**SAMPLE PRIOR AUTHORIZATION LETTER OF MEDICAL NECESSITY FOR THE**

**CardioMEMS™ Heart Failure (HF) System**

**The following template is a sample prior authorization 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**.

1. It is important to provide the most complete information to assist with the prior authorization process.

1. 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: Prior Authorization Department

[Insurance Company name]

[Insurance Company address]

[Fax:]

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

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

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

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

**Re: Prior Authorization Request for Pulmonary Artery (PA) Sensor Implant (CPT‡ code 33289)**

Dear [Payor contact name]:

I am writing to request a prior authorization of coverage and/or pre-determination for a **CardioMEMS™ HF System** on behalf of my patient, [Patient Name].

**Indication**: CardioMEMS™ HF System is indicated for wirelessly measuring and monitoring pulmonary artery (PA) pressure and heart rate in New York Heart Association (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.

**Summary of Patient Qualifications**

[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)?
* If no HFH, what are the NMP/NT-proBNP values? Date?
* 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 the CardioMEMS™ HF System?

 **Our request:**

Although commercial plans are not required to follow National Coverage Determinations (NCDs), it is important to note that Medicare has approved coverage for the CardioMEMS HF System under NCD, CAG-00466N, with Coverage with Evidence Development (CED).[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.

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.
* 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.
* 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.

I have discussed the procedure with my patient, and we have concluded the CardioMEMS™ PA Sensor implant is the best and most effective means to manage [his/her] heart failure with the goal of reducing heart failure hospitalizations.

My patient, [patient name] will benefit greatly from this procedure. [Her/His] quality of life and well-being are greatly impacted by heart failure. In addition to heart failure, [patient] qualifies for the implant based on the current indication, clinical documentation, and my examination supports the determination of this patient’s need for CardioMEMS™ HF System.

Based on meeting all the required criteria above, my patient, [patient name] is an appropriate candidate for the CardioMEMS™ HF System.

We are requesting confirmation that this therapy be considered a covered benefit based on medical necessity. I request authorization for all costs associated with the surgical implantation of the sensor, accompanying accessories, facility fees, and physician professional fees, including follow-up. The charge for the device is included in the facility fees. The implant procedure will be scheduled at [Name of the clinic or facility].

**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 pressure sensor with delivery catheter, including all system components (device code for Medicare facility claims).

**Background**

The CardioMEMS™ PA Sensor measures pulmonary artery (“PA”) pressures. The CardioMEMS™ PA Sensor is permanently implanted into the pulmonary artery using a 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. The sensor endothelializes in the pulmonary artery. The implanted device does not contain batteries so there will be no replacement cost associated with batteries/battery depletion. Clinicians accessing the PA pressure data remotely, then adjust medications and treatment, based on hemodynamic PA pressure data captured by the CardioMEMS™ HF System. The CardioMEMS™ HF System automatically generates data reports for physicians to make time-sensitive and potentially critical treatment decisions based on measures collected remotely via patient transmitter with the goal of reducing heart failure hospitalizations.

PA pressures are a major determinant of the symptoms, clinical status, risk of hospitalization and mortality in patients with heart failure (HF). Physicians attempt to estimate the level of such pressures by monitoring clinical signs, symptoms, and body weight, but these parameters are too insensitive and intermittent to prevent hospitalizations. Therefore, usual care and management does not provide physicians and other healthcare providers information to accurately predict and prevent decompensation leading to hospitalization.[3](#_Costanzo,_M._R.,) Many important changes in patients’ heart failure status are not associated with symptoms or other components of “usual care”. This allows the decompensation process to progress to the point that hospitalization prevention is not possible. PA pressure guided heart failure management using CardioMEMS™ HF System is more effective in preventing hospitalization and improving quality of life in patients with NYHA Class II or III symptoms who’ve been previously hospitalized or have elevated natriuretic proteins. The CardioMEMS™ HF System was approved for use by the FDA in May of 2014 with updated indication in 2022 and has been commercially available since approval.[4](#_U.S._Food_and)

Utilizing CardioMEMS™ HF System to remotely obtain PA pressure trends allows clinicians to assess patient volume shifts and personalize diuretic management to avoid volume overload or depletion without face-to-face clinical evaluation. This is supported by the recent statement from the Heart Failure Society of America (HFSA)[5](#_Gorodeski_EZ,_Goyal) which reads:

*“CardioMEMS™ HF System, 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.”*

**Clinical Evidence Summary Highlights**

Clinical research has shown the safety and efficacy of the CardioMEMS™ HF System based on the pivotal CHAMPION IDE clinical trial. The randomized, controlled CHAMPION clinical trial enrolled patients with NYHA Class III HF with a prior HFH in the last 12 months. Patients in the CardioMEMS™ HF System 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). In the randomized trial (n=550), all patients studied were implanted with the CardioMEMS™ PA Sensor, but clinicians had access to the PA pressures for the treatment group and the control group was managed with usual care (no access to PA pressures) to better understand whether hemodynamic monitoring provided early insight to decompensation events.

CardioMEMS™ HF System was safe and effective for all patient subgroups, including those with reduced left ventricular function, preserved left ventricular ejection fraction, pulmonary hypertension, and a history of myocardial infarction and/or atrial fibrillation.

* Patients whose HF treatment decisions were based on hemodynamic monitoring data obtained from the CardioMEMS™ HF System experienced a statistically significant 28% relative risk reduction in HF-related hospitalizations vs. control patients at 6 months and had a 37% reduction in HF-related hospitalizations over the study duration (15 + 7 months).[6](#_Abraham,_W._T.,)
* CardioMEMS™ HF System guided care was the first intervention to favorably impact clinical outcomes in patients with heart failure and preserved left ventricular ejection fraction.[7](#_Adamson_PB,_Abraham)
* Early, commercial experience of hemodynamic-guided HF management suggests PA pressure reductions achieved with hemodynamic monitoring in the real world are comparable to those observed during the CHAMPION clinical trial.5 Further, a nationwide evaluation of the HF hospitalization (HFH) reduction in CardioMEMS™ HF System patients (45% reduction) was accompanied by a cost saving of $10,510 at 6 months for Medicare.[5](#_Gorodeski_EZ,_Goyal)
* A large post-FDA approval study in 1,200 patients followed for 2 years demonstrated very consistent reductions in hospitalizations that persisted for the entire follow-up period.[8](#_Heywood_JT,_Jermyn)

In 2021, clinical research from the largest prospective randomized remote hemodynamic monitoring trial, (GUIDE HF),[9](#_Lindenfeld_J,_et)reinforced the superior 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-bind study across 118 centers in the US and Canada. All patients were implanted with the CardioMEMS™ PA 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 period, which was the pre-specified primary outcome of the trial, demonstrated a statistically significant 19% treatment benefit in the primary composite endpoint of heart failure decompensation events and mortality, which was driven by a 28% reduction in HF hospitalizations. When combining class II and III patients, a 24% reduction was seen in the primary endpoint favoring treatment group patients compared to control (p=0.014).[9](#_Lindenfeld_J,_et) This is complementary to the benefits seen in the CHAMPION trial, which supports the current indication for CardioMEMS™ HF System. 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™ HF System continue to be sustained. The randomized results of the GUIDE-HF trial demonstrated 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. Among the total of 1022 patients with attempted device implantations, 1000 of which were successful, 99.2% of patients were free from a device or system-related complication. The occurrence rate observed in GUIDE-HF is consistent with that observed in all prior CardioMEMS™ HF System trials demonstrating a strong safety profile of the device and implantation procedure.[9](#_Lindenfeld_J,_et)

The GUIDE-HF results build on a large body of evidence that continues to demonstrate a benefit of reduction in heart failure hospitalizations and the durability of the CardioMEMS™ HF System. In addition, GUIDE-HF established that the treatment effect extends to patients (NYHA Class II & III) with mild to moderate HF as well as those without a previous HFH.[8](#_Heywood_JT,_Jermyn)

In addition to these two US-based RCTs, clinical results from the MONITOR-HF randomized controlled trial evaluated the effectiveness of remote hemodynamic monitoring in addition to standard of care (SoC) with high prescription rates of contemporary GDMT on quality of life (QoL) and heart failure hospitalizations (HFH) in heart failure patients compared to SoC HF management using GDMT and diuretics in the Netherlands.[10](#_Brugtts_JJ_et)

In this prospective, multicenter, open-label, randomized controlled trial (N=348), hemodynamic monitoring using the CardioMEMS™ HF System resulted in a significant improvement in QoL with a +7.13 point difference in mean KCCQ-OS score. Significantly more patients in the CardioMEMS-HF arm experienced an improvement in KCCQ score than in the SoC group, and a significantly smaller proportion of patients in the CardioMEMS-HF arm experienced a decline in score.[10](#_Brugtts_JJ_et)

**Safety Profile Across the Studies**

|  |  |  |
| --- | --- | --- |
| **Trial** | **Patients** | **Freedom from DSRCs % (n/N)** |
| RCT: GUIDE-HF[9](#_Lindenfeld_J,_et) | 1022 | 99.2% (1014/1022) |
| RCT: CHAMPION IDE[11](#_Brugtts_JJ_et)  | 575 | 98.6% (567/575) |
| RCT: MONITOR-HF1013[**9**](#_Lindenfeld_J,_et) | 172 | 97.7% (168/172) |
| Post-approval Study: US[12](#_Shavelle_DM_et)  | 1,214 | 99.7% (1210/1214) |
| MEMS-HF European Study[13](#_Angermann_CE,_Assmus)  | 236 | 98.3% (232/236) |
| **Total:** | **3,047** | **99.1% (3191/3219)** |

**Effect of PA Pressure Monitoring on HFH Across the Studies**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study** | **N** | **Follow up** | **HFH Reduction** | **p-value** |
| RCT: GUIDE-HF (NYHA Class II & III)[9](#_Lindenfeld_J,_et) | 946 | 8.6 mo. | 32% | p < 0.01 |
| RCT: CHAMPION IDE[11](#_Givertz_MM,_Stevenson) | 550 | 18 mo. | 33% | p < 0.0001 |
| RCT: MONITOR-HF[10](#_Brugtts_JJ_et) | 176 | 48 mo | 44% | p = 0.0053 |
| Contemporary Control: Propensity Matched Outcomes[14](#_Abraham_J,_Bharmi)  | 2174 | 12 mo. | 24% | p < 0.001 |
| MEMS-HF European Study[15](#_Angermann_CE,_Assmus) | 234 | 12 mo. | 62% | p < 0.0001 |
| Post-approval Study: US[12](#_Shavelle_DM_et) | 1200 | 24 mo. | 57% | p < 0.0001 |

There are now three randomized clinical trials (CHAMPION, GUIDE-HF and MONITOR-HF), a propensity matched outcomes analysis based on a large Medicare claims database (Abrahams et al., 2019), and two prospective trials with the US Post approval study and the European MEMS-HF study supporting the efficacy and safety of CardioMEMS™ HF System. All trials to date have shown a consistent and reliable benefit of the CardioMEMS™ HF System in reducing heart failure hospitalizations for NYHA Class III patients who have had a prior HF hospitalization in the prior year.

**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.[16](#_Lindenfeld_J,_Costanzo) 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.[16](#_Lindenfeld_J,_Costanzo)

In the United Kingdom, 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.[17](#_National_Institute_for) Based on the current review of the local evidence and recent publications (GUIDE-HF included) supporting CardioMEMS™ HF System, 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.

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

**In closing**

Given my patient meets all the necessary criteria outlined in the NCD and the substantial clinical evidence supporting the efficacy and safety of the CardioMEMS™ HF System, it is imperative that the commercial plan provides coverage for this procedure. Medicare’s national approval, now extended to all Medicare Advantage Plans, further highlights its medical necessity and effectiveness, indicating that it should no longer be considered experimental or investigational. Providing coverage for the CardioMEMS™ HF System will ensure that the patient receives the medically necessary care to manage their heart failure effectively and reduce the risk of hospitalizations.

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:

# [NCA - Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (CAG-00466N) - Decision Memo](https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=313" \t "_blank" \o "https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=n&ncaid=313)

# Anthem medical Policy Investigational Criteria ADMIN 00005. [ADMIN.00005 Investigational Criteria](https://www.anthem.com/dam/medpolicies/abc/active/policies/mp_pw_a044153.html)

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