



**Tracking Form for Applicants for New Technology Add-on Payments under
the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal
Year (FY) 2013**

1. Technology Name:

Implantable Hemodynamic Monitor System (IHMS)

2. Manufacturer Name:

CardioMEMS, Inc

3. Trade Brand of Technology:

Champion™ HF Monitoring System

4. Brief Description of Service or Device:

The Champion™ HF Monitoring System (System) provides Pulmonary Artery (PA) hemodynamic data using a wireless sensor. PA hemodynamic monitoring is used in the management of heart failure (HF). Changes in PA pressure can be used along with heart failure signs and symptoms to adjust medications. The system utilizes radiofrequency (RF) energy to power the Sensor and to measure PA pressure. The system consists of 3 components:

- A. Wireless Implantable Hemodynamic Sensor/Monitor (Sensor) which is implanted into the distal PA
- B. External Patient Measurement System (Patient Measurement System)
- C. Patient Data Management System (Patient Database)

The system provides the physician with the patient's PA pressure waveform including systolic, diastolic, and mean pressures as well as heart rate. The sensor is permanently implanted into the distal PA using transcatheter techniques in the catheterization laboratory where it is calibrated to the mean PA pressure using a Swan-Ganz catheter. PA hemodynamic measurements are taken by the patient in a supine position at home daily or at a frequency determined by the patient's physician. The patient measurement system consists of a padded antenna and electronics unit that guides the patient through the short reading process. The data can be recorded from the home, hospital, physician's office, or clinic. The hemodynamic data, including a detailed 18 second continuous waveform, is transmitted to a secure website that serves as the patient database so that PA monitoring is available to the physician or nurse at any time via the internet

(For the complete application requirements, please see the instructions at http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage--.

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Newness Criterion

Note: To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the Medicare severity diagnosis related groups (MS-DRGs).

5. Date of Food and Drug Administration (FDA) approval (or expected approval) for the device or service:

There are currently no FDA approved devices performing this function. CardioMEMS submitted a PMA to the FDA in 2010. FDA approval is anticipated in the first quarter of 2012.

6. Was the product available on the market immediately after FDA approval? If not, please provide the date that the medical service or technology came on the market (i.e. first sales or availability) and an explanation for any delay (i.e. manufacturing issues, shelf life concerns or other reasons).

Not Applicable

7. Does the technology have an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and/or ICD-10-PCS procedure code(s) or is an application pending?
 - a. If yes, please provide the ICD-9-CM and/or ICD-10-PCS procedure code(s) used to identify the clinical procedure(s) with which the medical service and technology is used.

A new ICD-9-CM procedural code (38.26) describing the implantation of the CardioMEMS device became effective October 1, 2011 and is assigned to DRG 264.

Procedure Code	Description	O.R.	MDC	MS-DRG
38.26	Insertion of implantable pressure sensor without lead for intracardiac or great vessel hemodynamic monitoring	Y	05	264

- b. If there is no existing ICD-9-CM and/or ICD-10-PCS code that captures this new technology, please indicate whether you will be applying for a new code. (Refer to http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/01_overview.asp#TopOfPage for more information.) We note that, if the product were to receive add-on payment status approval, it would need to be distinctly identifiable by ICD-9-CM and effective October 1, 2013 by ICD-10-PCS code(s) in the MedPAR claims data in order to receive add-on payment.

Not Applicable

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8. Have you submitted an application for outpatient pass-through payments under the Medicare outpatient prospective payment system? If so, please provide the tracking number or, if it was approved, please provide the date of approval. (Please refer to http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage for more information.)

An application for a New Technology APC or a Transitional Pass-through Payment will be submitted after FDA approval

Cost Criterion

Note: To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of the lesser of 75 percent of the standardized amount increased to reflect the difference between costs and charges or 75 percent of 1 standard deviation beyond the geometric mean standardized charge for all cases in the MS-DRGs to which the new technology is assigned. Table 10 from the annual final rule lists the thresholds by MS-DRG. The most recent version of Table 10 can be downloaded at: <https://www.cms.gov/AcuteInpatientPPS/FR2012/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS1250507&intNumPerPage=10>.

Provide the following information to demonstrate the technology or service meets the criterion.

8. What is the anticipated average standardized charge per case involving this new technology? For details how to standardize charges please refer to the technical appendix of the application form.

Proprietary information provided in the application to CMS.

9. **A.** What is the total estimated cost per case for the service or technology (this will include all costs involved in the case, including the cost of the service or device)?

Proprietary information provided in the application to CMS.

B. What is the cost of the technology per patient? Please provide a breakdown how the cost of the technology is calculated (i.e. **Drugs**- Average dosage or number of units per patient (ml/kg/hr); **Devices**- breakdown of the cost of all components used in the new technology, clearly showing which components are the “new” ones).

Proprietary information provided in the application to CMS

10. List the Medicare severity diagnosis-related groups (MS-DRGs) to which cases involving this new technology will most likely be assigned.

MS-DRG 264

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11. What is the anticipated volume of Medicare cases involving of this technology in FY 2013 (by MS-DRG)?

Proprietary information provided in the application to CMS.

Clinical Improvement Criterion

Note: To qualify for a new technology add-on payment, the technology or service must represent a substantial clinical improvement over existing technologies or services.

12. Please provide a short synopsis of the following clinical issues added to the new technology. Use the regular application to submit full details.
 - a. Briefly describe how the new service or technology represents a substantial clinical improvement over existing services or technologies:

The CardioMEMS HF Monitoring System is effective in reducing the occurrence of HF related hospitalizations in NYHA Class III heart failure patients. In addition, the device is safe in view of the rarity of device and system related complications occurring over the course of the clinical trial. All primary and secondary study endpoints were successfully achieved.

The study findings support the new technology application and the CMS criterion for clinical improvement as the implantable hemodynamic monitor system resulted in:

Primary Efficacy:

- 28% Reduction in rate of HF-related hospitalizations at 6 months and 37% reduction at 15 months in NYHA Class III patients that were already on optimal medical care (including standard drug and device therapy, daily weight measurements, and regular access to heart failure specialists).

Secondary Efficacy:

- Decrease in Mean Pulmonary Artery Pressure
- Decrease in number of subjects hospitalized for HF
- Increase in Days Alive Outside of Hospital
- Improvement in Minnesota Living with Heart Failure Score

The CHAMPION trial proved that with knowledge of class III heart failure patients' pulmonary artery pressures, physicians improved medical management and lowered pulmonary artery pressures leading to fewer HFR hospitalizations and better quality of life.

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- b. List all published peer-reviewed articles relevant to the new service or technology.

The following is a list of publications enclosed with the New Tech application.

1. Abraham WT, Adamson PB Bourge RC, et al: **“Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomized controlled trial”** *The LANCET, February, 10, 2011 DOI:10.1016/S0140-6736(11)60101-3*
2. Adamson PB, Abraham WT, Bourge RC, et al: **“CHAMPION trial rationale and design: the long-term safety and clinical efficacy of a wireless pulmonary artery pressure monitoring system.”** *J Card Fail 2010*
3. Ritzema J, Troughton R, Melton I, et al: **“Physician-directed patient self-management of left atrial pressure in advanced chronic heart failure.”** *Circulation 2010; 121:1086-1095.*
4. Bourge RC, Abraham WT, Adamson PB, Aaron MF, Aranda JM Jr., Magalski A, 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; 51:1073-1079.*
5. Verdejo HE, Castro PF, Concepcion R, et al: **“Comparison of a radiofrequency-based wireless pressure sensor to Swan-Ganz catheter and echocardiography for ambulatory assessment of pulmonary artery pressure in heart failure.”** *J Am Coll Cardiol 2007; 50:2375-2382.*
6. Castro PF, Concepcion R, Bourge RC, et al: **“A wireless pressure sensor for monitoring pulmonary artery pressure in advanced heart failure: initial experience.”** *J Heart Lung Transplant 2007; 26:85-88.*
7. Adamson PB, **“Ambulatory Hemodynamics in patients with chronic heart failure: implications for volume management in elderly patients.”** *AJGC 2005; 14:236-241.*
8. Bennett T, Kjellstrom B, Taepke R, Ryden L. **“Development of Implantable Devices for Continuous Ambulatory Monitoring of Central Hemodynamic Values in Heart Failure Patients”.** *PACE 2005; 28:573-584.*
9. Kjellström B, Igel D, Abraham J, Bennett T, Bourge R. **“Trans-telephonic monitoring of continuous hemodynamic measurements in heart failure patients”.** *Journal of Telemedicine and Telecare 2005; 11:240-244.*
10. Steinhaus D, Reynolds D, Gadler, F, et.al **“Implant Experience with an Implantable Hemodynamic Monitor for the Management of Symptomatic Heart Failure.”** *PACE 2005; 28: 747-753*

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11. Adamson PB, Reynolds D, Luby A, Magalski A, Steinhaus D, Linde C, Braunschweig F, Rydén L, Böhm M, Ståblein A, Takle T, Bennett T. **“Ongoing right ventricular hemodynamics in heart failure: clinical value of measurements derived from an implantable monitoring system”**. *J Am Coll Cardiol* 2003; 41:565-71.
12. Ohlsson A, Steinhaus D, Kjellstrom B, Ryden L, Bennett T. **“Central hemodynamic responses during serial exercise tests in heart failure patients using implantable hemodynamic monitors”**. *European Journal of Heart Failure* 2003; 5:253-59.
13. Braunschweig F, Linde C, Eriksson MJ, et.al **“Continuous haemodynamic monitoring during withdrawal of diuretics with congestive heart failure.”***Eur Heart J* 2002;23:59-69.
14. Magalski A, Adamson PB, Gadler F, et.al **“Continuous ambulatory right heart pressure measurements with an implantable hemodynamic monitor: a multicenter, 12 month follow-up study of patients with chronic heart failure patients”**. *J Card Fail* 2002;23:59-69
15. Ohlsson A, Kubo S, Steinhaus D, Connelly D, Adler S, Bitkover C, Nordlander R, Ryden L, Bennett T. **“Continuous ambulatory monitoring of absolute right ventricular pressure and mixed venous oxygen saturation in patients with heart failure using an implantable haemodynamic monitor: Results of a 1 year multicentre feasibility study”** *Eur Heart J* 2001; 22:942-954.
16. Ohlsson A, Nordlander R, Bennett T, Bitkover C, Kjellstrom B, Lee B, Ryden L. **“Continuous ambulatory haemodynamic monitoring with an implantable system: The feasibility of a new technique.”** *Eur Heart J* 1998;19:174-184
17. Chuang P, Wilson RF, Homans DC, Stone K, Bergman T, Bennett, TD, Kubo S. **“Measurement of pulmonary artery diastolic pressure from a right ventricular pressure transducer in patients with heart failure.”** *J of Cardiac Failure* 1996; 2:41-46.
18. Steinhaus DM, Lemery R, Bresnehan Jr. DR, Handlin L, Bennett T, Moore A, Cardinal D, Foley L, Levine R. **“Initial experience with an implantable hemodynamic monitor.”** *Circulation* 1996;93:745-52.
19. Ohlsson A, Beck R, Bennett T, Nordlander R, Ryden J, Astrom H, Ryden L. **“Monitoring of mixed venous oxygen saturation and pressure from biosensors in the right ventricle: A 24 hour study in patients with heart failure.”** *EurSoc of Card* 1995; 16:1215-1222.
20. Ohlsson A, Bennett T, Nordlander R, Ryden J, Astrom H, Ryden L. **“Monitoring of pulmonary arterial diastolic pressure through a right ventricular pressure transducer.”** *J of Cardiac Failure* 1995; 1:161-168.

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21. Reynolds DW, Bartelt N, Taepke R, Bennett TD. **“Measurement of pulmonary artery diastolic pressure from the right ventricle.”** *J Am Coll Cardiol* 1995;25:1176-82.

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