

## **Medicare Approves New Technology Add-On Payments of up to \$53,000 for SynCardia's Total Artificial Heart Through FY 2011**

SynCardia

**CMS Encourages SynCardia to Submit New Technology Add-On Application If and When Freedom&trade; Portable Driver Undergoing Clinical Study Receives FDA Approval**

**TUCSON, Ariz. &ndash; Aug. 26, 2010** -- On Aug. 16, the Centers for Medicare and Medicaid Services (CMS) published its [FY 2011 Hospital Inpatient Prospective Payment System \(PPS\) final rule](#) [1], approving new technology add-on payments of up to \$53,000 for the SynCardia temporary Total Artificial Heart (TAH-t) through FY 2011. The decision is effective Oct. 1, 2010.

CMS stated in its ruling that, &ldquo;Commenters supported our proposal to continue add-on payments for the TAH-t&hellip; We agree with the commenters that, for patients with biventricular heart failure, the TAH-t continues to represent a substantial clinical improvement.&rdquo;

SynCardia Systems, Inc., manufacturer of the Total Artificial Heart, informed CMS of the company&rsquo;s recent use of the 13.5 lb Freedom&trade; portable driver, which provides increased mobility so that stable patients who are eligible may leave the hospital while waiting for a donor heart. SynCardia asserted that this new driver further demonstrates that the Total Artificial Heart represents a substantial clinical improvement.

SynCardia also noted that the use of this portable driver increased the operating costs of the Total Artificial Heart and requested that the new technology add-on payment be increased accordingly. However, CMS noted that because the Freedom driver is undergoing an [Investigational Device Exemption \(IDE\) clinical study](#) [2] and is not FDA-approved, it is unable to increase the new technology add-on payments for FY 2011.

CMS stated in its ruling, &ldquo;We would encourage the manufacturer to submit a new technology add-on payment application if and when it expects to receive FDA approval for&hellip; the Freedom driver.&rdquo;

SynCardia&rsquo;s Total Artificial Heart has been approved for new technology add-on payments since FY 2009. It is the world&rsquo;s only FDA, Health Canada and CE approved Total Artificial Heart.

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### **About SynCardia Systems, Inc.**

SynCardia Systems, Inc. is the Tucson-based manufacturer of the world&rsquo;s only FDA, Health Canada and CE approved Total Artificial Heart: the SynCardia

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temporary Total Artificial Heart. There have been more than 850 implants of the Total Artificial Heart, accounting for more than 200 patient years of life on the device.

Originally used as a permanent replacement heart, the Total Artificial Heart is currently approved as a bridge to human heart transplant for people dying from end-stage biventricular failure. The Total Artificial Heart is the only device that provides immediate, safe blood flow of up to 9.5 L/min *through both ventricles*.

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### Links:

[1] <http://www.cms.gov/AcuteInpatientPPS/IPPS2011/list.asp#TopOfPage>

[2] <http://www.syncardia.com/Medical-Professionals/clinical-trials.html>

[3] <http://www.syncardia.com/Medical-Professionals/sign-up-for-news-updates.html>

[4] <http://www.syncardia.com/>

[5] [http://twitter.com/SynCardia\\_News](http://twitter.com/SynCardia_News)

[6] <mailto://www.syncardia.com/2010-Press-Release/disaacs@syncardia.com>

[7] <http://www.syncardia.com/2010-Press-Release/medicare-approves-new-technology-add-on-payments-for-fy-2011.html>