**SAMPLE PRIOR AUTHORIZATION LETTER OF MEDICAL NECESSITY**

**FOR THE**

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

**Instructions for completing the sample prior authorization letter:**

1. Please customize the prior authorization template based on the medical appropriateness of the CardioMEMS HF System for your patient. Fields required for customization are **highlighted in yellow**.
2. It is important to provide the most complete information to assist with the prior authorization process.
3. After you have customized the prior authorization letter, please make sure to delete any specific instructions for completion that are highlighted throughout the letter so the health plan does not misinterpret the information.

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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**

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 predetermination of coverage and/or prior authorization 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 III heart failure patients who have been hospitalized for heart failure in the past year. Physicians use the hemodynamic data for heart failure management with the goal of reducing heart failure hospitalizations. The service provided is an implant of the CardioMEMS™ HF System in an [inpatient / outpatient]setting at [facility name] provided to [patient’s name] on [procedure date].

The CardioMEMS™ HF System 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. The CardioMEMS device is implanted using a minimally invasive right heart catheterization procedure. Based on measures collected remotely via patient transmitter, the CardioMEMS HF System automatically generates data reports for physicians to make time-sensitive and potentially critical treatment decisions with the goal of reducing hospitalizations.

PA pressures are a major determinant of the symptoms, clinical status and risk of hospitalization in patients with heart failure (“HF”). 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). 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 (Costanzo). The CardioMEMS HF Sensor allows monitoring of PA pressure to improve outcomes in NYHA Class III patients and continued monitoring of PA pressure data improves the care of chronic heart failure patients (Costanzo). The CardioMEMS HF System was approved for use by the FDA in May of 2014, and has been commercially available since approval.

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 meeting the FDA approved labeling. The following is also provided, including: [please complete the bullets below]

* NYHA Class III Heart Failure

ICD10 Diagnosis [\_\_\_\_\_] [\_\_\_\_\_] [\_\_\_\_\_\_]

* Prior Heart Failure Hospitalization within the past twelve months – Date [ ] [ ] [ ]

I also feel that my patient would benefit from the CardioMEMS HF System as:

 [ ]  Currently at risk for future heart failure related hospitalizations

[ ]  Management by conservative means only (signs, symptoms and weight measures) is ineffective

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 is greatly impacted by heart failure. In addition to heart failure, [patient] also suffers from:

|  |  |
| --- | --- |
| [ ]  Atrial Fibrillation | [ ]  Hypertension  |
| [ ]  Chronic Systolic Heart Failure  | [ ]  Peripheral Circulatory Disorder  |
| [ ]  Congestive Cardiomyopathy | [ ]  Myocardial Dysfunction  |
| [ ]  Congestive Heart Failure  |[ ]
| [ ]  Coronary Artery Disease  |[ ]
| [ ]  Ischemic Myocardial Infarction  |[ ]

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 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 |

I have attached relevant excerpts from the patient’s medical record, a copy of the FDA approval letter and an overview of the CardioMEMS HF System technology. I believe that the CardioMEMS HF System 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:

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.

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.

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.

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.

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.

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.

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

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.

SJM-HER-0517-0070 | Item approved for U.S. use only.