**Destination Therapy:** Patient Selection and Current Outcomes

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**ABSTRACT** Long-term left-ventricular assist device (LVAD) support as destination therapy (DT) is a promising new alternative for the growing population of patients with advanced heart failure. In this article, we summarize the clinical trials that led to the approval of LVAD use as DT in the US national policies regulating candidate selection and DT center accreditation. We review current guidelines for candidate selection, clinical tools to assess candidate operative risk, and outcomes of DT.

Recent estimates suggest that 250-500,000 patients in the United States are in the terminal phase of end-stage heart failure (ESHF) refractory to maximized medical therapy. \(^1\) Prognosis of these patients is dismal, with a mean survival of 3.4 months and one-year rate of 6% for patients who reached inotropic dependence. \(^2\)

At this advanced stage of heart failure, heart transplantation (HT) is the only means of improving survival. This option, however, is available only to a few. It is estimated that 80,000 to 150,000 patients with advanced heart failure could potentially benefit from HT in the United States every year, if more than 2200 HT were performed. \(^3\) In the recent years, implantation of a permanent left-ventricular assist device (LVAD) as destination therapy (DT) has emerged as a promising alternative to HT. In this article, we summarize the clinical trials that led to the approval of DT in the United States, guidelines for candidate selection, and national policies regulating DT center accreditation and review current outcomes of this therapy.

### DT FEASIBILITY TRIALS

The success of LVAD implantation as “bridge to transplant” (BTT) in candidates with profound heart failure led to the investigation of chronic mechanical circulatory support (MCS) as an alternative to HT. The first DT feasibility trials were designed over 15 years ago, including the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial \(^4\) and the Investigation of Nontransplant-Eligible Patients Who Are Inotrope Dependent (INTREPID) trial, \(^5\) which evaluated the use of the two most popular pulsatile LVAD systems in the United States in the early 1990s, the HeartMate (HM) VE (Thoratec Laboratories Corp., Pleasanton, CA, USA) and Novacor (WorldHeart, Ottawa, Canada), respectively, as well as the European LionHeart Clinical Utility Baseline Study (CUBS) trial, which evaluated the use of Arrow LionHeart (LionHeart Ventricular-Assist System; Arrow International, Reading, PA, USA). \(^6\)

All of the above clinical trials revealed superior outcomes of LVAD over medical therapy for ESHF, as we have previously summarized in Table 1. \(^7\)

The landmark REMATCH trial was one of the most remarkable endeavors in the history of clinical trials in heart failure, as it randomized the sickest heart failure patients ever studied to either medical therapy or LVAD implantation. The trial was conducted between May 1998 and July 2001 at 20 US hospitals. Of the over 900 screened patients with ESHF, the study randomized 68 patients to HM VE LVAD and 61 patients to medical therapy. The REMATCH trial entry criteria were as follows: New York Heart Association (NYHA) class IV heart failure symptoms, left ventricular ejection fraction (LVEF) <25%, either peak oxygen consumption <12 mL/kg/min or dependence on intravenous inotropic infusion, optimal medical therapy for at least 60 of the last 90 days, projected life expectancy of less than two years, and not eligible for transplant.

Results of the REMATCH trial revealed significant improvement of the quality of life in patients supported with LVAD and improved one-year survival from 25% to 52%. These data led to the US Food and Drug Administration (FDA) approval of the modified HeartMate XVE LVAD for use as DT in November 2002, \(^8\) thus launching a new era of surgical therapy for advanced heart failure.

### The HeartMate II DT trial

Recently published, the HeartMate II DT trial \(^9,10\) is now the largest clinical trial of DT. The trial evaluated the use of the second generation, nonpulsatile axial...
flow pump, the HeartMate II (HM II) LVAD (Thoratec Laboratories Corp., Pleasanton, CA, USA). The study was conducted between March 2005 and May 2007 and enrolled 200 patients with ESHF ineligible to HT at 38 US hospitals. The trial entry criteria were similar to those of the REMATCH trial. The study randomized patients to LVAD therapy in a 2:1 fashion; 134 patients received continuous flow axial flow device, the HM II LVAD, and 66 patients underwent the HM XVE LVAD implantation. Results of the HeartMate II DT trial revealed significant improvement of the quality of life and functional capacity with both types of devices. Patients supported with HM II LVAD had significantly improved two-year survival when compared to HM XVE recipients (58% vs. 24%, respectively) and significantly improved probability of freedom from stroke and device failure at two years, as compared to the recipients of pulsatile devices (Table 1).

REGULATORY ISSUES PERTAINING TO DT IN THE UNITED STATES

Approved devices

The HM XVE LVAD was the first FDA-approved device for use as DT in the United States. This first-generation pusher-plate pump, illustrated in Figure 1A, underwent several modifications after completion of the REMATCH trial to reduce the rate of infections and improve device durability. The clinical studies confirmed better safety profile and greater reliability of the modified device.11 Our ability to detect device “end-of-life” has also improved and the mortality due to device failure substantially decreased (from 11% with HM VE in the REMATCH trial12 to 0.01% with HM XVE in the post-REMATCH era12). Despite these improvements, the longevity of the HM XVE pump remains limited. The pump offers only an average of 1.5 years of continuous support, with 73% likelihood of device exchange at two years.12

A generational step forward is the continuous axial flow device, the HM II LVAD, which is illustrated in Figure 1B. The device has been approved by the US FDA for implantation as BTT in April 200813 and as DT in January 2010. The longevity of HM II appears to be significantly superior to first generation devices. Some patients were maintained for more than four years without device exchange. Only 9% of patients supported with HM II required pump replacement, as compared to 34% of HM XVE recipients.9 A further increment improvement of pump durability is anticipated with the introduction of third generation pumps, which utilize magnetically levitated centrifugal flow, without bearings, such as the investigational WorldHeart Rotary Pump, DuraHeart, and HeartMate III LVAD.

The new generation axial flow and rotary pumps are smaller, quieter, easier to operate, and have lighter batteries with a longer life span, which obviates many of the problems reported with older-design pumps. As new device technology is evolving, the pump design will continue to become more user friendly. An important characteristic of the ideal pump for life-long support would be either minimal or anticoagulation-free design. This is particularly important in the geriatric population of DT recipients. Associated with aging noncardiac conditions that predispose to bleeding, as well as the increased prevalence of malignancy and comorbidities in this population, which would require intermittent discontinuation of anticoagulation for elective surgeries or stopping it altogether, may all jeopardize patient safety. Moreover, the recently described acquired von Willebrand disease in elderly would require intermittent discontinuation of anticoagulation for elective surgeries or stopping it altogether, may all jeopardize patient safety. Moreover, the recently described acquired von Willebrand disease in elderly would require intermittent discontinuation of anticoagulation for elective surgeries or stopping it altogether, may all jeopardize patient safety. Moreover, the recently described acquired von Willebrand disease in elderly would require intermittent discontinuation of anticoagulation for elective surgeries or stopping it altogether, may all jeopardize patient safety. Moreover, the recently described acquired von Willebrand disease in elderly would require intermittent discontinuation of anticoagulation for elective surgeries or stopping it altogether, may all jeopardize patient safety.
Figure 1. Components of the left-ventricular assist device (LVAD). The pictures show first-generation pusher-plate HeartMate I LVAD (A) and second generation axial flow HeartMate II LVAD (B). Both pumps are composed of inflow cannula, which is inserted into the apex of the left ventricle, and the outflow cannula, which is anastomosed to the ascending aorta. In the pusher-plate LVAD blood returns from the lungs to the left side of the heart and exits through the left ventricular apex and across an inflow valve into the prosthetic pumping chamber. It is then actively pumped through an outflow valve into the ascending aorta. In the axial flow device, the blood exits through the left ventricular apex and into the LVAD, which pumps throughout cardiac diastole and systole into the ascending aorta, with the rotor being the only moving part. The pumping chambers for both devices are placed within the abdominal wall or peritoneal cavity. A percutaneous driveline carries the electrical cable and electronic control (and air vent to the battery packs in the first generation pump), which are worn on a shoulder holster and belt, respectively. (Adopted from Slaughter MS, et al. N Engl J Med, 2009; 361:2241-51.)

Indications for DT

All recipients of DT should meet the general criteria for LVAD implantation as published by the Centers for Medicare and Medicaid Services (CMS). These criteria were based largely on the entry criteria into the REMATCH trial, including: (1) class IV NYHA symptoms for at least 60 of the last 90 days despite maximized oral therapy, including dietary salt restriction, diuretics, digitalis, beta-blockers, and angiotensin converting enzyme (ACE) inhibitors (if tolerated), or requirement of inotropic support as outlined by the AHA/ACC guidelines for heart failure treatment15; (2) LVEF of ≤25%; (3) peak oxygen consumption of <12 mL/kg/min or
The clinician’s level of uncertainty as to the final outcome of LVAD implantation is best illustrated in the INTERMACS Registry report, which depicts various degrees of certainty as to where chronic LVAD support will lead; from definitely BTT (46%) to likely to be eligible (27%), with moderate likelihood of becoming eligible (9%) to unlikely to become eligible (5%) and DT (9%). Therefore, one should not assume that DT would in the future preclude transplantation. The reverse is also true, as many of the “definite” BTT candidates, and in particular those with ABO “O” blood type, large body size, and presence of anti-HLA antibodies, may ultimately become recipients of DT, as they are unlikely to match a suitable donor heart.

Center accreditation for DT

In an effort to assure safe device implantations such as DT, in March 2007 the Joint Commission and the US CMS issued a list of criteria and minimum standards required for hospitals to become accredited DT sites. These requirements followed publication of the 2003 proposal set forth by the Board of Directors of the International Society for Heart and Lung Transplantation (ISHLT), which outlined the recommended minimal requirements for the DT center infrastructure, clinical care management, performance measurement, and personnel training.

According to the above recommendations, the DT-accredited hospital should meet the following criteria to become certified with the Joint Commission: (1) center should have facilities with the infrastructure to support VAD placement, including adequate staff and facilities to perform and recover patients after cardiac surgery; (2) center should be an active continuous member of a national, audited INTERMACS Registry (Interagency for Mechanical Circulatory Support), which collects clinical information on all recipients of MCS in the United States; (3) center should have a board-certified cardiac surgeon who meets the following volume requirement: has placed 10 VADs as bridge to transplant or DT or total artificial heart in the last 36 months with current activity in the last 12 months and has performed at least one VAD placement within the last 18 months.

US EXPERIENCE WITH DT IN THE POST-REMATCH ERA

In anticipation of great national demand for DT, the number of DT-accredited hospitals proliferated rapidly. As of April 2010, there were 85 accredited sites. The geographical location of the accredited hospitals is shown in Figure 2. It is notable that 95% of these sites have active heart transplant programs and more than half are located in the East Coast regions. These are the most active HT regions in the United States. The majority of high-risk status 1A and 1B candidates are listed in this location, with the highest proportion of those requiring MCS as BTT.

It is notable that the number of DT implants performed at each of the above DT sites has been relatively small. We have previously shown that the majority (53%) of 377 DT recipients between 1998 and 2005 received devices at centers that performed fewer than four DT implants. At the time of the study closure in November 2005, more than two-thirds (69%) of the 68 accredited hospitals performed fewer than four DT implants. Overall, only approximately 100 patients underwent DT every year during the first five years after FDA approval of DT, which totals ∼500 patients who received HM XVE LVAD and ∼600 patients who were subsequently enrolled in the HM II LVAD DT trial. These numbers represent less than 15% of all implanted MCS devices in the United States.

The very large gap between the anticipated demand for DT and the actual number of performed procedures reflects the continued limited public awareness that this therapy is available, as well as clinicians’ reluctance to refer patients earlier in the disease course. The belief that DT is the “end-of-life” treatment often results in referrals that are too late in the disease course, when the risk of surgery is too high. According to the INTERMACS Registry, as many as two-thirds (62%) of DT recipients underwent while in cardiogenic shock (INTERMACS level 1) or deteriorating on inotropes (INTERMACS level 2). Unfortunately, such restricted application of DT to the sickest patients perpetuates the vicious cycle of poor outcomes and reluctance to refer patients for this therapy earlier. It is important to emphasize that DT should be reserved only for stable patients with advanced heart failure, as an elective surgery.

Survival with DT

We have previously reported outcomes of the first 309 patients who underwent implantation of the HeartMate XVE LVAD in the post-REMATCH era. The
analysis revealed no significant improvement of long-term survival compared to the HeartMate VE LVAD used in the REMATCH trial. As illustrated in Figure 3, despite several device modifications and its improved safety and reliability profile, the one-year survival had not improved with pulsatile pumps (55% in the REMATCH cohort and 55% in the post-REMATCH era as reported in the HM II DT trial). However, with the second generation, continuous flow devices, the long-term survival increased substantially from 55% and 24% at one and two years with the use of HM XVE to 68% and 58% at one and two years with the use of HM II, respectively9,10 (Figure 3).

The institutional experience with DT may have a significant impact on outcomes of this therapy. We have recently shown that patients who received one of the first four DT implants of pulsatile pumps at a given institution were able to achieve 47.8% one-year survival, whereas the survival of those who received DT at centers that performed more than nine DT implants improved by nearly 20%, to 67.4% at one year.19 Although we were not able to elucidate which aspects of center experience were the most critical, better selection of candidates, systemic approach to surgical and postoperative care, as well as the long-term medical management may have all contributed to the improved outcomes.

Although LVAD implantation in the post-REMATCH era continues to be associated with substantial survival benefit as compared to medical therapy (26% one-year survival in the medical arm of the REMATCH trial), the outcomes of DT remain substantially inferior to those of HT (85% one-year survival).20 In order to better understand the key determinants of successful use of LVAD as alternative to HT, in this article we sought to discuss separately the determinants of the operative outcomes and the long-term survival of patients supported with DT.
Operative mortality

Operative mortality remains a major concern with DT. The risk of death with LVAD implantation in clinical trials of DT often exceeded by several times the risk of LVAD surgery in patients “bridged” to HT or the operative risk of HT. The probability of death within three months after LVAD surgery was 18% with continuous flow pumps in the HM II DT trial,9 26% to 28% with pulsatile devices in the post-REMATCH era and the HM II DT trial,9,12 30% in the REMATCH trial,4 50% in the INTREPID trial,5 and nearly 60% in the CUBS trial.6 Analysis of the post-REMATCH cohort revealed that as many as two-thirds of deaths during the first year of pump support occurred prior to hospital discharge (76 of 120 deaths).12

It is important to note that in all of the above clinical trials of pulsatile and nonpulsatile DT pumps, as well as in the recipients of HM XVE LVAD in post-REMATCH era in the United States, nearly all of the postoperative deaths occurred with a functional device. No device failed causing a patient death in the first year of LVAD support in the REMATCH trial6 and only 0.01% in the post-REMATCH era.12 Patients who died during this period suffered late sequelae of operative complications, such as sepsis, right heart failure, and multiorgan failure. Nearly all of these deaths occurred within three months from device surgery.

Long-term survival with DT

In order to illustrate the long-term benefits of device implantation in patients who underwent successful device placement, Figure 4 shows one-year survival of recipients of HM XVE who have been discharged home with the pump. The one-year conditioned survival on the first pump support in the post-REMATCH era was 78%. There was no significant improvement in the postdischarge long-term survival since the REMATCH era. Our previous analysis of the post-REMATCH cohort revealed that the main causes of death after hospital discharge were sepsis and stroke, which accounted for 27% and 15% of all postdischarge deaths.12

These data raise the important issue of postdischarge medical management of DT recipients, and in particular prevention of infection and rigorous treatment of medical risk factors for stroke, such as hypertension and diabetes. Prevention of infection in patients supported with LVAD is critical. Unfortunately, presence of external driveline renders these patients vulnerable to infectious complications. Two previous studies of pulsatile pumps comparing early- to late-enrollment REMATCH trial21 and outcomes of the four largest volume US centers in the post-REMATCH era22 suggested that infection was the only complication, the rates of which significantly decreased as center experience increased, underscoring the importance of vigilant medical therapy and meticulous driveline care. Compared to first-generation pumps, a significantly lower risk of infection, stroke, and improved overall long-term outcomes were observed in the recipients of the nonpulsatile HM II LVAD. This was attributed to the improved design of the percutaneous leads and modular components, which improved device longevity.

APPROACH TO PATIENT REFERRED FOR DT

All patients with advanced heart failure referred to DT center should first undergo evaluation for the potentially reversible factors contributing to the worsening of heart failure symptoms, such as the adequacy of current medical therapy, atrial fibrillation, ventricular dysynchrony, etc. In a patient with ischemic or valvular heart disease, this will involve assessment of myocardial viability and/or severity of valvular disease to determine their candidacy for percutaneous or surgical therapy. A common clinical dilemma is patients presenting with ischemic heart disease and moderate
to large area of viability, who have the potential of improving their native heart function with revascularization, but who are deemed too high operative risk due to severity of LV dysfunction. In these cases, we may recommend coronary bypass surgery with LVAD backup; however, the practice may vary between centers as there are no strict guidelines as how to proceed in this population. In contrast, for patients with a small area of viable myocardium and/or isolated RV viability, there is a general agreement that a primary LVAD implantation with/without coronary bypass to right coronary artery should be preferred. In general, rescue DT implantation should be discouraged in patients in acute cardiogenic shock or postcardiotomy shock, as these implantations carry high risk of mortality and complications.

Once all reversible causes of symptomatic heart failure are addressed, medical therapy should be optimized with up-titrations of vasodilators, diuretics, and use of biventricular pacing, as indicated. If possible, a one- to two-month period of maximal medical therapy is administered to assess therapeutic response. If therapy is felt to be at an optimal level, then the LVAD evaluation process begins. This comprehensive process may take two to three weeks, as we have previously described, and includes the following steps: (1) assessment of clinical severity of heart failure (clinical presentation, cardiopulmonary stress testing, hemodynamic studies), (2) assessment of device feasibility (right ventricular function, arrhythmia, anatomic and body size considerations), (3) exclusion of device-related contraindications (coexisting life-limiting illnesses, psychosocial and age-related considerations), and (5) assessment of LVAD operative risk. During the evaluation time, patients may benefit from aggressive optimization of risk factors, including continuous infusion of intravenous inotropes.

Assessment of operative risk in DT candidates

Since the primary goal of elective DT placement is to discharge patients home in a better condition than before LVAD, it is imperative that all candidates for DT undergo thorough assessment of operative risk and medical optimization prior to day of surgery. Unfortunately, the current guidelines for selection of DT candidates, including the criteria published by the US CMS and the ISHLT guidelines for MCS implantation, are very broad and there are little data available from the prospective trials in BTT and clinical experiences with DT to allow accurate assessment of the operative risk. One of the recently developed clinical tools to estimate the risk of LVAD surgery in patients referred for DT is the DT Risk Score.

DT risk score (DTRS)

It has been recognized for several years that the operative outcomes of LVAD implantation directly correlate with the severity of heart failure. This association has been confirmed in the recent analysis of the INTERMACS severity of heart failure at the time of device implant. Implantations performed in patients too late in the disease course, with severe functional impairment, end-organ dysfunction and right ventricular failure, malnutrition, thrombocytopenia, or infection, have been consistently associated with adverse outcomes.

It has also been recognized for several years that nearly every composite risk score assessing severity of multiorgan impairment has closely correlated with outcomes of LVAD surgery, including the Acute Physiology and Chronic Health Evaluation (APACHE) and Sequential Organ Failure Assessment (SOFA) scores. Risk scores have also been derived in critically ill patients undergoing LVAD implantation, such as the Columbia University–Cleveland Clinic Score. Since in ambulatory patients referred for DT the vital organ function is normal, the critical illness screening scales reveal low risk, and cannot be used to risk stratify this population. Thus, we sought to identify a risk scale that would help clinicians assess the risks involved in LVAD surgery in the stable, ambulatory patients referred for DT.

The risk score was derived from the US population of mostly ambulatory DT recipients and intended to help estimate the probability of in-hospital death after elective LVAD surgery in patients who are not eligible for HT. The DTRS can be calculated from simple clinical parameters, as shown in Table 2. Patients who have acceptable operative risk (cumulative DTRS >16) were more likely to survive surgery and be discharged home and have better long-term survival outcomes (one-year survival ranging between 71% and 80%) than high-risk operative candidates whose prognosis was very poor (one-year survival <15%), or even inferior to the outcomes of patients enrolled in the medical arm of the REMATCH trial (one-year survival 28%), as illustrated in Figure 5.

The proposed DTRS, however, has many limitations. First, the majority of patients in the derivation cohort were ambulatory men with large body surface area to accommodate the HM XVE LVAD. Because of the low prevalence of critically ill patients who required mechanical ventilation or intraaortic balloon pump support

### TABLE 2

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<tr>
<th>Patient Characteristics</th>
<th>Weighted Risk Score</th>
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<tr>
<td>Platelet count ≤ 148 × 10^9/μL</td>
<td>7</td>
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<tr>
<td>Serum albumin &lt;3.3 g/dL</td>
<td>6</td>
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<tr>
<td>International normalization ratio &gt;1.1</td>
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<tr>
<td>Vasodilator therapy (nesiritide, nipride, hydralazine, nitrates)</td>
<td>4</td>
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<tr>
<td>Mean pulmonary artery pressures ≤ 25 mmHg</td>
<td>3</td>
</tr>
<tr>
<td>Aspartate aminotransferase &gt;45 U/mL</td>
<td>2</td>
</tr>
<tr>
<td>Hematocrit &lt;34%</td>
<td>2</td>
</tr>
<tr>
<td>Blood urea nitrogen &gt;51 U/dL</td>
<td>2</td>
</tr>
<tr>
<td>No intravenous inotropes (unable to tolerate)</td>
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and patients with body surface area <1.8, these important risk factors did not enter the DTRS model. The risk score was derived from a population of mostly older patients. Previous studies have shown that advanced age by itself may account for nearly 3-fold increase of the operative risk of LVAD surgery, thus rendering this a high-risk population. Last, the DTRS did not include the information of echo assessment of heart anatomy and function of the INTERMACS level of clinical severity of heart failure, the definitions of which were formulated when the study was closed.

Since its publication in 2007, the DTRS has not been validated in the DT population, as the vast majority of DT recipients in the United States have been enrolled in the clinical trial of the new generation axial flow pump. It will be probably several years before the number of DT implantations performed nationally will be sufficient to validate this model. However, we have recently shown data suggesting that the DTRS may be applicable in sicker patients “bridged” to HT despite the obvious differences between the two populations, as BTT recipients are usually younger, undergoing emergent implants, with more severe heart failure, and more likely to undergo HT, the parameters for which the original DTRS did not account.29

Assessment of long-term survival benefit

When considering elderly patients for DT, it is important to remember that their overall life expectancy on pump support will be determined by the presence of comorbidities and patient survival and quality of life will improve only as much as heart failure contributed to their prognosis and symptoms. Thus patients with life expectancy less than two years due to comorbid conditions should not be considered for DT. It will be important in the future to better estimate life expectancy attributed to noncardiac illnesses in the geriatric population. Emotional and psychological burden of LVAD therapy in the elderly should also be taken in to account, as everyday living with a pump may present a significant challenge to these patients and their families.

At last, it is important to realize that all patients supported with DT will live on pump support until their biological death. The end-of-life issues, therefore, must be approached with special consideration and patients counseled on this issue before considering this treatment. Clinical algorithms have been developed to approach patients and their families when facing dying LVAD recipients.30 Development of life-limiting diseases while on device support or catastrophic complications may render these patients incapable of self-care and institutions providing DT should be prepared to have designated facilities with trained staff to take long-term care of these patients.

### TABLE 3

<table>
<thead>
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<th>Financial Trends in Destination Therapy</th>
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<tr>
<td><strong>REMATCH</strong></td>
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<tr>
<td>Hospital length of stay</td>
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<tr>
<td>Hospital costs</td>
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<tr>
<td>Reimbursement across destination therapy centers</td>
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DRG = diagnosis-related group; FY = fiscal year.

*The value was calculated for the fiscal year 2009, as median Medicare base payment across the 62 DT centers approved by Medicare. [Adopted from Miller et al. JHLT, 25(7), 2006.]
In the United States, the reimbursement of DT is provided by Medicare and private payers. Medicare reimburses approximately $181,800 for the primary device implant across Medicare DT-certified centers. These payments increased significantly since early 2002 ($40,000) to 2009 ($177,000) and are anticipated to continue to rise to $188,000 in 2010 (Table 3). In addition to Medicare coverage, there is a broad private payer coverage for all devices. Payment for outpatient accessories and supplies can also be obtained both from Medicare and/or from private payers, which may be negotiable at discharge or carved out on inpatient bill. Overall, the analysis of DT claims from the post-REMATCH era implantation of HM XVE LVAD and devices implanted as part of the HM II DT clinical trial revealed that 95% of all cases were covered and paid by commercial insurance companies (Thoratec corporation, personal communication, 2010).

REFERENCES