**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**.
2. It is important to provide the most complete information to assist with the prior authorization process.
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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[Date]

[Payer contact name]

[Payer contact title]

[Payer]

[Street address]

[City, State, zip code]

**Re: Request for Prior Authorization of Medical Services for Pulmonary Artery Sensor Implant Procedure for Remote Monitoring of Heart Failure**

Patient name: [First and last name]

Patient date of birth: [XX/XX/XXXX]

SS # [XXX-XX-XXXX]

Insurance ID # [XXXXXXXXXXXXXXX]

Group # [XXXXXXXXXX]

Date of Service: [XX/XX/XXXX]

Dear [Payer contact name]:

I am writing to request a prior authorization of coverage and/or pre-determination for a **CardioMEMS™ Heart Failure (HF) System** on behalf of my patient, [Patient Name]. The 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. The service proposed to be provided is an implant of the CardioMEMS HF System in an [inpatient / outpatient]setting at [facility name] for [patient’s name] on [procedure date].

**Background**

The CardioMEMS Sensor measures pulmonary artery (“PA”) pressures. The CardioMEMS 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 the sensor 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 may then adjust medications and treatment, based on hemodynamic PA pressure data captured by the CardioMEMS HF System. Based on measures collected remotely via patient transmitter, CardioMEMS automatically generates data reports for physicians to make time-sensitive and potentially critical treatment decisions with the goal of reducing heart failure hospitalizations.

PA pressures are a major determinant of the symptoms, clinical status and risk of hospitalization in patients with heart failure (HF)1. Physicians attempt to estimate the level of such pressures by monitoring clinical signs, symptoms and body weight. However, the current standard of care may not adequately provide physicians the ability to accurately predict decompensation (Costanzo)[[1]](#footnote-2). Most patients whose HF is managed by routine care procedures still show evidence of elevated PA pressures and remain at high risk of hospitalization for heart failure.1 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, and continued monitoring of PA pressure data improves the care of chronic heart failure patients.[[2]](#footnote-3) The CardioMEMS HF System was approved for use by the FDA in May of 2014 and has been commercially available since approval.[[3]](#footnote-4)

Utilizing CardioMEMS 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)[[4]](#footnote-5) 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.”*

**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 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)5. In the randomized trial (n=550), all patients studied were implanted with the CardioMEMS 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 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).[[5]](#footnote-6)
* 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 patients (45% reduction) was accompanied by a cost saving of $10,510 at 6 months for Medicare.[[6]](#footnote-7)

In 2021, clinical research from the largest remote hemodynamic monitoring trial, (GUIDE HF),2 reinforces 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 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. When combining class II and III patients, a 24% reduction was seen in the treatment group compared to control (p=0.014).2 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 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 trials demonstrating a strong safety profile of the device and implantation procedure.

**Safety Profile Across the Studies**

|  |  |  |
| --- | --- | --- |
| **Trial** | **Patients** | **Freedom from DSRCs % (n/N)** |
| RCT: GUIDE-HF2 | 1022 | 99.2% (1014/1022) |
| RCT: CHAMPION IDE5 | 575 | 98.6% (567/575) |
| Post-approval Study: US[[7]](#footnote-8) | 1,214 | 99.7% (1210/1214) |
| MEMS-HF European Study[[8]](#footnote-9) | 236 | 98.3% (232/236) |
| **Total:** | **3,047** | **99.2% (3023/3047)** |

The new 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.

**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)2 | 946 | 8.6 mo. | 32% | p < 0.01 |
| RCT: CHAMPION IDE5 | 550 | 18 mo. | 33% | p < 0.0001 |
| Contemporary Control: Propensity Matched Outcomes[[9]](#footnote-10) | 2174 | 12 mo. | 24% | p < 0.001 |
| MEMS-HF European Study8 | 234 | 12 mo. | 62% | p < 0.0001 |
| Post-approval Study: US7 | 1200 | 24 mo. | 57% | p < 0.0001 |

There are now two randomized clinical trials (CHAMPION and GUIDE-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. 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.

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.10 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 Monitoring](https://www.nice.org.uk/guidance/ipg711/chapter/1-Recommendations)

**Our request**

Because your health plan has no coverage criteria on Cardiac Hemodynamic Monitoring, I am specifically requesting prior authorization for this procedure based on my patient’s meeting the FDA approved labeling. This coverage consideration based on “reasonable and necessary” guidelines is similar to the coverage guidance provided by all the traditional Medicare fee-for-service administrative contractors (MACs).

I have discussed the procedure with my patient, and we have come to the conclusion to proceed with the implant to best manage [his/her] heart failure with the goal of reducing heart failure hospitalizations.

I feel that [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.

[Insert paragraph explaining, in your own words, why CardioMEMS is medically necessary for this patient. Consider documenting how the patient’s condition reflects the on-label use of the product (e.g., the CardioMEMS HF System is indicated for treating patients who have 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;\* 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.]

[**\*NT-proBNP and BNP Thresholds According to Ejection Fraction and BMI.** An elevated natriuretic peptide level is defined as an NT-proBNP level ≥ 1000 pg/mL or a BNP level ≥ 250 pg/mL. Thresholds are dependent on left ventricular ejection fraction and body mass index, using a 4% reduction 3 per BMI unit over 25 kg/m2. For more information, please see the IFU.]

Based on the above, I strongly feel that my patient 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 and that associated professional fees for the surgery and follow-up will be covered. I request authorization for all costs associated with the surgical implantation of the sensor, accompanying accessories, including physician professional fees and facility fees. The charge for the device is included in the facility fees. The implant procedure will be scheduled at [Name of the clinic or facility].

**[The CPT codes listed below represent the CardioMEMS implant procedure and it is the customer’s responsibility for the accuracy of codes utilized here.]**

**The procedure codes supporting the implant consist of the following:**

**Physician Procedure Codes**

|  |  |  |
| --- | --- | --- |
| **Code** | **Description** | **Units** |
| 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 | 1 |

**Facility Procedure Codes**

|  |  |  |
| --- | --- | --- |
| **Code** | **Description** | **Units** |
| 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 | 1 |
| C2624\* | Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components. | 1 |

[\*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.]

I have attached relevant excerpts from the patient’s medical record, a copy of the FDA approval letter and an overview of the CardioMEMS technology. I believe that the CardioMEMS implant is medically reasonable and necessary and warrants prior authorization of coverage and payment for these services.

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]

**Appendix**

**CardioMEMS™ HF System Key Clinical Publications**

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

1. 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.
2. 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.
3. Abraham J, Bharmi R, Jonsson O, et al. Association of Ambulatory Hemodynamic Monitoring of Heart Failure With Clinical Outcomes in a Concurrent Matched Cohort Analysis. *JAMA Cardiol.* 2019;4(6):556–563. doi:10.1001/jamacardio.2019.1384
4. 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.
5. 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.
6. Benza, R. L., Raina, A., Abraham, W. T., Adamson, P. B., Lindenfeld, J., Miller, A. B., . . . Yadav, J. (2015). Pulmonary hypertension related to left heart disease: Insight from a wireless implantable hemodynamic monitor. *The Journal of Heart and Lung Transplantation, 34*(3), 329-337.
7. Costanzo, M. R., Adamson, P. B., Abraham, W. T., Jeffries, B., Neville, S., Cowart, P., . . . Jadav, J. S. (2012). Diuretic use guided by a wireless implanted pulmonary artery pressure monitoring system in NYHA class III heart failure patients: Observations from the CHAMPION trial. *Circulation, 126*, A19396. Abstract 19396. Available at http://circ.ahajournals.org/cgi/content/meeting\_abstract/126/21\_MeetingAbstracts/A19396. Accessed June 16, 2015.
8. Desai AS, Bhimaraj A, Bharmi R, Jermyn R, Bhatt K, Shavelle D, Redfield MM, Hull R, Pelzel JA, Davis K, Dalal N, Adamson PB, Heywood JT, Reduction in heart failure hospitalizations with ambulatory hemodynamic monitoring seen in clinical trials is maintained in the ‘real world’, *JACC* (2017), doi: 10.1016/j.jacc.2017.03.009.
9. 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)
10. 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).
11. 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
12. Krahnke, J. S., Abraham, W. T., Adamson, P. B., Bourge, R. C., Bauman, J., Ginn, G., . . . for the CHAMPION Trial Study Group. (2014). Heart failure and respiratory hospitalizations are reduced in heart failure subjects with chronic obstructive pulmonary disease using an implantable pulmonary artery pressure monitoring device. *Journal of Cardiac Failure, 21*(3), 240-249
13. Lindenfeld J, et al. Haemodynamic-guided management of heart failure (GUIDE-HF): a randomised controlled trial. The Lancet. 2021;398(10304):991-1001.
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. 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: PMC743421
16. Lutz Frankenstein, Andrew Remppis, Manfred Nelles, Bernd Schaelling, Dieter Schellberg, Hugo Katus, Christian Zugck, Relation of N-terminal pro-brain natriuretic peptide levels and their prognostic power in chronic stable heart failure to obesity status, European Heart Journal, Volume 29, Issue 21, November 2008, Pages 2634–2640, <https://doi.org/10.1093/eurheartj/ehn388>
17. Abbott Indications for Use, https://www.cardiovascular.abbott/us/en/hcp/products/heart-failure/pulmonary-pressure-monitors/cardiomems/indications-safety-warnings.html
1. Costanzo, M. R., Adamson, P. B., Abraham, W. T., Jeffries, B., Neville, S., Cowart, P., . . . Jadav, J. S. (2012). Diuretic use guided by a wireless implanted pulmonary artery pressure monitoring system in NYHA class III heart failure patients: Observations from the CHAMPION trial. Circulation, 126, A19396. Abstract 19396. Available at http://circ.ahajournals.org/cgi/content/meeting\_abstract/126/21\_MeetingAbstracts/A19396. Accessed June 16, 2015. [↑](#footnote-ref-2)
2. Lindenfeld, J., Zile, M. R., Desai, AS, Bhatt, K., Ducharme, A., Horstmanshof, D., . . . Haemodynamic-guided management of heart failure (GUIDE-HF): a randomized controlled trial. (2021). Lancet, 6736(21), 01754-2. [↑](#footnote-ref-3)
3. 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) [↑](#footnote-ref-4)
4. 4 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-5)
5. 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. [↑](#footnote-ref-6)
6. Desai A, et al. Reduction in heart failure hospitalizations with ambulatory hemodynamic monitoring seen in clinical trials is maintained in the ‘real world.’ J Am Coll Cardiol. 2017. [↑](#footnote-ref-7)
7. 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-8)
8. Angermann CE, 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 Journal of Heart Failure.02020;22:1891 –1901. [↑](#footnote-ref-9)
9. Abraham J, Bharmi R, Jonsson O, et al. Association of Ambulatory Hemodynamic Monitoring of Heart Failure With Clinical Outcomes in a Concurrent Matched Cohort Analysis. JAMA Cardiol. 2019;4(6):556–563. doi:10.1001/jamacardio.2019.1384

10 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-10)