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

Last Approval: 8/9/2023
Next Review Due By: August 2024

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 (CDC 2023; NHLBI 2022). Approximately 6.2 million adults in the United States have been diagnosed with heart failure (CDC 2023). 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) (CDC 2023). Despite the availability of evidence-based medical and device therapies for CHF, morbidity, mortality, and costs remain high (Borlaug & Colucci 2023). Estimates state "11.6 per 1000 individuals aged 55 years and older per year [are] hospitalized for [HF] treatment (Hayes 2022)." The severity of CHF is classified by a patient's functional status using the New York Heart Association (NYHA) system (AHA 2023; Hayes 2022).

The CardioMEMS™ Heart Failure (HF) System (Abbott) is a wireless implantable hemodynamic monitor (IHM) for use at home to reduce HF hospitalizations in NYHA class III patients (refer to 'Supplemental Information' section for description of HF classes). The system consists of an implantable pulmonary artery (PA) sensor, which is implanted in the distal PA, a transvenous delivery system, and an electronic sensor that processes signals from the implantable PA sensor and transmits PA pressure (PAP) measurements to a secure database. The continuous monitoring-IHM system is permanently implanted in the PA via a right-heart catheterization procedure that can be performed in an outpatient setting by a cardiac surgeon. This device allows remote hemodynamic monitoring via a wireless system that measures systolic, diastolic, and mean PAPs every 18 seconds. An electronic system transmits the generated data to a secure network where it is available for the interpretation by the treating physician and clinical team to access, review, and make any necessary treatment adjustments with the goal of reducing HF hospitalizations (FDA 2014; Hayes 2022).

Regulatory Status

At this time, only the CardioMEMS device has been granted approval by the FDA. Other devices (such as Chronicle® and ImPressure®) that monitor cardiac output by measuring changes in pressure in the PA or the right ventricular outflow tract are not supported by the evidence that is currently available.

The CardioMEMS™ Champion Heart Failure Monitoring System was approved for marketing by the FDA through the premarket approval process (PMA) under the product code MOM (P100045) (system, hemodynamic, implantable) in May 2014. The CardioMEMS HF 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 Class II HF and those whose blood tests reported high levels of natriuretic peptides, indicating worsening HF (FDA 2022). The CardioMEMS HF 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 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 HF hospitalizations, emergency department visits, and death (FDA 2022).

COVERAGE POLICY

The Wireless Pulmonary Artery Pressure Monitoring (CardioMEMS) for CHF **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 PAP measurement device in individuals with HF 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 HF 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.

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 6 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, HF 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 n-terminal pro-B-type natriuretic peptide (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. 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 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-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 HF 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 (IHM) 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 IHM 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 HF. The primary outcomes observed were total HF-related hospitalizations, worsening HF events (HF hospitalization and ED and urgent clinic visits for intravenous HF therapy), all-cause mortality, combined all-cause mortality and HF hospitalization, and combined all-cause mortality and worsening HF events. Total HF hospitalizations for patients regardless of EF were 591 hospitalizations reported out of 1314 patients receiving IHM-guided care compared to 836 hospitalizations reported out of 1365 patients receiving standard care. This showed a 26% reduction in hospitalizations for IHM-guided care. Total worsening HF events regardless of EF were 650 total events for 1314 patients receiving IHM-guided care compared to 889 total events for 1365 patients receiving standard care. This showed a 29% reduction in HF events for patients receiving IHM-guided care. All-cause mortality for all patients regardless of EF was 110 deaths in 1103 patients receiving IHM-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 HF hospitalizations for all patients regardless of EF were 621 total events reported for 1103 patients receiving IHM-guided care compared to 802 total events reported for 1121 patients receiving standard care, representing a 22% reduction in favor of IHM-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 IHM-guided care compared to 855 total events in 1121 patients receiving standard care, representing a 20% reduction in favor of IHM-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 IHM-guided care compared to 681 events for those receiving standard care, showing a 25% reduction in favor of IHM-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 HF, had a HF-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 HF-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 HF 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 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 HF 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 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 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 HF-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.

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). 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 HF events compared with the control group." The ACC states that this therapy may be most beneficial for "individuals with [HF with preserved EF] who:

- Experience ≥ 1 hospitalization for HF 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 HF 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 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 **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 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 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 PAP monitoring based on a low quality of evidence (Atherton et al. 2018). The guidelines state "implantable PAP monitoring systems may be considered for individuals with a history of HF-related hospitalizations with a reduced or preserved left ventricular EF and "have persistent moderate HF symptoms despite optimal care to decrease hospitalization for HF." The rationale for this recommendation is that a "change in PAP is considered a marker of change in volume status and perhaps an early predictor of hospitalization for HF."

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 HF 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

CPT	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) Codes

HCPCS	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

08/09/2023	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.

REFERENCES

1. American Heart Association (AHA). Classes and stages of heart failure. Updated June 7, 2023. Accessed July 14, 2023. https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure/.
2. Atherton JJ, Sindone A, De Pasquale CG, et al. National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand: Guidelines for the prevention, detection, and management of heart failure in Australia 2018. Heart Lung Circ. 2018 Oct;27(10):1123-1208. doi: 10.1016/j.hlc.2018.06.1042. PMID: 30077227.
3. Borlaug BA, Colucci WS. Treatment and prognosis of heart failure with preserved ejection fraction. Updated June 1, 2023. Accessed July

14, 2023. www.uptodate.com/.
4. Brinkley DM, Guglin ME, Bennett MK, et al. Pulmonary artery pressure monitoring effectively guides management to reduce heart failure hospitalizations in obesity. JACC Heart Fail. 2021 Nov;9(11):784-794. doi: 10.1016/j.jchf.2021.05.020. Epub 2021 Sep 8. PMID: 34509410.
5. Centers for Disease Control and Prevention (CDC). Heart failure. Updated January 5, 2023. Accessed July 14, 2023. https://www.cdc.gov/heartdisease/heart_failure.htm/.
6. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: "LCD L36419 outpatient wireless pulmonary artery pressure monitoring for HF"). Retired July 1, 2020. Accessed July 18, 2023. https://www.cms.gov/medicare-coverage-database/search.aspx/.
7. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (no National Coverage Determination identified for CM-IHM). Accessed July 18, 2023. https://www.cms.gov/medicare-coverage-database/search.aspx/.
8. Curtain JP, Lee MMY, McMurray JJ, et al. Efficacy of implantable haemodynamic monitoring in heart failure across ranges of ejection fraction: a systematic review and meta-analysis. Heart. 2023 May 15;109(11):823-831. doi: 10.1136/heartjnl-2022-321885. PMID: 36522146; PMCID: PMC10314022.
9. Gibson J, McGrath K, Miller RJH, et al. Ambulatory pulmonary artery pressure monitoring reduces costs and improves outcomes in symptomatic heart failure: A single-centre canadian experience. CJC Open. 2022 Dec 26;5(3):237-249. doi: 10.1016/j.cjco.2022.12.008. PMID: 37013072; PMCID: PMC10066443.
10. Hayes. Health technology assessment: CardioMEMS implantable hemodynamic monitor (Abbott) for managing patients with heart failure. Published November 24, 2015. Updated July 28, 2022. https://evidence.hayesinc.com/.
11. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the american college of cardiology/american heart association joint committee on clinical practice guidelines. Circulation. 2022 May 3;145(18):e895-e1032. doi: 10.1161/CIR.0000000000001063. Epub 2022 Apr 1. Erratum in: Circulation. 2022 May 3;145(18):e1033. Erratum in: Circulation. 2022 Sep 27;146(13):e185. Erratum in: Circulation. 2023 Apr 4;147(14):e674. PMID: 35363499.
12. Kittleson MM, Panjrath GS, Amancherla K, et al. 2023 ACC expert consensus decision pathway on management of heart failure with preserved ejection fraction: a report of the american college of cardiology solution set oversight committee. J Am Coll Cardiol. 2023 May 9;81(18):1835-1878. doi: 10.1016/j.jacc.2023.03.393. Epub 2023 Apr 19. PMID: 37137593.
13. McDonagh TA, Metra M, Adamo M, et al. 2021 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure. Eur Heart J. 2021 Sep 21;42(36):3599-3726. doi: 10.1093/eurheartj/ehab368. Erratum in: Eur Heart J. 2021 Oct 14; PMID: 34447992.
14. National Heart, Lung, and Blood Institute (NHLBI). Heart failure. Updated March 24, 2022. Accessed July 14, 2023. https://www.nhlbi.nih.gov/health/heart-failure/.
15. United States Food and Drug Administration (FDA). CardioMEMS HF System (P100045/S056). Published February 18, 2022. Accessed July 14, 2023. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm/.
16. United States Food and Drug Administration (FDA). CardioMEMS HF system (P100045A). Notice of Approval May 28, 2014. Accessed July 26, 2023. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm/.