



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

1. Technology Name:

Implantable Hemodynamic Monitor (IHM) and Pressure Sensing Lead

2. Manufacturer Name:

Medtronic, Inc

3. Trade Brand of Technology:

Chronicle® Implantable Hemodynamic Monitoring (IHM) System

4. Brief Description of Service or Device:

The implantable hemodynamic monitor (IHM) system is comprised of an implantable monitor and a pressure sensing lead placed in the right ventricular outflow tract. The IHM system continuously measures and stores multiple pressure-related hemodynamic parameters for an ambulatory patient until the data can be retrieved for analysis. The IHM pressure related parameters provide access to hemodynamic information that can be used to optimally tailor medical therapy to the individual patient with compromised hemodynamic function while at home and pursuing their activities of daily living without subjecting the patient to multiple invasive procedures.

**New Criteria**

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 diagnosis related groups (DRGs).

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

The Pre-Market Approval application was submitted to the FDA on August 30, 2005. FDA approval is anticipated in the Spring of 2006.

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) procedure code(s) or is an application pending?
  - a. If yes, please provide the ICD-9-CM procedure code(s) used to identify the clinical procedure(s) with which the medical service and technology is used.

A request for unique ICD-9-CM procedure codes was presented to the ICD-9-CM Coordination and Maintenance Committee on September 29, 2005. Unique codes were requested for the insertion or replacement of the sensor and the subcutaneous device. A request was also made that notes for two existing ICD-9-CM procedure codes be revised to accommodate revision of the cardiac pocket and removal and repositioning of the pressure sensing lead. We believe this request is being considered within the context of overall revisions being considered to the notes for codes 37.79 and 37.99. The proposed ICD-9-CM procedure codes specific to the IHM system are:

ICD-9-CM Procedure Code	Description
00.56 (new)	Insertion or replacement of implantable sensor for intracardiac hemodynamic monitoring
00.57 (new)	Implantation or replacement of subcutaneous device for intracardiac hemodynamic monitoring
37.79 (revised)	Revision or relocation of cardiac device pocket
37.99 (revised)	Other Removal without replacement of implantable sensor for intracardiac hemodynamic monitoring Removal without replacement of subcutaneous device for intracardiac hemodynamic monitoring Repositioning of implantable sensor for intracardiac hemodynamic monitoring

- b. If there is no existing ICD-9-CM code that captures this new technology, please indicate whether you will be applying for a new code. (Refer to <http://www.cms.hhs.gov/paymentsystems/icd9> for more information.)
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://cms.hhs.gov/providers/hopps/apc.asp> for more information.)

To date, application has not been made for a New Tech APC or pass through payment. The anticipated date of FDA approval would not support an application being made until Spring of 2006.

## **Cost Criteria**

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 75 percent of one standard deviation above the average charges for the DRG(s) to which the technology or service is assigned.

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. 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)? 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).

Proprietary information provided in the application to CMS.

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

As indicated in the response to question 7, Medtronic recently requested specific ICD-9-CM procedure codes for implant of the implantable hemodynamic monitor and pressure sensing lead. Until a final decision is issued on the request for new codes, CMS advised us of interim coding for the IHM system. CMS advised that the pressure sensing lead should be coded using 89.63, Pulmonary artery pressure monitoring and the implant of the IHM device should be coded using 37.79, Revision or relocation of cardiac device pocket. These interim codes would map IHM system implant procedures to DRG 117.

11. What is the anticipated volume of Medicare cases involving of this technology in FY 2007 (by DRG)?

Proprietary information provided in the application to CMS.

## **Clinical Improvement**

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 study findings support the new technology application and the CMS criteria for clinical improvement as the implantable hemodynamic monitor and pressure sensing lead result in:

- Reduced HF-related event rates in patients that were already on best medical care (including standard drug and device therapy, daily weight measurements, and regular access to experienced heart failure clinicians). Results showed a reduction in the overall rate of heart failure-related events (heart failure related hospitalizations, emergency department and urgent clinic visits requiring IV therapy), and a reduction in the relative risk of a heart failure-related hospitalization. The results were most pronounced for NYHA Class III patients.
- Decreased the rate of subsequent diagnostic or therapeutic interventions as patients with IHM no longer require right heart catheterizations (Swan-Ganz) for a point in time only measurement, which poses significant patient risk and expense to the health care system.
- Allowing clinicians to obtain an accurate measurement on an ambulatory patient, providing the opportunity to adjust treatment in a timely and individualized manner. Intra-cardiac pressures from the system are accurate and reliable, using pressure changes to optimize medications and fluid balance reduce the risk of a heart failure related hospitalization (in all patients studied) and overall heart failure related events (in NYHA Class III patients).

- b. List of published peer-review articles relevant to the new service or technology.

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

1. Adamson PB, “**Ambulatory Hemodynamics in patients with chronic heart failure: Implications for volume management in elderly patients.**” *AJGC* 2005; 14:236-241.
2. 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.
3. 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.

4. 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
5. 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.
6. 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.
7. 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.
8. 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
9. Ohlsson A, Kubo S, Steinhaus D, Connolly 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.
10. 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
11. 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.
12. 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.
13. 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.
14. 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.

15. 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.