



May 29, 2024

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RE: CAG-00466N Implanted Pulmonary Artery Pressure Sensor for Heart Failure Management

The American College of Cardiology (ACC) and the Heart Failure Society of America (HFSA) appreciate the opportunity to provide comment on the National Coverage Analysis (NCA) for Implanted Pulmonary Artery (PA) Pressure Sensor for Heart Failure (HF) Management. The societies are supportive of the development of a National Coverage Determination (NCD) for implanted PA sensors for HF Management. An NCD would rectify inconsistent coverage for Medicare beneficiaries across the country and ensure eligible patients have equitable access to this valuable technology. We recommend that the Centers for Medicare & Medicaid Services (CMS) cover Implanted PA Pressure Sensors for HF management in Medicare beneficiaries who meet the Food & Drug Administration's (FDA) approved indication of NYHA Class II or Class III heart failure with either a prior heart failure hospitalization in the past 12 months and/or elevated natriuretic peptide levels.

HF is a complex clinical syndrome with symptoms and signs that result from any structural or functional impairment of ventricular filling or ejection of blood. According to data from CMS, the prevalence of HF among people enrolled in Medicare was 12% in 2022.¹ HF is the leading cause of hospitalization among older adults, and Medicare enrollees with heart failure have the highest readmission rate of any condition.^{1,2} The incorporation of implantable hemodynamic monitoring (IHM) services into the management of HF could bring about significant improvements in Medicare patient outcomes. The device is deployed through the pulmonary artery to monitor vascular pressure and to guide targeted HF treatment. The innovative technology allows for real-time monitoring of

¹ Centers for Medicare & Medicaid Services. Data SNAPSHOT: Heart Failure Disparities in Medicare Fee-For-Service Beneficiaries. <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Snapshot-Heart-Failure.pdf>

² Emmons-Bell S, Johnson C, Roth G. Prevalence, incidence and survival of heart failure: a systematic review. *Heart*. 2022 Aug 11;108(17):1351-1360.



key physiological parameters, enabling healthcare providers to make timely and informed decisions about treatment adjustments. By facilitating early intervention at the onset of symptom exacerbation, the technology has the potential to drastically reduce the rate of hospital readmission, a common and costly occurrence in the HF patient population. Furthermore, the technology empowers patients, giving them an active role in managing their condition and improving their quality of life (QOL).

There are a number of studies that serve as evidence to demonstrate improved outcomes when the appropriate patients are monitored and managed with an implantable pulmonary artery pressure sensor, including the CHAMPION pivotal, randomized control trial (RCT),³ U.S. Post-Approval Study (PAS),⁴ the MEMS-HF study,⁵ the CardioMEMS HF Post-Market Study (COAST)⁶ and the GUIDE-HF RCT.⁷ Additionally, the GUIDE-HF single arm study, which was presented at the Heart Failure Society of America's Conference in October 2023 and is anticipated to be published soon, showed comparable results to the primary trial, indicating a functional benefit even in patients with elevated NT-pro BNP levels without prior hospitalization.

Since the submission of the NCD request, notable data has been published to further underscore the benefit of PA pressure sensor monitoring in select patients. MONITOR-HF was an open-label, randomized clinical trial conducted across 25 centers in the Netherlands with QOL as the primary endpoint. Patients with moderate-to-severe heart failure who received hemodynamic monitoring experienced significant improvements in QOL and a reduction in heart failure hospitalizations, following guideline-directed medical therapy (GDMT). The overall summary score mean improvement in the Kansas City Cardiomyopathy Questionnaire was 7.05 in the treatment group compared to -0.08 for the standard care group at 12 months ($p=0.013$). An improvement ≥ 10 points was seen in 41.7% in the monitored arm vs 30.6% in the standard care (OR 1.85, p 0.020). These results align with other randomized studies demonstrating improvement in QOL cited in the NCD request. Also notable was the benefit of reducing HF hospitalizations from 0.678 in control group to 0.38 per patient-year in the CardioMEMS-monitored group (HR 0.56, CI 0.38-0.84, $p=0.0053$).⁸

³ Abraham WT, Stevenson LW, Bourge RC, et al. CHAMPION Trial Study Group. Sustained efficacy of pulmonary artery pressure to guide adjustment of chronic heart failure therapy: complete follow-up results from the CHAMPION randomised trial. *Lancet*. 2016 Jan 30;387(10017):453-61.

⁴ Shavelle DM, Desai AS, Abraham WT, et al. CardioMEMS Post-Approval Study Investigators. Lower Rates of Heart Failure and All-Cause Hospitalizations During Pulmonary Artery Pressure-Guided Therapy for Ambulatory Heart Failure: One-Year Outcomes From the CardioMEMS Post-Approval Study. *Circ Heart Fail*. 2020 Aug;13(8):e006863.

⁵ Angermann, C, Abmus, B, et al. Pulmonary-Artery-Pressure-Guided Therapy in Ambulatory Patients with Symptomatic Heart Failure: The CardioMEMS European Monitoring Study for Heart Failure (MEMS-HF). *European J of Heart Failure*. 2020

⁶ Cowie MR, Flett A, Cowburn P, et al. Real-world evidence in a national health service: results of the UK CardioMEMS HF System Post-Market Study. *ESC Heart Fail*. 2022 Feb;9(1):48-56.

⁷ Lindenfeld J, Zile MR, Desai AS, et al. Haemodynamic-guided management of heart failure (GUIDE-HF): a randomised controlled trial. *Lancet*. 2021 Sep 11;398(10304):991-1001.

⁸ Brugts JJ, Radhoe SP, Clephas PRD, et al. MONITOR-HF investigators. Remote haemodynamic monitoring of pulmonary artery pressures in patients with chronic heart failure (MONITOR-HF): a randomised clinical trial. *Lancet*. 2023 Jun 24;401(10394):2113-2123.



We would also like to highlight a recent meta-analysis, which concluded that the use of an implantable hemodynamic monitor improves survival rates in patients with HF with reduced Ejection Fraction (HFrEF). The HF management guided by hemodynamic monitoring significantly reduced overall mortality with an HR of 0.75 (95% CI: 0.57-0.99); $P = 0.043$. Furthermore, HF hospitalizations were significantly reduced with an HR of 0.64 (95% CI: 0.55-0.76); $P < 0.0001$. The analysis showed an evident decrease in HF hospitalization within the first year of monitoring and the benefits in terms of reduced mortality become apparent after the first year.⁹

Currently, Abbott's CardioMEMS HF System is the only FDA approved device for remote hemodynamic monitoring for HF patients. There are several IHM services currently under development for HF management, including the Cordella System by Endotronix. The Cordella System PROACTIVE-HF Trial enrolled 456 patients at 75 hospitals in the U.S., Belgium, and Ireland with Class III symptoms, prior HF hospitalization or urgent visit and/or elevated NT-proBNP level $> 1500\text{pg/ml}$ with $\text{LVEF} \leq 0.50$ or ≥ 800 for $\text{HF} > 0.50$, corrected for BMI. Participants were initially randomized followed by conversion to an open label trial after discussions with the FDA regarding clarification of current approved clinical indications for Class III HF. Primary effectiveness endpoint was a performance goal of 0.43 event/patient 6 months established prospectively with FDA, achieved 0.15 (CI 0.12-0.20, lower than performance goal, $p < 0.0001$) and also ($p = 0.03$) compared to the 0.28 rate for 72 patients implanted in the formal control arm prior to conversion to single arm at or before 6 months. This study was recently accepted for publication by JACC Heart Failure.¹⁰

The societies recommend that the developed NCD apply to all future hemodynamic devices that are approved by the FDA and indicated for wirelessly measuring and monitoring pulmonary artery pressure and heart rate in NYHA Class III or II heart failure patients who either have been hospitalized for heart failure in the previous year and/or have elevated natriuretic peptides. This approach ensures that the NCD remains relevant and applicable as new technologies emerge, supporting ongoing advancements in HF management.

Clinical Indications For Use Of Implantable PA Pressure Sensors For HF Management Among Medicare Beneficiaries

Data supports the benefits of ambulatory hemodynamic monitoring in the Medicare population to reduce HF hospitalization. A retrospective cohort study used U.S. Medicare claims data from patients undergoing a PA pressure sensor implantation between June 2014 to December 2015, and

⁹ Lindenfeld J, Costanzo MR, Zile MR, Ducharme A, Troughton R, Maisel A, Mehra MR, Paul S, Sears SF, Smart F, Johnson N, Henderson J, Adamson PB, Desai AS, Abraham WT; GUIDE-HF, CHAMPION, and LAPTOP-HF Investigators. Implantable Hemodynamic Monitors Improve Survival in Patients With Heart Failure and Reduced Ejection Fraction. *J Am Coll Cardiol*. 2024 Feb 13;83(6):682-694.

¹⁰ Guichard JL, Bonno EL, Nassif ME, et al. Seated Pulmonary Artery Pressure Monitoring in Patients with Heart Failure: Results of the PROACTIVE-HF Trial. *J Am Coll Cardiol Heart Fail*. In press.

the rates of HF hospitalization during predefined periods before and after implementation were compared. The results showed that among 1,114 patient receiving the implants, there were 1,020 HF hospitalizations in the 6 months prior compared with 381 HF hospitalizations, 139 deaths, and 17 ventricular assist device implantations and/or transplants in the 6 months after implantation (HR=0.55 $p<0.001$) with estimated cost-saving \$7433/patient. These benefits align with those demonstrated in the trials and were sustained to 1 year, supporting the “real world” effectiveness of an implanted PA pressure sensor to manage HF.¹¹

Treatment efficacy is consistent across the spectrum of FDA indications; however, individuals at a higher risk experience greater absolute benefit as long as they have not become refractory to diuretic therapy. Overall, the higher absolute clinical benefit of reduced hospitalization is most pronounced in patients with higher absolute risk, which are those patients classified with Class III and Class II HF with prior hospitalization. The relative benefit is parallel in Class III and Class II HF patients without hospitalization and with elevated BNP or NT-proBNP. All patients were required to have elevated BNP or NT-proBNP levels for enrollment in trials.¹²

The benefit of remote monitoring using PA pressure sensors has been shown across all EF ranges, including HF_rEF and HF with preserved EF (HF_pEF). In fact, the benefit is equal, if not higher, in patients with HF_pEF.^{13,14} Additionally, the hospitalization criterion is particularly relevant in patients with whom BNP or NT-proBNP levels are lower, such as patients with obesity. The data shows lack in apparent variants across subgroups, and that subgroups consistently benefit from utilization of the technology. Real-world experience demonstrates a larger representation of subgroups, including minorities. The data indicates there is no significant difference among subgroups, and all subgroups consistently benefit from the technology.¹⁵

The societies endorse a patient selection criteria that aligns with the GUIDE-HF trial. As outlined in the NCD request, patients must present with the following conditions:

- A NYHA Class II or Class III HF symptoms present over the previous 30 days despite maximally tolerated guideline-directed medical and device therapies irrespective of left ventricular ejection fraction (LVEF).

¹¹ Desai AS, Bhimaraj A, Bharmi R, Jermyn R, Bhatt K, Shavelle D, Redfield MM, Hull R, Pelzel J, Davis K, Dalal N, Adamson PB, Heywood JT. Ambulatory Hemodynamic Monitoring Reduces Heart Failure Hospitalizations in "Real-World" Clinical Practice. *J Am Coll Cardiol*. 2017 May 16;69(19):2357-2365.

¹² Desai AS, Maisel A, Mehra MR, et al. GUIDE-HF Investigators. Hemodynamic-Guided Heart Failure Management in Patients With Either Prior HF Hospitalization or Elevated Natriuretic Peptides. *JACC Heart Fail*. 2023 Jun;11(6):691-698.

¹³ Adamson PB, Abraham WT, Bourge RC, et al. Wireless pulmonary artery pressure monitoring guides management to reduce decompensation in heart failure with preserved ejection fraction. *Circ Heart Fail*. 2014 Nov;7(6):935-44.

¹⁴ Shavelle DM, Desai AS, Abraham WT, et al. CardioMEMS Post-Approval Study Investigators. Lower Rates of Heart Failure and All-Cause Hospitalizations During Pulmonary Artery Pressure-Guided Therapy for Ambulatory Heart Failure: One-Year Outcomes From the CardioMEMS Post-Approval Study. *Circ Heart Fail*. 2020 Aug;13(8):e006863.

¹⁵ Desai AS, Bhimaraj A, Bharmi R, Jermyn R, Bhatt K, Shavelle D, Redfield MM, Hull R, Pelzel J, Davis K, Dalal N, Adamson PB, Heywood JT. Ambulatory Hemodynamic Monitoring Reduces Heart Failure Hospitalizations in "Real-World" Clinical Practice. *J Am Coll Cardiol*. 2017 May 16;69(19):2357-2365.

- Be able to tolerate dual antiplatelet or anticoagulation therapy for one-month post implantation
 - Meet the anatomical considerations per the manufacturer’s indications for use (IFU) for appropriateness of sensor functionality, such as body mass index and chest circumference.
 - Have one hospitalization related to HF in the past 12 months.
- OR
- Have elevated NT-proBNP or BNP defined per the manufacturer’s IFU.

Implantable PA pressure sensors for HF management are not recommended for Class IV patients. Those patients who are classified as Class IV during hospitalization or an urgent clinic visit must be stabilized to Class III prior to evaluating their suitability for a PA pressure sensor implant.

Health Disparities and Health Equity

Achieving health equity in HF management is a multifaceted challenge that involves various factors such as race and ethnic disparities, access to care, socioeconomic, and other social determinants of health (SDOH). Addressing health disparities is crucial to achieving healthy equity in HF management. Access and implementation of an implanted PA pressure sensor for HF monitoring could play a vital role in narrowing these disparities. Remote monitoring is particularly important for patients who are disadvantaged by a rural location and/or lack of transportation to access a clinic for in-person evaluation.

Although data on the use of IHM and its racial impact is limited, existing data on racial disparities within HF^{16,17,18,19} shed light on the SDOH that influence various racial and ethnic groups, which can impact HF management outcomes. A study presented at the American College of Chest Physicians (CHEST) 2023 Conference investigated racial and ethnic disparities in the utilization of ambulatory hemodynamic monitoring. The findings indicate comparable rates of IMH implantation among Black, Hispanic, and White patients, pointing to an absence of significant disparities in the utilization of this technology within the three populations.²⁰ This underscores the potential of IHM, like CardioMEMS, to contribute to health equity by providing uniform access to advanced HF management tools across diverse patient populations.

¹⁶ Agarwal MA, Fonarow GC, Ziaian B. National Trends in Heart Failure Hospitalizations and Readmissions From 2010 to 2017. *JAMA Cardiol.* 2021;6(8):952–956.

¹⁷ Savitz ST, Leong T, Sung SH, et al. Contemporary reevaluation of race and ethnicity with outcomes in heart failure. *J Am Heart Assoc.* 2021;10:e016601

¹⁸ Rathore SS, Foody JM, Wang Y, et al. Race, quality of care, and outcomes of elderly patients hospitalized with heart failure. *JAMA.* 2003;289:2517–2524

¹⁹ Vivo RP, Krim SR, Liang L, et al. Short- and long-term rehospitalization and mortality for heart failure in 4 racial/ethnic populations. *J Am Heart Assoc.* 2014;3:e001134.

²⁰ [Racial and ethnic disparities in the utilization of ambulatory pulmonary artery pressure monitoring in the United States in a nationally representative cohort. chestnet.org.](https://www.chestnet.org)



Another significant equity concern pertains to Medicare patients access to PA pressure sensor monitoring. Currently, coverage varies based on geographic location, with some Medicare Administrative Contractors (MACs) providing coverage, while others do not. Additionally, many Medicare Advantage plans also do not cover this service. Implementing an NCD would effectively address this inequity by ensuring equal opportunities for accessing this technology across the country for all Medicare beneficiaries.

Facility and Operator Requirements

It is imperative that all facilities have the necessary infrastructure to fully support the comprehensive use of an implantable PA pressure sensor monitoring device. The societies concur with the proposed requirements for the team performing the implementation as outlined in the NCD request. While the NCD request suggests the requirement of the presence of a single monitor on-site for the implant and subsequent monitoring, we strongly recommend requiring two monitors be accessible to the team across sites. This would allow for continuous access in various hospital areas and beyond, including the catheterization lab, outpatient clinics, or the office setting. Additionally, it would provide for the needs of inpatients who do not have their transmission devices, allowing for consistent data transmission from their hospital beds.

We emphasize the critical need for additional facility requirements to ensure sites have the infrastructure in place to support patient monitoring and formulate care plans. It is essential that facilities have a trained professional on staff to educate and evaluate patients and their caregivers prior to implementation for cognitive and physical ability to participate actively in the data transmission and responsive plans for intervention. Moreover, it is imperative for facilities to employ staff with the proper training to conduct monitoring reviews at least 2 to 3 times per week during the initial first 90 days post-implantation and weekly thereafter once stability is established. In addition to the regular reviews, staff must be available also to respond to automatic alerts and to provide review of monitored data at least 2 to 3 times in the week of an episode requiring intervention to avert decompensation. Furthermore, the facility must have physician staff to take responsibility for oversight of data, short-term and long-term care plans for each patient, and oversee patient education and management. The inclusion of these requirements would ensure maintenance of a high standard of care that is necessary to ensure the technology is utilized effectively when most needed, thereby facilitating timely interventions and improving patient outcomes.

PA pressure sensor monitoring is reasonable and necessary in select patients and promises substantial improvements in patient outcomes and a reduction in HF hospitalizations. We support Medicare coverage for PA Pressure Sensor Monitoring for HF Management and thank CMS for the



opportunity to provide comment on the NCA. Please direct any questions or concerns to Amanda Stirling, Regulatory Affairs Associate, at 202-375-6553 or astirling@acc.org.

Sincerely,

A handwritten signature in black ink that reads "Cathleen Biga".

Cathleen Biga, MSN, FACC
President
American College of Cardiology

A handwritten signature in black ink that reads "James C. Fang".

James C. Fang, MD, FHFA
President
Heart Failure Society of America