**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.

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MAT-2311912 v1.0 | Item approved for U.S. use only.

[Physician Letterhead]

[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**]

**Services:**

**Professional Services**

|  |  |
| --- | --- |
| **Code** | **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 |

**Facility Services**

|  |  |
| --- | --- |
| **Code** | **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 |
| C2624 | Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components. |

[\*C2624 is the HCPCS code required for reporting with CPT‡ 33289 for Medicare patients when this procedure is performed in the outpatient hospital. Commercial payers may not require prior authorization for C2624 as they may not require this for reporting with CPT‡ 33289. Please verify coding with your commercial payer.]

Please note, this is for illustrative purposes only and should be customized based on medically necessity and relevance.

Dear [Payer contact name]:

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 (PA) pressure.

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

[Insert paragraph explaining, in your own words, why CardioMEMS is medically necessary for this patient. Consider documenting how the patient’s condition and symptoms reflect the on-label use of the product (i.e., the CardioMEMS HF System is indicated for treating NYHA Class II or III patients with a prior hospitalization for heart failure the previous year and/or an elevated natriuretic peptides.); why less extensive interventions or usual care are inadequate in light of the patient’s condition; and your expectations of the patient’s outcomes without the CardioMEMS procedure.  Where appropriate, please describe how the intended use is consistent with the FDA approved indication and provide diagnosis codes supporting the procedure.]

**I am requesting an expedited review.**

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 an elevated natriuretic peptides.[[1]](#footnote-2)

The hemodynamic data are used by physicians for HF management and with the goal of controlling PA pressure and reducing HF hospitalizations. I believe that the CardioMEMS will allow us to more closely monitor [Patient Name]’s pulmonary pressures and volume status, which are indications that allow for actionable interventions with diuretics and other 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 the sensor 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 a rational basis for the selection of medication dosagesii-iv and can reduce HF hospitalizations and improve patient outcomes. Based on measures collected remotely via the patient home electronics unit, the CardioMEMS 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 with heart failure.

***Clinical Evidence***

In 2021, clinical research from the largest remote hemodynamic monitoring trial, GUIDE HF,v 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% 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.

Clinical research has shown the safety and efficacy of CardioMEMS (CHAMPION). The randomized, controlled (CHAMPION)ii 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).[[2]](#footnote-3) 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.iii 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 (Heywood).

The Desai et al. (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.
* This reduction in HF hospitalization was associated with a cost savings of $7,433 per patient-6 months and $11,260 per patient-year.[[3]](#footnote-4)

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]](#footnote-5)

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 Failurevi and 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 (NCT 02279888) met the following:

* Primary efficacy endpoint: Decreased HF hospitalizations by 57% at one year
* Primary safety endpoint: 99.6% freedom from device/system related complications and 99.9% freedom from pressure sensor failure at one year[[5]](#footnote-6)i

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. MEMS-HF 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.[[6]](#footnote-7)i

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.viii 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.

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

***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.[[7]](#endnote-2)v

This is supported by the recent statement from the Heart Failure Society of America (HFSA)ix which reads:[[8]](#footnote-8)

*“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, in light of [patient name]’s specific clinical need, and the scientific evidence for this technology. I believe that in this case the CardioMEMS implant is medically reasonable and necessary and as such this service should receive prior authorization of coverage and payment.**

I have included additional support for your consideration, including medical records, FDA approval letter, and an appendix of publications on the use of the CardioMEMS HF System.

Please let me know if I can provide any additional information and thank you for your attention.

Sincerely,

[Physician’s name and credentials]

[Title]

[Name of practice]

[Street address]

[City, State, zip code]

[Phone number]

**Enclosures:**

[Patient medical records/chart notes]

[FDA Approval letter – CardioMEMS™ HF System]

[CardioMEMS™ HF System Technical and System Description

1. i U.S. Food and Drug Administration, P100045/S056 CardioMEMS HF System (2022) [Premarket Approval (PMA) (fda.gov)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100045S056)

   ii Abraham, W. T., et al. CHAMPION Trial Study Group. (2011). Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. Lancet, 377, 658-666.

   iii Desai et al, Ambulatory hemodynamic monitoring reduces heart failure hospitalizations in ‘real world’ clinical practice. JACC. 2017.

   iv 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. [↑](#footnote-ref-2)
2. v Lindenfeld J, et al. Haemodynamic-guided management of heart failure (GUIDE-HF): a randomised controlled trial. The Lancet. 2021;398(10304):991-1001. [↑](#footnote-ref-3)
3. [↑](#footnote-ref-4)
4. [↑](#footnote-ref-5)
5. vi Shavelle DM 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. doi: 10.1161/CIRCHEARTFAILURE.119.006863. Epub 2020 Aug 6. PMID: 32757642; PMCID: PMC7434214. [↑](#footnote-ref-6)
6. vii 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.

   viii 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 [↑](#footnote-ref-7)
7. **Appendix**

   U.S. Food and Drug Administration, P100045/S056 CardioMEMS HF System (2022) [Premarket Approval (PMA) (fda.gov)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100045S056)

   Abraham, W. T., Adamson, P. B., Bourge, R. C., Aaron, M. F., Costanzo, M. R., Stevenson, L. W., . . . CHAMPION Trial Study Group. (2011). Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. Lancet, 377, 658-666.

   1. Abraham W. T., Stevenson LW, Bourge RC, Lindenfeld JA, Bauman JG, Adamson PB. 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.

   Abraham, J. 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.

   1. Adamson PB, Ginn G, Ander SD, Bourge RC, Abraham WT. Remote haemodynamic-guided care for patients with chronic heart failure: a meta-analysis of completed trials. Eur J Heart Fail. 2016 Sep 16. doi: 10.1002/ejhf.638.

   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.

   Bourge RC, Abraham WT, Adamson PB, et al. Randomized controlled trial of an implantable continuous hemodynamic monitor in patients with advanced heart failure: The COMPASS-HF study. J Am Coll Cardiol. 2008;51(11):1073-9.

   Costanzo MR, Stevenson LW, Adamson PB, Desai AS, Heywood JT, Bourge RC, Bauman J, Abraham WT. Interventions Linked to Decreased Heart Failure Hospitalizations During Ambulatory Pulmonary Artery Pressure Monitoring. JACC Heart Fail. 2016 May;4(5):333-44. doi: 10.1016/j.jchf.2015.11.011. Epub 2016 Feb 10. PMID: 26874388.

   Desai AS, et al. Ambulatory hemodynamic monitoring reduces heart failure hospitalizations in "real- world" clinical practice. JACC. 2017;69(19):2357-65.

   Gorodeski EZ, Goyal P, Cox ZL, Thibodeau JT, Reay RE, Rasmusson K, Rogers JG, Starling RC. 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 Card Fail. 2020 Jun;26(6):448-456.

   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 patients implanted with the CardioMEMS sensor. https://doi.org/10.1161/CIRCULATIONAHA.116.026184 Circulation. 2017;CIRCULATIONAHA.116.026184 Originally published February 20, 2017.

   Lindenfeld J, Zile MR, Desai AS, et al. Haemodynamic-guided management of heart failure (GUIDE-HF): a randomised controlled trial. Lancet. 2021;398(10304):991-1001. doi:10.1016/S0140-6736(21)01754-2. PMID: 34461042.

   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

   Rohde LE, Palombini DV, Polanczyk CA, et al. A hemodynamically oriented echocardiography-based strategy in the treatment of congestive heart failure. J Card Fail. 2007;13(8):618-25.

   Shavelle DM 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. doi: 10.1161/CIRCHEARTFAILURE.119.006863. Epub 2020 Aug 6. PMID: 32757642; PMCID: PMC7434214.

   Vanderheyden M, Houben R, Verstreken S, et al. Continuous monitoring of intrathoracic impedance and right ventricular pressures in patients with heart failure. Circ Heart Fail.2010;3(3):370-7. [↑](#endnote-ref-2)
8. ix 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). [↑](#footnote-ref-8)