**SAMPLE APPEAL TEMPLATE**

**NOT MEDICALLY NECESSARY / INVESTIGATIONAL EXPERIMENTAL**

**CardioMEMS™ HF System**

**The following template is a sample appeal letter.**

1. Customizations should be based on the medical appropriateness of the CardioMEMS™ HF System for the patient. Fields for customization include, but may not be limited to, those **highlighted in yellow**.
2. It is important to provide the most complete information to assist with the appeal of a prior authorization denial.
3. Highlighted text should be deleted prior to the submission of this letter to any health plan, so the health plan does not misinterpret the information.

Do not include this instruction page in your submission.

**Important Safety Information**

**CardioMEMS™ HF System**

**Brief Summary:**Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

**CardioMEMS™ HF System Indications and Usage:** The CardioMEMS HF System is indicated for wirelessly measuring and monitoring pulmonary artery pressure and heart rate in NYHA Class II or III heart failure patients who either have been hospitalized for heart failure in the previous year and/or have elevated natriuretic peptides. The hemodynamic data are used by physicians for heart failure management with the goal of controlling pulmonary artery pressures and reducing heart failure hospitalizations.

**CardioMEMS HF System Contraindications:**The CardioMEMS HF System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

**CardioMEMS HF System Adverse Events:** Potential adverse events associated with the implantation procedure include, but are not limited to, the following: air embolism, allergic reaction, infection, delayed wound healing, arrhythmias, bleeding, hemoptysis, hematoma, nausea, cerebrovascular accident, thrombus, cardiovascular injury, myocardial infarction, death, embolization, thermal burn, cardiac perforation, pneumothorax, thoracic duct injury and hemothorax.

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[Date]

Attention: Appeals Department

Reference number: [ ]

[Payer Name]

[Street address]

[City, State, zip code]

[Fax]

**Re: Expedited Appeal of Denial for Coverage of the CardioMEMS™ HF System**

Patient Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Policy Holder Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Patient ID #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Policy, Group, or Claim # \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Diagnosis**: [**list ICD10 DX code and diagnosis code descriptor**]

***Procedure Codes:***

**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.

**C2624:** Implantable wireless pulmonary artery (PA) pressure sensor with delivery catheter, including all system components (device code for Medicare facility claims).

**I am requesting an expedited review by a board-certified appropriate physician with a background in treating heart failure.**

Dear [Payor] member appeals,

I am writing to you on behalf of my patient, [name]to request a reconsideration of the denial of prior authorization for the **CardioMEMS™ HF System** to wirelessly measure and monitor pulmonary artery pressure.

While commercial plans are not mandated to follow Medicare guidelines, it is important to highlight Medicare has issued a National Coverage Determination (NCD) with Coverage with Evidence Development (CED), for the CardioMEMS™ HF System for patients meeting specific criteria (CAG-00466N).[1](#_NCA_-_Implantable)

I understand that you have consider the CardioMEMS™ HF System “investigational”.[2](#_Anthem_medical_Policy) While medical policies can have differing criteria, in the Anthem Medical Policy "investigational" means that the procedure, treatment, supply, device, equipment, facility or drug (all services) does not meet the Company Technology Evaluation Criteria because it does not meet **one or more** of the following criteria:

* have final approval from the appropriate government regulatory body; **or**
* have the credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community which permits reasonable conclusions concerning the effect of the procedure, treatment, supply, device, equipment, facility or drug (all services) on health outcomes; **or**
* be proven materially to improve the net health outcome; **or**
* be as beneficial as any established alternative; **or**
* show improvement outside the investigational settings.[2](#_Anthem_medical_Policy)

However, the CardioMEMS™ HF System is clearly not investigational and experimental based on this criterion and should be covered for my patient because:

* It has received final approval from the appropriate government regulatory body, FDA on May 28, 2014.[3](#_U.S._Food_and)
* It has credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community which permits reasonable conclusions concerning the effect of the procedure, treatment, supply, device, equipment, facility or drug (all services) on health outcomes.

Specifically:

* It has proven materially to improve the net health outcome.
* It is beneficial as any established alternative.
* It has shown improvement outside the investigational settings.
* (See Appendix 1 – 17)

It is my recommendation that [patient] [urgently] needs this device and procedure due to [his/her] heart failure status.

**Patient Clinical History**

[Insert paragraph explaining, in your own words, why CardioMEMS™ HF System is medically necessary for this patient]

* What is the diagnosis code supporting the CardioMEMS™ HF System procedure?
* Has the patient been diagnosed with chronic HF for at least 3 months?  Date of diagnosis?
* What is the patient’s NYHA classification?
* Has the patient been hospitalized for heart failure?  Date(s)?
* Has the patient been on GDMT for at least 3 months?
* Has the patient been evaluated for, and received if appropriate, an ICD, CRT-P, or CRT-D (≥3 months prior to implantation)? If yes, Date of implantation?
* Has the patient had a major cardiovascular event within the last 3 months?
* Does the patient have access to reliable connectivity for daily IPAPS data submission?
* Is there additional information that qualifies this patient for CardioMEMS™ HF System?

**Background**

Heart Failure (HF) is a chronic, progressive syndrome that is characterized by congestion, fluid retention, as well as inadequate cardiac output. Without proper management, HF worsens and develops into acute decompensated heart failure (ADHF), a condition associated with increased hospitalization and mortality rates. [Patient Name]’s HF requires active management in addition to monitoring traditional heart failure signs, symptoms, and measures.

The CardioMEMS™ HF System is FDA approved for wirelessly measuring and monitoring pulmonary artery pressure in New York Heart Association (NYHA) Class II or III heart failure patients with a prior hospitalization for heart failure the previous year and/or elevated natriuretic peptides.[2](#_Anthem_medical_Policy)

Hemodynamic data are used by physicians for HF management and with the goal of controlling PA pressure and reducing HF hospitalizations. I believe the CardioMEMS™ HF System will allow us to more closely monitor [Patient Name]’s pulmonary pressures and volume status, which are indications that allow for proactive and personalized interventions with diuretics and optimize HF medications.

The CardioMEMS™ PA Sensor is permanently implanted into the pulmonary artery (PA) using a safe, well-understood, standard, right heart catheterization and over-the-wire interventional procedure. Nitinol wire loops on both ends of the sensor hold it in place in the pulmonary artery (PA). The sensor endothelializes in the pulmonary artery (PA).

Ongoing monitoring of PA pressure, used in conjunction with clinical signs and symptoms, can provide an objective[4](#_Abraham,_W._T.,), [5](#_Abraham_et_al.), [6](#_Desai_et_al,)and can reduce HF hospitalizations, improve patient QOL and outcomes, and improve survival. Based on measures collected remotely via the patient home electronics unit, the CardioMEMS™ HF System pairs with a securely designed data platform that automatically generates easy-to-read reports for physicians. This gives physicians the ability to make time-sensitive and potentially critical treatment decisions for patients prior to escalation to decompensated heart failure.

***Clinical Evidence***

There is now ample clinical evidence beginning in 2014 reinforcing the benefits of hemodynamic management of patients using the CardioMEMS™ HF System. This includes three randomized controlled trials in addition to many others, studying over 8,000 patients. The CardioMEMS™ HF System has been implanted in over 40,000 patients to date.

**MONITOR-HF**

The most recent randomized controlled trial to investigate the benefits of hemodynamic monitoring with CardioMEMS™ HF System (MONITOR-HF) was conducted in the Netherlands and published in The Lancet in May 2023. [7](#_Brugtts_JJ_et) The objective of the MONITOR-HF trial was to evaluate the effectiveness of remote hemodynamic monitoring on quality of life and heart failure hospitalizations in heart failure patients compared to standard care.

This was an independent investigator-initiated study designed and run by the Erasmus MC University Medical Centre. The study was funded by the Dutch Ministry of Health and National Health Care Institute. Abbott had no part in the design, conduct of the study, or any of its components, analyses, or writing.

In this prospective, multicenter, open-label, randomized controlled trial (N=348), hemodynamic monitoring using the CardioMEMS™ HF System resulted in a significant, and clinically meaningful improvement in quality of life, with a +7.13-point difference in mean KCCQ-OS score. Patients in the CardioMEMS-HF arm also had a 44% reduction in HFH as compared to the SoC group, consistent with observed results from prior CardioMEMS HF System studies. The reduction in HFH rate in the CardioMEMS patients was associated with a significant reduction in mean PAP over the follow-up period, as well as a significant reduction in NT-proBNP levels.[6](#_Desai_et_al,)

Patients managed with CardioMEMS™ HF System had nearly twice as many changes in GDMT, including diuretics, compared to standard of care. Hemodynamic management using CardioMEMS™ HF System facilitated personalized GDMT modification including, but not limited to, effective titration of diuretics, resulting in improved outcomes.

These results are consistent with results of other trials involving CardioMEMS™ HF System, which has now demonstrated consistent and improved outcomes in three prospective RCTs (along with CHAMPION and GUIDE-HF) across Europe and North America. The positive benefits have been consistent, independent of evolving and improving GDMT since the first RCT in 2011. The study showed that even in a European healthcare system, where there is already high utilization of contemporary GDMT, managing HF patients with the CardioMEMS HF System significantly improves quality of life, and reduces PA pressures, HF hospitalizations, and BNP levels. These outcomes are driven by facilitating personalized GDMT modification including effective titration of diuretics and neurohormonal therapy. This was the first RCT to evaluate PA pressure monitoring against a usual care group for whom clinician contact was not increased as part of the trial and was arguably the best representation of a true standard of care control.

**Meta-Analysis Demonstrates Improved Survival**

In Feb 2024, a meta-analysis was published in the *Journal of the American College of Cardiology* to study the effects of implantable hemodynamic monitors on survival in patients with heart failure and reduced ejection fraction.[7](#_Brugtts_JJ_et) The meta-analysis was a combined patient-level data analysis of HFrEF patients from CHAMPION, GUIDE-HF, and LAPTOP-HF, and was the first meta-analysis to demonstrate a survival benefit for HF patients managed hemodynamically.

At 2 years of follow-up, results from this patient-level meta-analysis demonstrated that remote hemodynamic monitoring of patients with HFrEF reduced mortality risk by 25%, and reduced heart failure hospitalization by 36% at 12 months. A key finding of this study besides the improved survival for these patients was that a mortality benefit becomes evident with a longer follow-up period of >1 year using hemodynamic management. Though this longer-term survival benefit has long been suspected for patients managed hemodynamically, this is the first time that it has been clearly demonstrated.[8](#_Adamson_PB,_Abraham)

In 2021, clinical research from the largest remote hemodynamic monitoring trial, GUIDE-HF,[9](#_Lindenfeld_J,_et) reinforces the outcomes and proven benefits of the CardioMEMS™ HF System including reductions in heart failure hospitalizations and freedom from device or system-related complications. This trial was designed to evaluate the following:

* Whether the CardioMEMS™ HF System could reduce heart failure hospitalizations, urgent outpatient visits, and mortality in patients with heart failure across the spectrum of symptom severity (NYHA functional Class II–IV) in 12 months and,
* Whether qualification utilizing an elevated BNP (B-type natriuretic peptide) or NT-pro B-type natriuretic peptide is appropriate in lieu of a prior heart failure hospitalization within 12 months.

The study was comprised of 1,022 patients randomized in a multicenter, single-blind study across 118 centers in the US and Canada. All patients were implanted with the CardioMEMS’ sensor but randomized either to the control or treatment arm where in the treatment arm, clinicians had access to the pulmonary artery pressures to proactively manage patients’ heart failure compared to the control patients who were managed with usual care.

The results from the pre-COVID-19 follow up demonstrated a statistically significant 19% treatment benefit in the primary composite endpoint which was driven by a 28% reduction in HF hospitalizations. NYHA Class II & III patients demonstrated a 24%[6](#_Desai_et_al,) treatment benefit in the composite primary endpoint in the pre-COVID 19 follow up. This is complementary to the benefits seen in the CHAMPION trial for which supports the current indication for CardioMEMS. The randomized results of GUIDE-HF and the totality of evidence to date support the benefits of remote hemodynamic management in appropriate HF patients.

The safety outcomes for CardioMEMS continued to be sustained. The randomized arm of the GUIDE-HF trial achieved a freedom from device or system-related complications (DSRC) of 99.2%. Over 3,000 patients have now been followed in prospective trials with > 98% freedom from DSRC) in each study.[10](#_Lindenfeld_J,_Costanzo)

Clinical research has shown the safety and efficacy of CardioMEMS (CHAMPION). The randomized, controlled (CHAMPION)[11](#_Givertz_MM,_Stevenson) clinical trial enrolled patients with NYHA Class III HF with a prior HFH in the last 12 months. Patients in the CardioMEMS’ treatment group experienced a significantly lower risk of HF hospitalizations or death, shorter hospital stays, improved quality of life, and a greater number of days alive outside the hospital compared to the control group, with no increase in adverse events (CHAMPION).[11](#_Givertz_MM,_Stevenson) The growing body of evidence, including the publication in *Circulation* of the first 2,000 consecutive, commercial patients implanted with CardioMEMS demonstrated that the general-use of implantable hemodynamic technology in a non-trial setting leads to significant lowering of pulmonary artery (PA) pressures.[6](#_Desai_et_al,) In addition, the study demonstrated that patients outside the clinical trial were compliant with their therapy in transmitting their pulmonary artery (PA) pressures daily with an average of 1.2 days.[12](#_Heywood_JT,_Jermyn)

The (2017) retrospective analysis of Medicare claims data demonstrated that patients with CardioMEMS had the following:

* 45% reduction in HF hospitalizations at 6 months which compared favorably with the 28% reduction observed in the CHAMPION pivotal trail at 6 months.[10](#_Lindenfeld_J,_Costanzo)
* This reduction in HF hospitalization was associated with a cost savings of $7,433 per patient-6 months and $11,260 per patient-year.[6](#_Desai_et_al,)

Similarly, a recent retrospective study evaluating 1087 patients receiving a CardioMEMS™ PA Sensor were matched to a control arm (patients who were like those implanted with CardioMEMS technology but did not receive the therapy) using a matching algorithm from the Medicare claims database. The Abraham et al. (2019) publication in *JAMA Cardiology* demonstrated that patients in the CardioMEMS™ HF System treatment arm had a significantly lower rate of mortality (30% reduction) and HF hospitalization at 12 months (24% reduction) than a cohort of concurrently treated, propensity-matched control patients.[4](#_Abraham,_W._T.,)

The CardioMEMS post approval study (PAS) was presented at the 2019 American College of Cardiology Scientific Expo that demonstrated the effectiveness and safety of PA pressure-guided therapy for HF in 1200 patients for one year. This study was then published in Circulation Heart Failureand demonstrated continued safety and strong efficacy of CardioMEMS technology beyond the CHAMPION trial. Patients were used as their own control for the comparison of HF hospitalizations prior to implant with CardioMEMS and post implant after one year. The PAS[9](#_Lindenfeld_J,_et) (NCT 02279888) met the following:

* Primary efficacy endpoint: Decreased HF hospitalizations by 57% at one year.[9](#_Lindenfeld_J,_et)
* Primary safety endpoint: 99.6% freedom from device/system related complications and 99.9% freedom from pressure sensor failure at one year.[5](#_Abraham_et_al.)

In addition, the [MEMS-HF study](https://onlinelibrary.wiley.com/doi/abs/10.1002/ejhf.1943) was published in the European Journal of Heart Failure in June 2020. CardioMEMS™ HF System was a prospective, single-arm, multi-center, open-label trial (N=234) conducted in Germany, The Netherlands, and Ireland. The objective was to evaluate the safety and efficacy of CardioMEMS in a real-world setting to determine safety and efficacy in a European clinical setting with focus on patient reported outcomes, functional assessment and hospitalization rates. The trial demonstrated a 62% reduction in HF hospitalizations among patients completing their 1-year follow up as well as significant improvement in patient functional status and quality of life with decreased levels of depression, and decreased NT-pro BNP levels over time.[13](#_Angermann_CE,_Assmus)

On November 24th, 2021, the National Institute for Health and Care Excellence (NICE) updated their Interventional Procedure Guidance (IPG711) for Percutaneous Implantation of Pulmonary Artery Pressure Sensors for monitoring treatment of Heart failure[.14](#_National_Institute_for) Based on the current review of the local evidence and recent publications (GUIDE-HF included) supporting CardioMEMS, NICE concluded that the evidence on the safety and efficacy of pulmonary artery pressure monitoring is adequate to support using this procedure in England and provided the positive recommendation of allowing for standard arrangements for healthcare providers to consider this procedure as an option for appropriately indicated patients.[13](#_Angermann_CE,_Assmus)

* For the comprehensive guidance document, please go to: NICE Guidance for [PAP](https://www.nice.org.uk/guidance/ipg711/chapter/1-Recommendations) Monitoring[14](#_National_Institute_for)

***Lifetime Remote Monitoring***

Remotely obtained PA pressure trends assess patient volume shifts and allow personalization of diuretic management to avoid volume overload or depletion without face-to-face clinical evaluation.[5](#_Abraham_et_al.)

This is supported by the recent statement from the Heart Failure Society of America (HFSA)[15](#_Gorodeski_EZ,_Goyal) which reads:

*“CardioMEMS, a hemodynamic monitor implanted into the pulmonary artery that remotely transmits pulmonary artery pressures, has been shown to reduce hospital readmissions and improve quality of life, and thus may be used in addition to telehealth visits to guide therapy.”*

**Our request**

**I urge you to reconsider your denial of the prior authorization, for the CardioMEMS™ HF System** **as I believe it is medically necessary for my patient. The decision to deny authorization limits access to essential care that directly impacts the patient’s health and well-being.**

Sincerely,

[Physician’s name and credentials]

[Title]

[Name of practice]

[Street address]

[City, State, zip code]

[Phone number]

**Enclosures:**

Patient Information

Clinical Documentation

FDA Approval

**APPENDIX:**

The published clinical data on the safety and effectiveness of CardioMEMS™ HF System include but are not limited to the following:

|  |  |
| --- | --- |
| 1. | NCA - Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (CAG-00466N) - Decision Memo |
| 2. | Anthem medical Policy Investigational Criteria ADMIN 00005. ADMIN.00005 Investigational Criteria |
| 3. | U.S. Food and Drug Administration, P100045/S056 CardioMEMS HF System Premarket Approval (PMA) (fda.gov) |
| 4. | Abraham, W. T., et al. CHAMPION Trial Study Group. (2011). Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomized controlled trial. Lancet, 377, 658-666. |
| 5. | Abraham et al. Association of ambulatory hemodynamic monitoring with clinical outcomes in a concurrent matched control analysis. JAMA Cardiology. doi:10.1001/jamacardio.2019.1384. Published online May 15, 2019. |
| 6. | Desai et al, Ambulatory hemodynamic monitoring reduces heart failure hospitalizations in ‘real world’ clinical practice. JACC. 2017. |
| 7. | Brugtts JJ et al. Remote Haemodynamic Monitoring of Pulmonary Artery Pressures in Patients with Chronic Heart Failure (MONITOR-HF): A randomized controlled clinical trial in a contemporary HF population. Lancet 2023 Jun 24;401(10394):2113-2123. doi: 10.1016/S0140-6736(23)00923-6 |
| 8. | Adamson PB, Abraham WT, Costanzo MR, Hasan A, Yadav C, Henderson J, Cowart P, Stevenson LW: Wireless pulmonary artery pressure monitoring guides management to reduce decompensation in heart failure with preserved ejection fraction. Circulation Heart Fail. 2014;7:935-944 |
| 9. | Lindenfeld J, et al. Haemodynamic-guided management of heart failure (GUIDE-HF): a randomised controlled trial. The Lancet. 2021;398(10304):991-1001. |
| 10. | Lindenfeld J, Costanzo MR, Zile MR, et al. Implantable Hemodynamic Monitors Improve Survival in Patients with Heart Failure and Reduced Ejection Fraction. J Am Coll Cardiol. 2024;83(6):682-694. doi:10.1016/j.jacc.2023.11.030 |
| 11. | Givertz MM, Stevenson LW, Costanzo MR, et al; CHAMPION Trial Investigators. Pulmonary artery pressure-guided management of patients with heart failure and reduced ejection fraction. J Am Coll Cardiol. 2017;70(15):1875-1886. doi:10.1016/j.jacc.2017.08.010 |
| 12. | Heywood JT, Jermyn R, Shavelle D, Abraham WT, Bhimaraj A, Bhatt K, Sheikh F, Eichorn E., Lamba S, Bharmi R, Agarwal R, Kumar C, Stevenson LW. Impact of practice based management of PA pressures in 2000 |
| 13. | Angermann CE, Assmus B, Anker SD, et al. Pulmonary artery pressure-guided therapy in ambulatory patients with symptomatic heart failure: the CardioMEMS European Monitoring Study for Heart Failure (MEMS-HF) [published online ahead of print, 2020 Jun 27]. Eur J Heart Fail. 2020;10.1002/ejhf.1943. doi:10.1002/ejhf.1943 |
| 14. | National Institute for Health and Care Excellence. (2021, November 24). Guidance: Percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure: Guidance. NICE. Retrieved December 29, 2021, from https://www.nice.org.uk/guidance/ipg711 |
| 15. | Gorodeski EZ, Goyal P, Cox ZL, et al. Virtual visits for care of patients with heart failure in the era of COVID-19: A statement from the Heart Failure Society of America. J Cardiac Fail 2020 (online publication). |