

**Tracking Form for Applicants for New Technology Add-on Payments
under the Acute Inpatient Prospective Payment System (IPPS) for
Federal Fiscal Year (FY) 2009**

1. Technology Name:

CardioWest™ temporary Total Artificial Heart (TAH-t)

2. Manufacturer Name:

SynCardia Systems, Inc.

3. Trade Brand of Technology:

CardioWest™ temporary Total Artificial Heart

4. Brief Description of Service or Device:

The CardioWest™ TAH-t system is a pulsatile biventricular device that is placed after the native ventricles are excised. The implantable device consists of two artificial ventricles, each made of a semi-rigid polyurethane housing with four flexible polyurethane diaphragms separating the blood chamber from the air chamber.

The surgical implantation procedure involves removal of the patient's native ventricles and valves. The right artificial ventricle is connected via the right atrial inflow connector to the right atrium and via the pulmonary artery outflow cannula to the pulmonary artery. The left artificial ventricle is connected via the left atrial inflow connector to the left atrium and via the aortic outflow cannula to the aorta.

The cannulae tunnel through the chest and are attached to seven-foot drivelines that connect to the external pneumatic Circulatory Support System (CSS) console. The CSS Console includes a laptop computer that provides noninvasive diagnostic and monitoring information to the user.

The Controller is the major component of the external CSS Console and supplies pulses of pneumatic pressure to the right and left drivelines, which connect into the air chambers of the respective implanted artificial ventricles via the cannulae.

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 CardioWest™ TAH-t received FDA Premarket Approval on October 15, 2004.

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).

Yes.

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?

An application to revise an existing code is 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.

While there is an existing ICD-9-CM procedure code that references an artificial heart, 37.52 (implantation of total replacement heart system), it is not clear whether that code accurately describes the implantation of the TAH-t. Because of this uncertainty, SynCardia made a submission to the ICD-9-CM Coordination and Maintenance Committee (“Committee”). That application was considered at the Committee’s September 27, 2007 meeting, and the recommendation at that time was to modify the language of 37.52 to accommodate the implantation and to recreate a new code 37.55 for the explant procedure. As reflected in the summary report from that meeting, there was support for the recommended changes.

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/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 code(s) in the MedPAR claims data in order to receive add-on payment.

See above.

- 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.)**

No.

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 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 DRGs to which the new technology is assigned. Table 10 from the annual final rule lists the thresholds by DRG. The most recent version of Table 10 can be downloaded at:

http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage.

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

- 9. 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.**

The anticipated average standardized charge per case involving the TAH-t, based on information collected to date, is \$750,114.69.

- 10. 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, clearly showing which components are the “new” ones).**

Currently, the cost to hospitals for the device is \$106,000. In addition, there may be a separate monthly cost to the hospitals for the use of the driver (the CSS Console) depending upon when the patient receives a heart transplant. The cost of the driver for the first 120 days is included in the \$106,000 cost noted above. However, if the patient continues to need the driver after 120 days, the monthly cost of the driver is \$4950.

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

The data relied on to demonstrate satisfaction of the cost criterion are primarily from cases that were assigned to DRG 103 or 525. With the change to Medicare Severity DRGs (MS-DRGs), cases in which the technology is utilized will most likely affect MS-DRGs 1, 2, or 215.

12. What is the anticipated volume of Medicare cases involving of this technology in FY 2009 (by DRG)?

The estimated fiscal year 2009 volume is approximately 180 cases, with virtually all of the cases expected to be assigned to MS-DRG 1.

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

13. 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 TAH-t provides a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. Specifically, patients suffering from biventricular failure are not good candidates for other mechanical circulatory devices, such as ventricular assist devices. The TAH-t, conversely, has been demonstrated to be an effective bridge-to-transplant for these patients. The TAH-t also significantly improves clinical outcomes for this patient population in that it provides for immediate restoration of hemodynamic function, which makes patients better candidates for heart transplants.

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

1. Copeland, J., et al., *Total Artificial Hearts: Bridge to Transplantation*, *Cardiol. Clin.* 21 (2003) 101-113.
2. Copeland, J., et al., *Cardiac Replacement with a Total Artificial Heart as a Bridge to Transplantation*, *N. Engl. J. Med* 2004; 351:859-67.

3. Leprince, P., et al., *Bridge to Transplantation with the Jarvik-7 (CardioWest) Total Artificial Heart: A Single-Center 15-Year Experience*, J. Heart and Lung Transplantation 2002; 22:12:1296-1303.
4. Copeland JG III, Smith RG, Arabia FA, et al., *Comparison of the CardioWest Total Artificial Heart, the Novacor Left Ventricular Assist System and the Thoratec Ventricular Assist System in Bridge to Transplantation*, Ann. Thoracic Surg. 2001; 71:Suppl:S92-S97.
5. Blanche, C., et al., *Heart Transplantation in Patients Seventy Years of Age and Older: a Comparative Analysis of Outcome*, J. Thoracic and Cardio. Surg. 2001; 121:532-41.
6. Demers, P., et al., *Long-Term Results of Heart Transplantation in Patients Older than 60 Years*, J. Thoracic and Cardio. Surg. 2003; 76:1; 224-231.
7. Morgan, J., et al., *Long-Term Results of Cardiac Transplantation in Patients 65 Years of Age and Older: A Comparative Analysis*. Society of Thoracic Surgeons 2003; 76:1982-7.
8. Morgan, J., et al., *Should Heart Transplantation be Considered as a Treatment Option for Patients Aged 70 Years and Older?* J. Thoracic and Cardio. Surg. 2003; 127:6: 1817-19.