



## Ventricular Assist Device (VAD) Trends

### Introduction

For individuals with a weakened heart or heart failure, cardiologists often recommend a ventricular assist device while awaiting a heart transplant or as a long-term treatment. These devices are showing trends of increasing utilization, expanding the previously limited scope of treatment options for patients with advanced heart failure.

Heart failure (HF) is a chronic, progressive inability of the heart to pump sufficient blood to meet the body's demands. Patients with unmanageable HF require specialized interventions, such as heart transplantation or mechanical circulatory support with equipment like a ventricular assist device (VAD). A VAD is a mechanical device that helps pump blood from the lower chambers of the heart (ventricles) to the body. While it does not replace the native heart, it does work to prolong the heart's life.

### Heartware HVAD®



### Thoratec Heartmate II®1



VADs are primarily used in two ways:

1. Bridge to transplant (BTT), where the device is typically intended for short- to intermediate-term support in patients actively listed for transplantation
2. Destination therapy (DT), where the device is inserted with the intention of long-term support in patients who are not candidates for transplantation

### Growth of chronic VAD support

The Scientific Registry of Transplant Recipients (SRTR) estimates that approximately 42 percent of all heart transplant patients have a device at the time of transplant.<sup>2,3</sup> This varies widely by state and facility. For example, in one Virginia facility, 91 percent of all heart transplant patients had a device implanted at the time of transplant.<sup>4</sup> The usage of VADs will continue to grow, particularly as new devices are tested and approved by the FDA. Heartware International, Inc., a medical device company, expects approval of its device for BTT in 2012.

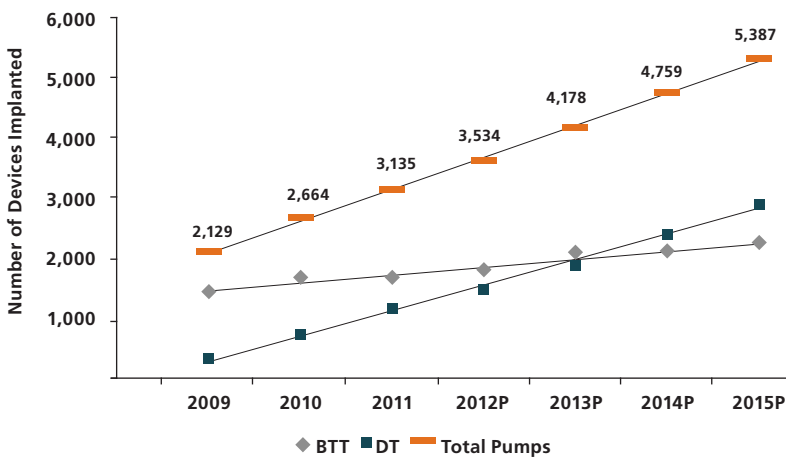
VAD utilization increased significantly following the Food and Drug Administration’s (FDA’s) approval of Thortec’s Heartmate II device for BTT in April 2008 and for DT in January 2010.

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Between 2009 and 2011, the use of VADs experienced nearly a 70 percent increase, from 2,129 implanted devices to 3,135.<sup>4</sup> Potential utilization is estimated to increase nearly 60 percent by 2015, with DT driving the majority of the growth.<sup>5</sup>

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### Increasing VAD Utilization Trends<sup>5</sup>



### Candidate selection

A VAD can help support a heart during short- to intermediate-term support, typically while waiting for a heart transplant (BTT), and long-term support for patients who are not candidates for transplantation (DT). Risk stratification is critical to determine the appropriate patients and the timing for advanced heart failure therapies in general.

If a patient has Stage D heart failure with severe LV dysfunction and standard therapies have already been utilized, the patient may wish to explore other options. These options may include the management of co-morbidities and tailored medical therapy/PA catheter. If these treatment options do not show suitable improvement, a patient may consider one of three options: continuous infusion inotropes, a treatment which alters the force or energy of muscular contractions, VAD implantation, and/or heart transplantation.

Although heart transplants are considered the gold-standard for advanced-stage heart failure, particularly with regard to survival and quality of life, the incidence of transplants is limited due to stringent selection criteria and the scarcity of acceptable donors.

A patient, therefore, may consider the other two options. According to medical experts, VADs are considered to have advantages over chronic IV inotropic support for multiple reasons, including:

- Normalization of cardiac output leading to improved renal function
- Reduction of pulmonary artery pressures
- Improved nutritional state
- Improved rehabilitation potential
- Early discharge from the hospital: LOS approximately two to four weeks

Given the complexities of VAD treatment and management, not all patients are appropriate for VAD implantation.

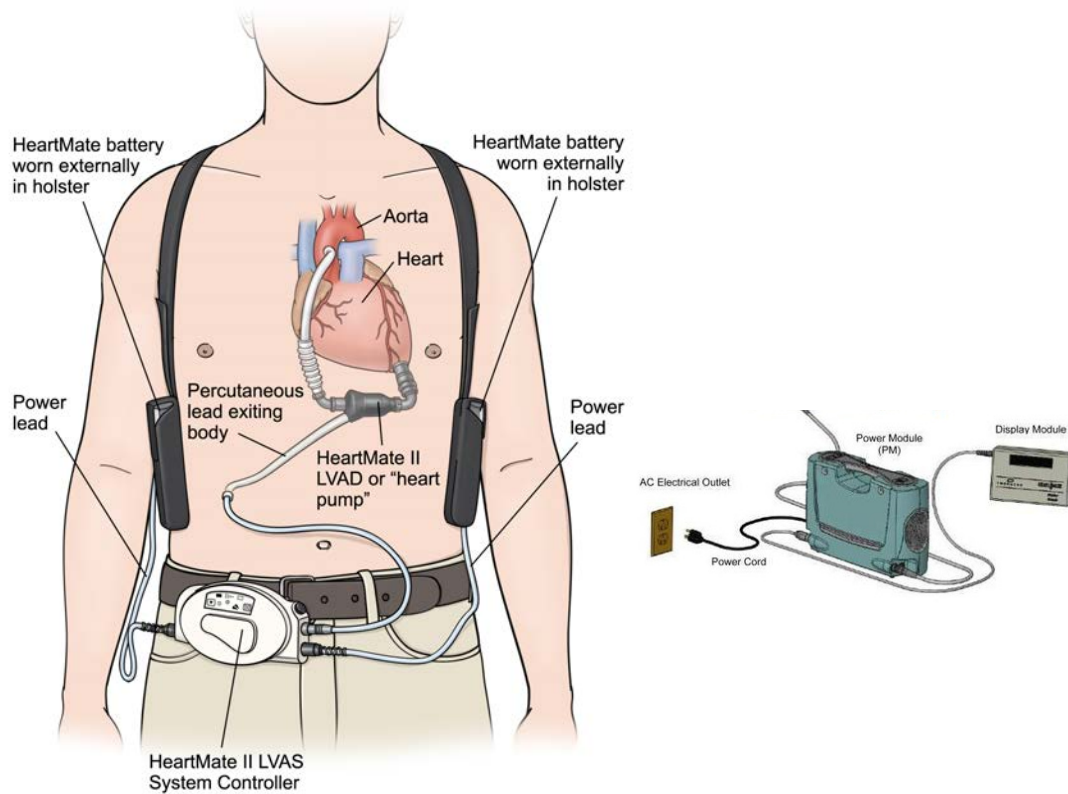
### **Complexity of patient management**

While successful VAD implantation has many potential benefits, including improved quality of life, stabilized heart condition, improved organ function and preparedness for heart transplant, it also carries risks, including blood clots, bleeding, infection, device malfunctions or other complications.

Post-implantation case management is a key component of effective VAD utilization, requiring the patient and the case manager to work together to determine:

1. Who is maintaining the hardware and who is providing the consumable supplies
2. When, where and how the implanting center and the referring physician will work together
3. Who will provide the necessary local clinical support, including EMT services and hospital emergency rooms, and are they aware of the patient and have they been trained properly on the device, particularly if the member is on a continuous flow pump
  - a. A recent study found that the majority of first responders did not know the patient had a VAD, and if they did know, the majority did not know what it was or how it functioned. This is in spite of the fact that they received in-service training on the patient.
4. What preparation is needed to negotiate billing intricacies with post-implantation services
  - a. Is this med/surg?
  - b. Is this DME?
  - c. How are the supplies paid for?
  - d. What is the billing code for the hardware?

## Thoratec Heartmate II®1 & Battery Charger



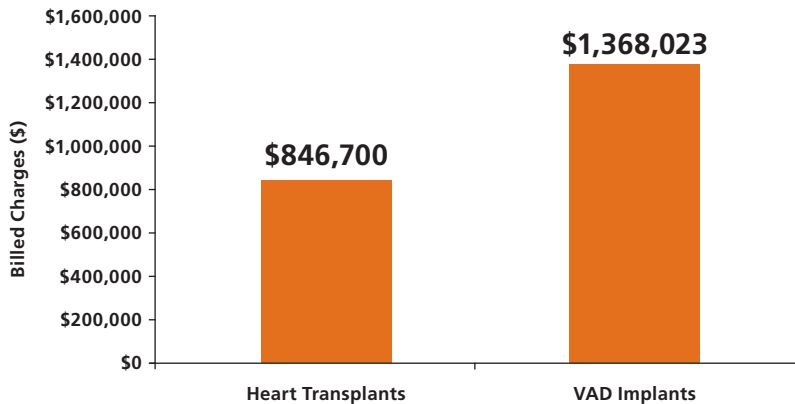
Patient management also includes maintaining the device. Although device failure with continuous flow devices is not common, other complications can occur once the VAD is implanted, particularly due to the drive line that comes out of a patient's body.

Rehospitalization in the first year following VAD implantation is common. A patient and case manager would work together to minimize the risk of complications.

### Associated cost trends

While it can be an essential life-saving option, a VAD comes with a large price tag. The average billed charges for the implantation and first-year maintenance of a VAD were \$1,368,023 between 2007 and 2010, and with each succeeding year, an additional \$30,000 to \$580,000 in post-implantation charges is likely to occur.<sup>6</sup>

### Heart Transplants and VAD Implants Comparison (1-year Average Cost of Procedure)<sup>6</sup>



After a VAD procedure, a patient can plan to face extremely high post-discharge and device maintenance costs. These costs are incurred through management services for the device and equipment, typically provided by the hospital or separate vendor. Vendors tend to charge higher rates, costing a patient anywhere from \$130,000 to \$300,000+ annually for device maintenance. Costs are also incurred through complications, follow-up medical services, and pharma.

A VAD patient can cost from three times (for BTT patient) to five times (for DT patient surviving 10 years) more than a heart transplant patient.

### Conclusion

To address the increasing utilization and risk, Optum has launched a VAD Centers of Excellence (COE) program which identifies best in class programs and contains costs from provider and durable medical equipment (DME). An innovative solution that focuses on superior management and clinical outcomes, Optum’s VAD program identifies, qualifies and contracts with those that demonstrate the best clinical outcomes, providing access to quality providers for VAD implantation as well as post-surgical maintenance.

Organizations covering the cost of VAD procedures and post-implant device maintenance face extremely unpredictable expenses. As the volume of procedures trends upward year after year, the importance of containing VAD costs becomes increasingly apparent. The Optum VAD program controls cost variation, mitigating financial risk through utilization of and emphasis on strategic contracting with COEs and VAD equipment vendors.

## Biographies

### Marjorie Chen, MEng, MBA

Marjorie Chen is the Product Director of Optum's Ventricular Assist Device (VAD) Program and Congenital Heart Disease Resource Services (CHDRS). Prior to Optum, Chen practiced process engineering and manufacturing operations within the medical device industry. She currently manages the CHDRS product and has developed the VAD program from concept to market. Chen holds a BS and Master of Engineering in Bioengineering from University of California, San Diego and an MBA from the University of Michigan.

### Molly Dickinson, MA

Molly Dickinson is a Product Specialist of Transplant Resource Services. Prior to joining the Transplant team, Dickinson practiced six-sigma project management across Optum Care Solutions. Dickinson graduated from the University of Wisconsin with a BA in Economics and a BS in Journalism. She holds an MA in Strategic Communications from the University of Minnesota.

### Dennis Irwin, MD

Dr. Irwin is board-certified in internal medicine and serves as National Medical Director for Optum. Dr. Irwin is a graduate of Case Western Reserve University School of Medicine and completed his postgraduate at UCLA. Prior to joining Optum, Dr. Irwin practiced internal medicine for the U.S. Public Health Service in Micronesia and has acted as Medical Director and President of Snowline Hospice of El Dorado County, Medical Director for Allianz Healthcare Re/LifeTrac Transplant Network and Chief Medical Officer for INTERLINK Health Services. Dr. Irwin develops programs to help achieve the best overall value in other high-cost, low volume areas such as ventricular assist devices and kidney paired donation.

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To learn more, contact your Optum™ sales representative, call **1.866.427.6845** or email us at **engage@optum.com** or visit **www.optum.com**.

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## Sources

- <sup>1</sup> Reprinted with the permission of Thoratec Corporation
- <sup>2</sup> Devices include ventricular assist devices (VAD), extracorporeal membrane oxygenation (ECMO), intraaortic balloon pump (IABP), and total artificial heart (TAH).
- <sup>3</sup> Scientific Registry of Transplant Recipients, accessed Dec. 19, 2011, [http://www.srtr.org/csr/current/Centers/TransplantCenters\\_New201106x.aspx?organcode=HR](http://www.srtr.org/csr/current/Centers/TransplantCenters_New201106x.aspx?organcode=HR)
- <sup>4</sup> SRTR data available as of April 30, 2011. Accessed July 12, 2011. <http://www.srtr.org/csr/current/Centers/centerdetail201106x.aspx?facility=VAUVTX1HR>.
- <sup>5</sup> Thoratec Corp, 2011 10-K Review, Barclays Capital, Healthcare, U.S. Medical Supplies & Devices, Feb 22, 2012
- <sup>6</sup> UnitedHealth Group Claims Database 2007-2010



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