January 5, 2010

Joanna Baldwin

Ms. Joanna Baldwin
Centers for Medicare & Medicaid Services
Mail stop c1-09-06
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Request for modification to NCD **20.9 - Artificial Hearts and Related Devices**

Dear Ms. Baldwin:

Thoratec Corporation would once again like to thank the Center for Medicare and Medicaid Services (CMS) for their continued consideration and modifications to National Coverage Determination (NCD) **20.9 - Artificial Hearts and Related Devices** which includes the coverage decision for left ventricular assist devices (VAD). Thoratec Corporation is a world leader in left ventricular devices to treat cardiovascular disease. Our Thoratec® VAD and HeartMate® have been implanted in more than 13,000 patients suffering from heart failure, and the HeartMate is the only left ventricular assist system approved by the FDA for use in both bridge-to-transplant and destination therapy.

The HeartMate II LVAS is intended for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from non-reversible left ventricular failure. The HeartMate II LVAS is under consideration by the Food and Drug Administration (FDA) for indications which include in patients with New York Heart Association (NYHA) Class IIIB or IV end-stage left ventricular failure who have received optimal medical therapy for at least 45 of the last 60 days, and who are not candidates for cardiac transplantation. We are asking CMS to modify the National Coverage Determination 20.9-Artificial Hearts and Related Devices to reflect the intent for use of this technology.

DEVICE DESCRIPTION

The HeartMate II Left Ventricular Assist System (LVAS) consists of an implanted axial flow blood pump and external components as shown in Figure 1. The HeartMate II is smaller than the HeartMate XVE LVAS which is also approved for the DT indication. Because of its size, the HeartMate II LVAS can be used in the treatment of smaller sized non-cardiac transplant patients.

These smaller size patients include mostly women and small stature men. It can also be used in patients with anatomic features which preclude use of the larger HeartMate XVE device.

The HeartMate II LVAS is powered through the System Controller, a microprocessor-based unit that initiates motor actuation, monitors and reports on system function, and serves as the primary interface with the system. Electrical power is provided by either a pair of wearable, rechargeable batteries (Figure 1), or through connection to a dedicated power supply (Power Module) as shown in Figure 2. The electrical power to the implanted blood pump is delivered through a percutaneous lead that connects the blood pump to the external System Controller.

Figure 1 – HeartMate II LVAS, Implantable and External Components
(Battery-powered Configuration)

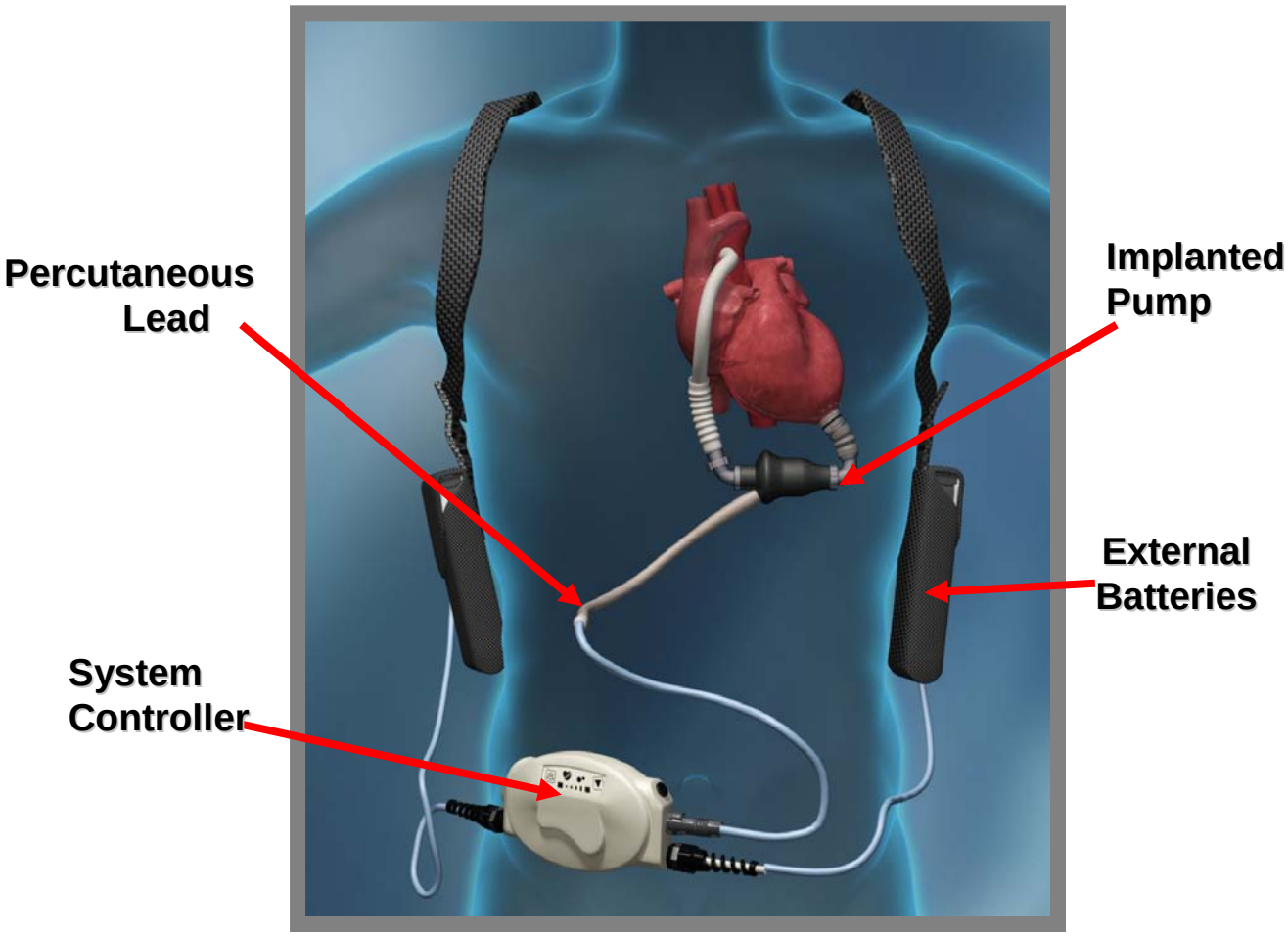
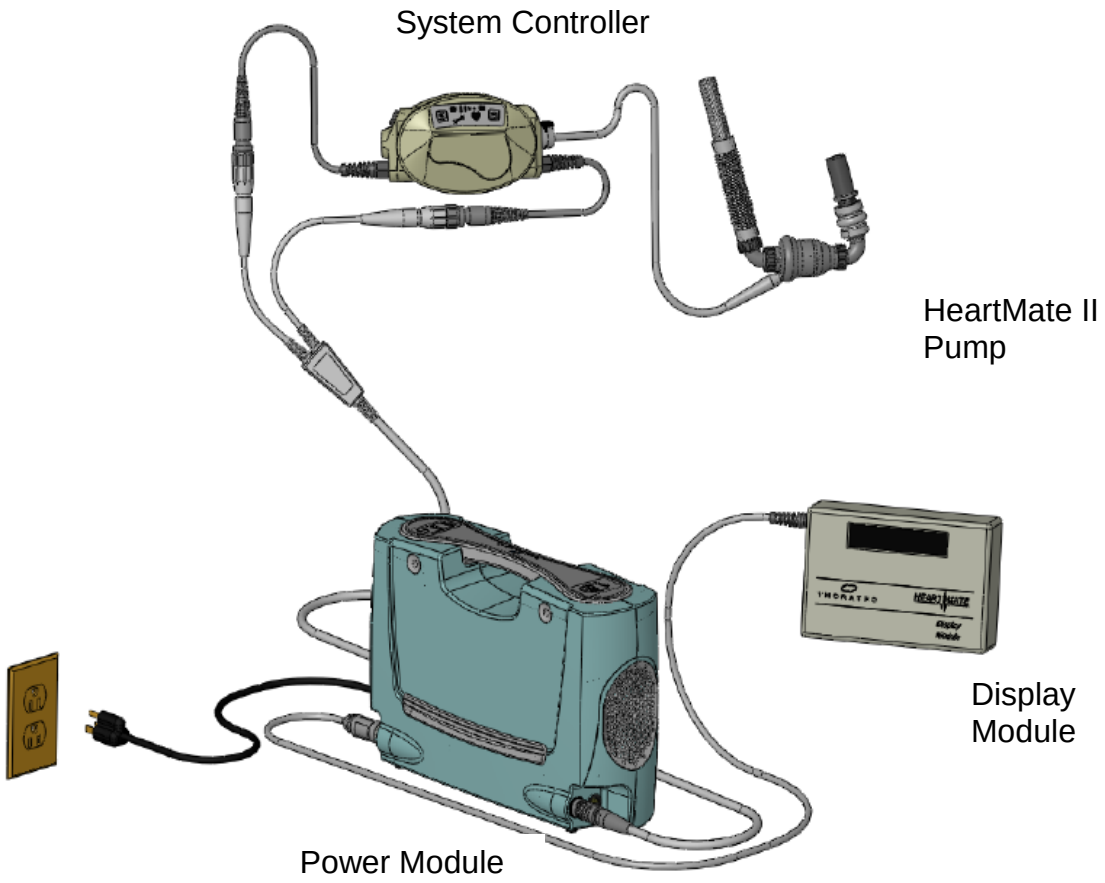


Figure 2 – HeartMate II LVAS Configuration with Power Module and System Monitor



ALTERNATIVE PRACTICES OR PROCEDURES

The current standard of care for patients in end-stage heart failure includes three treatment modalities; pharmacologic therapy (including digoxin, ACE inhibitors/Angiotensin II receptor blockers, beta blockers, diuretics and inotropes), cardiac transplantation, and mechanical circulatory support. Pharmacologic therapy has been demonstrated to improve symptoms and survival for patients in heart failure. Cardiac transplantation is limited to the number of organs available and to criteria for becoming a transplant candidate. For patients that are considered non-transplant candidates due to malignancy, comorbidities or age, and are refractory to pharmacologic therapy, the only approved device for long term mechanical circulatory support (i.e., destination therapy) is the HeartMate XVE LVAS. However, the HeartMate XVE LVAS is contraindicated for patients having a body surface area (BSA) of less than 1.5 m^2. The smaller size of the HeartMate II LVAS blood pump enables its use in a broader patient population, including the currently under-served population of small sized patients with end-stage heart failure, especially women and small stature men. Furthermore, it also allows the device to be used in patients with body habitus characteristics (such as tall and slender) that preclude implantation with larger systems.

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STUDY OVERVIEW

The objective of the study was to determine the safety and effectiveness of the HeartMate II LVAS as a destination therapy (DT) device in end-stage heart failure patients who were not candidates for cardiac transplantation. Effectiveness of the device was compared to the HeartMate XVE by evaluating a composite endpoint that included survival at two years, survival free of stroke resulting in a Modified Rankin Score > 3 or reoperation to repair or replace the device. The safety of the HeartMate II was documented by the incidence of adverse events and the incidence of device malfunctions and failures during LVAS support and was compared to the HeartMate XVE results.

In addition, a number of secondary objectives were evaluated during the study, including separate evaluations of each component of the composite endpoint (2 year survival, stroke rates, and device reliability), functional status (6-minute walk, patient activity Score, and NYHA classification), quality of life (Minnesota Living with Heart Failure and Kansas City Cardiomyopathy Questionnaire), assessment of all adverse events, re-operations, re-hospitalizations, and neuro-cognitive assessments (memory, language, visual/spatial perception, processing speed and abstract/executive function).

The results of the Heart Mate II Destination Therapy study were published in the New *England Journal of Medicine 200*9 with the following chart being noted in an editorial showing continuous improvement of left ventricular assist devices in the long-term support of end stage heart failure over the outcomes of those patients supported by medical management.

Destination Therapy Trials

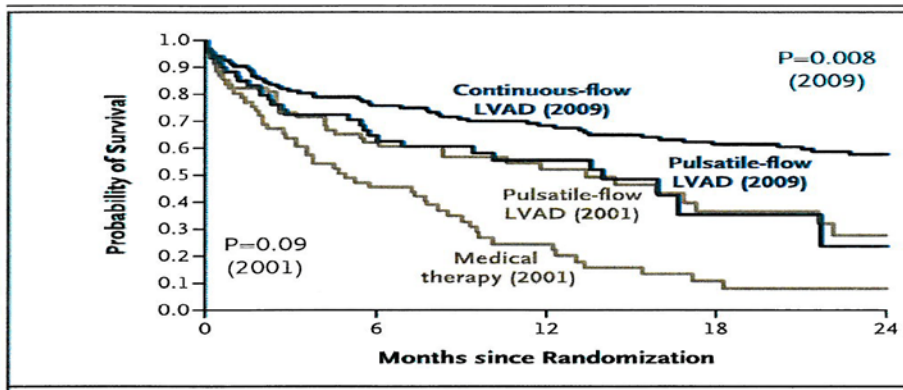

Figure 1. Survival Rates in Two Trials of Left Ventricular Assist Devices (LVADs) as Destination Therapy.
The curves labeled 2009 are those reported by Slaughter and colleagues in this issue of the *Journal*[2]; those labeled 2001 were reported for the REMATCH trial.[1]

Fang JC NEJM 2009

In order to support revision to the existing National Coverage Decision, attached please find:

1. Heart Mate II Summary of Safety and Effectiveness Data
2. Heart Mate II Bibliography
3. Indication for use with definition of Class 3B patients
4. Destination Therapy Patients Outcomes NYHA CLASS 3b vs Class 4 Table
5. Slaughter MS, Rogers JG, Milano CA, et al. Advanced heart failure treated with continuous-flow left ventricular assist device. N Engl J Med 2009;361:2241-51

Please feel free contact me at 617-416-6359 or email robin.bostic@thoratec.com if you have any additional questions.

Thank you for your consideration in this matter.

Very truly yours,

Robin Bostic
Corporate Vice President Health Policy and Government Affairs

cc: Madeline Ulrich, M.D.CMS
Marcel Salive, M.D. CMS