 months and mean pulmonary artery pressure was reduced from 34.9 ± 10.2 to 31.6 ± 10.4 mm Hg after 6 months (p<0.0001). In this ‘real-world’ cohort, there was a median of 1.2 days between remote pressure transmissions and > 98% weekly use of the system, demonstrating a high-level of adherence. However, similar to the limitations cited in the CHAMPION trial, safety and efficacy conclusions are precluded by the lack of both clinically meaningful data and long-term follow-up. Further, the registry data of this study cannot rule out medication changes/adjustments as a potential confounding variable.

Shavelle and colleagues (2020) conducted a multi-center, prospective, open-label observational CardioMEMS Post-Approval Study which enrolled 1200 participants with NYHA class III heart failure and at least 1 heart failure-related hospitalization within the preceding year. At 12 months, 875 participants remained in the study. The study particularly focused on subgroups defined by sex, race and ejection fraction. The primary efficacy outcome was the difference between rates of hospitalization compared to the year prior. The rate of heart failure-related hospitalization was significantly lower at 1 year compared with the year before implantation (0.54 [628 hospitalizations] versus 1.25 [1600 hospitalizations] events/participant-years, HR=0.43 [95% CI, 0.39–0.47]; p<0.0001). At 1 year post-implant, survival was 83.9% (95% CI, 81.7-85.8%). During the study period there were 5 (0.4%) device- or system-related complications and 1 (0.1%) pressure sensor failure. The significance of primary outcomes was robust across subgroups of gender, race and those with cardiac defibrillator devices. Study limitations include short-term follow-up and single arm, observational design. Additionally, the data source for heart failure-related hospitalizations was by self-report for the year prior to the study’s commencement, which introduces potential bias into the study’s primary efficacy outcome.

In 2020, Angermann and colleagues evaluated the safety and efficacy of the CardioMEMS in Germany, The Netherlands and Ireland to characterize the device’s performance outside of the United States. A total of 234 individuals with NYHA Class III heart failure were enrolled from 31 centers, implanted with a CardioMEMS sensor and received remote pulmonary artery pressure-guided heart failure management. Enrollment criteria included a minimum of one heart failure-related hospitalization in the previous year. At study-end (12 months) 180 study participants remained and the study’s co-primary endpoints, device- or system-related complications and pressure sensor failure, occurred in 4 of 239 (98.3% complication free), and 1 of 234 (99.6% failure free) study participants, respectively. At 12 months, 91 study participants experienced at least 1 heart failure-related hospitalization which was a 62% decrease from the year prior (0.60 vs 1.55 events/participant-year; HR 0.38, 95% CI, 0.31-0.48; p<0.0001). The NYHA class improved in 35.5% of the study cohort (83 study participants) and worsened to NYHA class IV in 1.7% (4 participants) by study end. Pulmonary artery pressure decreased progressively over the course of the study. A total of 21 serious adverse events were reported during implant attempts. By study end, 31(13.8%) participants died; none were considered device, system, or protocol-procedure related. Authors concluded that remote management of heart failure using the CardioMEMS device was both safe and feasible in the health systems studied outside the United States. Study limitations include short-term follow-up, single arm, observational design and results are not generalizable to the device’s performance within the United States.

In 2021, Brinkley and colleagues conducted a post-hoc analysis of the CardioMEMS Post-Approval Study (see Shavelle and colleagues (2020) described above). The Brinkley study’s primary aim was to determine the impact of obesity on the safety and efficacy of CardioMEMS. At baseline, pulmonary artery diastolic pressure was higher in participants with BMI ≥ 35 kg/m2 (n=358) regardless of ejection fraction. In both the obese and non-obese cohort, pulmonary artery pressures were significantly reduced at 12 months (p<0.0001). Heart failure-hospitalization rates were significantly reduced by > 50%: EF < 40% (BMI <35 kg/m2 [HR: 0.48; 95% CI: 0.41-0.55] and ≥ 35 kg/m2 [HR: 0.40; 95% CI: 0.31-0.53]) and EF ≥ 40% (BMI < 35 kg/m2 [HR=0.42; 95% CI, 0.35-0.52] and ≥ 35 kg/m2 [HR=0.34; 95% CI, 0.25-0.45]; p<0.0001). Although obesity did not appear to detrimentally affect performance of CardioMEMS relative to normal weight participants, the trial did not compare clinically relevant outcomes of CardioMEMS to standard medical care and follow-up was limited to 12 months.

In 2021, DeFelippis and colleagues conducted a post-hoc analysis of the CardioMEMS Post-Approval Study (see Shavelle and colleagues (2020) described above). The DeFelippis study’s primary objective was to examine potential gender differences in efficacy and safety of CardioMEMS. Women comprised 38% (n=452) of the study sample and were less likely to be White (78% of women versus 86% of men) and more likely to have nonischemic cardiomyopathy (44% of women versus 34% of men) and had significantly higher systolic blood pressure. Reductions in pulmonary artery pressure from baseline to 12 months in both men and women were similar. Both sexes experienced significant decreases in hospital-related HF over 12 months. There were no significant differences in change in hospital-related HF between men and women or all-cause mortality at 1 year. The study did not detect any efficacy or safety variations between men and women in CardioMEMS HF remote monitoring. This study shares the limitations of the CardioMEMS Post-Approval Study in that it was only 12 months in duration and did not compare this monitoring to standard medical care.

In 2021, Lindenfeld and colleagues published results from the randomized arm of the Hemodynamic-Guided Management of Heart

Failure (GUIDE-HF IDE) trial (n=1000). An observational arm of the study is ongoing (n=2600). All participants in the randomized arm received CardioMEMS pulmonary artery pressure sensor implants. Participants were then randomly assigned 1:1 to the treatment group or the control group. The treatment group received pulmonary artery pressure-guided management and standard-of-care guideline recommended medical therapy. The control group received standard-of-care guideline recommended medical therapy alone. The primary endpoint was a composite score of all-cause mortality and total heart failure events (heart failure hospitalizations and urgent heart failure hospital visits) at 12 months. At the randomized study's end, there were 253 primary endpoint events among 497 subjects in the treatment group and 289 out of 503 in the control group (HR=0.88; 95% CI, 0.74-1.05; p=0.16). There was no statistically significant difference in the composite measure or in any of its components (hospitalization rate, urgent heart failure visits, mortality). Approximately 1% of those enrolled experienced device or system-related complications. All participants received an implant and similar complication rates were seen in the treatment and control groups. The COVID-19 pandemic became a declared national emergency in the U.S. on March 13, 2020. At that time, there were 177 primary events in the intervention group and 224 events in the control group (HR=0.81; 95% CI, 0.66-1.00; p=0.049). This statistically significant difference was due to fewer heart failure hospitalizations in the treatment group than in the control group. The rates for urgent heart failure visits and mortality were not statistically different. This difference in primary events almost disappeared during the COVID-19 pandemic and hospitalization rates decreased from a broad range of conditions. Consistent with that phenomenon, there was a 21% decrease in the control group hospitalization rate following the onset of the national emergency; conversely, the hospitalization rate for the treatment group was slightly lower, but not statistically significant. The between-group difference for heart failure hospitalization was not statistically significant after the declaration of the pandemic emergency (HR=1.11; 95% CI, 0.80-1.55; p=0.53). Although the post-hoc analysis of pre-COVID-19 impact warrants further investigation, the a priori outcomes from the randomized arm of the GUIDE-HF trial did not demonstrate improved health outcomes from the use of hemodynamic-guided management for heart failure.

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). 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.

In 2023, Burgts and colleagues published results of an open-label RCT conducted across 25 sites throughout the Netherlands. 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 2023, Heywood and colleagues published results of the previously described CardioMems post-approval study (Shavelle, 2020) through 2 years of follow-up. Of the originally enrolled 1200 participants 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 2023, Iaconelli and colleagues conducted a meta-analysis of both pre-print and published RCTs (four trials in total). 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, "Haemodynamic 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."

In 2022, the ACC/AHA published guidelines on the management of HF in which the following recommendations were made:

1. In selected adult patients with NYHA class III HF and history of a HF hospitalization in the past year or elevated natriuretic peptide levels, on maximally tolerated stable doses of GDMT with optimal device therapy, the usefulness of wireless monitoring of PA pressure by an implanted hemodynamic monitor to reduce the risk of subsequent HF hospitalizations is uncertain.
2. In patients with NYHA class III HF with a HF hospitalization within the previous year, wireless monitoring of the PA pressure by an implanted hemodynamic monitor provides uncertain value

The Cordella PA Pressure Sensor System, is currently being investigated in the PROACTIVE-HF IDE Trial, a single-arm, prospective, multicenter clinical trial enrolling 350 participants with Class III heart failure (NCT04089059); estimated study completion is November 2025. Other devices that monitor cardiac output through the implantation of a pulmonary sensor to measure pulmonary artery pressure have been investigated in clinical trials, but thus far, none have received FDA approval.

In summary, the current evidence base remains 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 RCTs are necessary to establish whether health outcomes are significantly improved relative to standard of care for heart failure management.

Background/Overview

Individuals with chronic heart failure are at increased risk of developing acute decompensated heart failure, which often requires hospitalization. Hence, early identification of individuals at greatest risk of imminent heart failure is important. Current risk management strategies involve frequent clinical assessment of signs and symptoms and continual cardiac hemodynamic monitoring in a clinical setting. Changes in cardiac hemodynamics may be indicative of change or progression of heart disease (FDA, 2014).

Several novel approaches have been investigated as techniques to measure cardiac hemodynamic variables in an outpatient setting. One such proposed technique involves the implantation of a wireless pressure sensor in the pulmonary artery during a right heart catheterization procedure to measure pulmonary artery pressure and heart rate in individuals with heart failure. Pressure readings are transmitted wirelessly to an external monitor and database where information may be used by clinicians and clinical staff to guide treatment decisions and monitor individuals from their home or other non-clinical setting.

The CardioMEMS HF System has been approved by the FDA for individuals with heart failure, classified as NYHA Class II and III. The CardioMEMS HF System consists of an implantable pulmonary artery sensor, delivery system, and Patient Electronics System (PES). The implantable sensor is permanently implanted in the pulmonary artery during a right heart catheterization procedure. The sensor is roughly the size of a small paper clip and does not require external batteries or wires for operation (FDA, 2012).

Definitions

Cardiac catheterization: A general term describing the use of a thin catheter that is advanced into the bloodstream through an artery at the groin, arm or neck, followed by injection of a contrast agent (dye) that visualizes the coronary arteries and chambers of the heart. Cardiac catheterization, which can be done for diagnostic or therapeutic/interventional purposes or both, can be used to describe imaging of the coronary arteries, (also referred to as coronary angiography), or the heart chambers.

Heart failure: A condition in which the heart no longer adequately functions as a pump. As blood flow out of the heart slows, blood returning to the heart through the veins backs up, causing congestion in the lungs and other organs.

Hemodynamic/Haemodynamic: Study of blood flow or circulation.

New York Heart Association (NYHA) Definitions: The NYHA classification 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.

Right heart: Describes the two chambers on the right side of the heart; the right atrium, which receives the blood returning from the rest of the body, and the right ventricle that pumps this blood to the lungs.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
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
ICD-10 Diagnosis	
	All diagnoses

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Websites for Additional Information

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Description, Rationale, and References sections.
Reviewed	11/10/2022	MPTAC review. Updated Description, Rationale, Background/Overview and References sections.
Reviewed	11/11/2021	MPTAC review. Updated Description/Scope, Rationale and References sections.
Reviewed	11/05/2020	MPTAC review. Updated Rationale and References sections.
Reviewed	11/07/2019	MPTAC review. Updated References section.
Reviewed	01/24/2019	MPTAC review. Updated References section.
	12/27/2018	Updated Coding section with 01/01/2019 CPT and HCPCS changes; added 33289, 93264; code C9741 deleted 12/31/2018.
Reviewed	01/25/2018	MPTAC review. Updated Rationale and References sections.
Reviewed	02/02/2017	MPTAC review. Updated Rationale and References sections.
Reviewed	02/04/2016	MPTAC review. Updated Description, Rationale, Background, References, Websites and Index sections. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. Updated Description, References and Index sections.
New	02/05/2015	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.