Thoratec Corporation would like to thank the Center for Medicare and Medicaid Services (CMS) for the opportunity to comment on three issues outlined by CMS in the February 7, 2013 National Coverage Determination announcement.

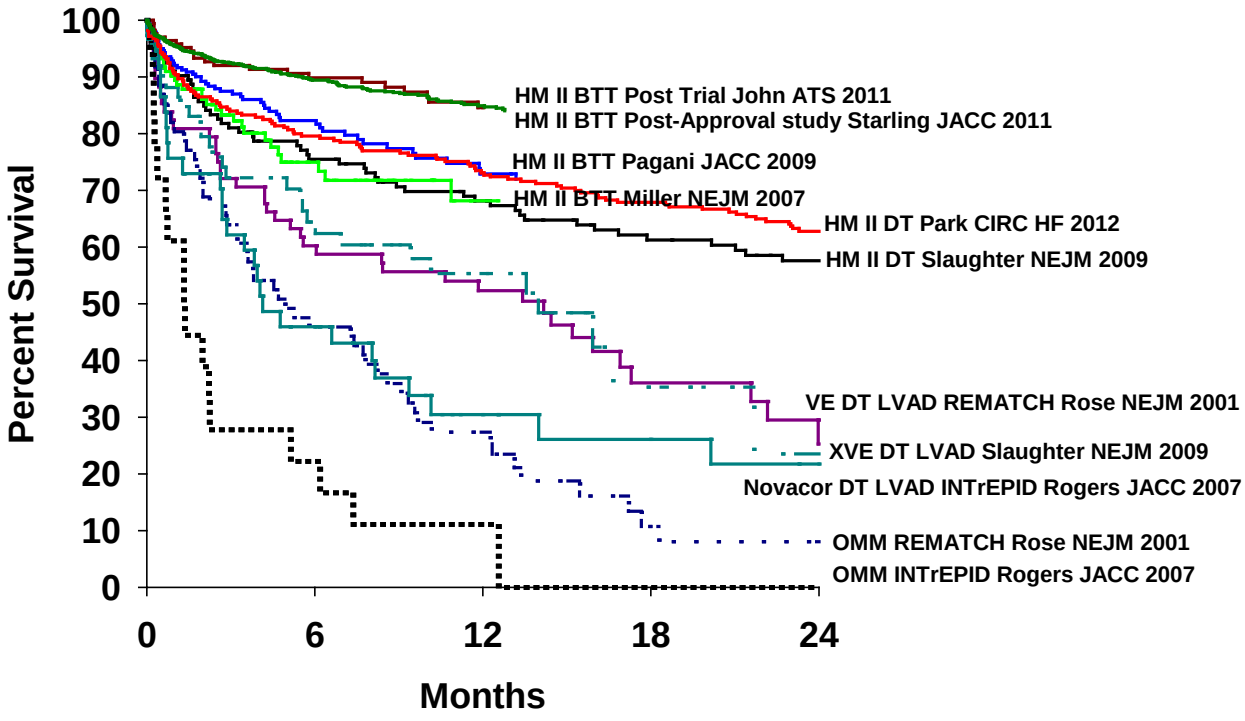
- The clinical evidence supporting identification of patients expected to experience improved health outcomes with VAD placement.
- Healthcare team and hospital standards that optimize patient outcomes.
- Evidence to support the current requirement for certification of hospitals implanting VADs for Destination Therapy.

1. <u>The clinical evidence supporting identification of patients expected to experience improved health outcomes with VAD placement.</u>

A. Survival

Survival has continuously improved for patients with VADs over the course of various bridge to transplantation (BTT) and destination therapy (DT) clinical trials as shown in Figure 1.

Figure 1: Improving survival over the course of different LVAD trials



This trend is evident in the current era as well. Destination Therapy outcomes have continued to improve with the HeartMate II (HMII) VAD. Shown below are the 1 and 2 year survival reported by Drs. Slaughter (NEJM 2009; 361:2241-51) and Park (Circ HF 2012; 5:241-248). Note well the 5% increase found in both 1 and 2 year survival for HM

II Pivotal Trial Continued Access Protocol patients consistent with ongoing improvement in VAD related outcomes.

Table 1: HMII Destination Therapy Outcomes

Reference	Study	Enrollment period	N	1Y Survival	2Y Survival
Slaughter, Rogers, Milano et al NEJM 2009;361:2241-51	HM II Pivotal Trial Primary Data Cohort	3/05- 5/07	134	68%	58%
Park, Milano, Tatooles et al Circ HF 2012; 5:241-248	HM II Pivotal Trial Continued Access Protocol (CAP)	5/07- 3/09	281	73%	63%

B. Indications

HM II FDA DT Indications

Destination therapy (DT) is indicated for patients with New York Heart Association (NYHA) Class IIIB or IV end-stage left ventricular failure that have received optimal medical therapy for at least 45 of the last 60 days, and are not candidates for cardiac transplantation.

NYHA classifications as defined by the FDA include**;**

NYHA Class IIIB: Cardiac disease resulting in marked limitations of physical activity. Patients are comfortable at rest. Mild physical activity causes fatigue, palpitation, dyspnea, or anginal pain.

NYHA Class IV: Cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

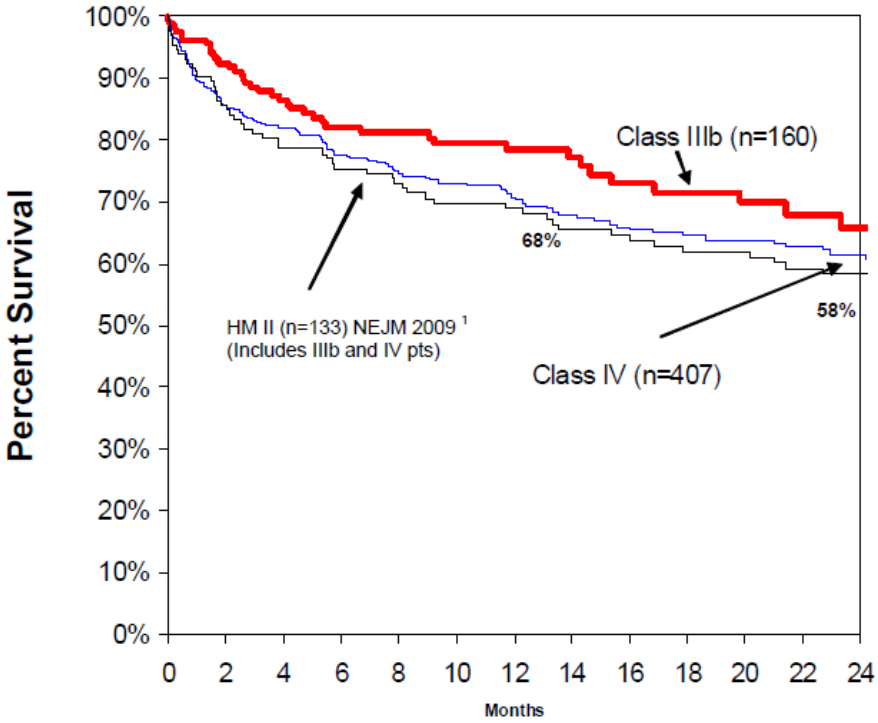
Patient characteristics associated with NYHA IIIB and IV

In the primary cohort of the randomized destination therapy trial, [1] 21% of the patients were in NYHA Class IIIB with cardiac disease resulting in marked limitations of physical activity. Patients were comfortable at rest yet mild physical activity caused fatigue, palpitation, dyspnea, or anginal pain. In a recent analysis of patients receiving the HMII as Destination Therapy, outcomes in 160 NYHA Class IIIB patients were compared to 407 NYHA Class IV patients[3]. Table 2 shows the demographics of the two groups of patients. Figure 2 shows a comparison of survival between the two groups reflecting at least similar if not improved survival for those patients defined as Class IIIB.

Table 2: Comparison of Class IIIB Patients vs. Class IV patients receiving the HMII as Destination Therapy

	NYHA Class IIIB (n=160)	**NYHA Class IV (n=407)**	**p**
Mean age (yrs)	63 ± 11	63 ± 12	0.87
Female (%)	16	25	**0.02**
Ischemic Etiology (%)	59	62	0.63
Serum Sodium (mM/L)	135 ± 3.7	134.7 ± 4.7	0.32
BUN (mg/dL)	33.3 ± 23.9	35.1 ± 23.2	0.41
Creatinine (mg/dL)	1.5 ± 0.6	1.5 ± 0.6	0.84
Pre-albumin (mg/dL)	20.5 ± 8.2	18.0 ± 6.6	**0.001**
AST (U/L)	37.3 ± 67.0	38.7 ± 39.8	0.81
Treatment (%) ACEi Beta blocker Inotropes IABP	 37 63 68 10	 27 46 81 25	 **0.02** **<0.001** **0.002** **<0.001**
CRT (%)	62	62	0.84
CVP (mmHg)	11.8 ± 6.1	13.2 ± 6.8	**0.02**
PCWP (mmHg)	22.4 ± 9.3	24.9 ± 7.9	**0.007**
Ejection Fraction (%)	16.5 ± 5.5	16.9 ± 5.7	0.41

Figure 2: Comparison of survival between NYHA Class IIIB and Class IV patients receiving the HMII

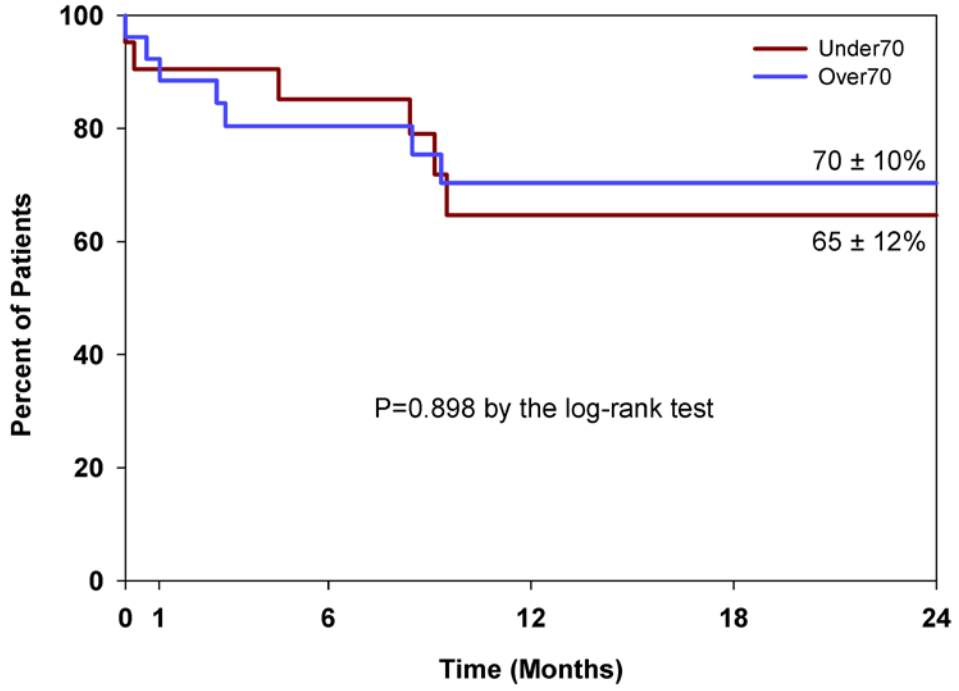


The findings of the study were as follows[3]:

- Despite being "less ill", 68% of the Class IIIB patients were treated with pre-implant inotropes, and 10% were supported with an IABP. These patients should be viewed as an expansion of class IV HF and not as an encroachment upon NYHA class III HF.
- Class IIIB patients had a similar and numerically higher survival compared to Class IV patients, although the difference was not statistically significant.
- Class IIIB and Class IV patients derived similar benefits in survival, quality of life, and functional capacity compared to before HMII implantation.

Another patient specific issue identified by CMS includes the impact of age and gender as a risk factor for mortality in patients undergoing HMII LVAD implantation[4]. Especially with regards to age, careful candidate evaluation including neurological, renal, nutritional and psychosocial assessments and meticulous patient management along with improved durability of the HM II, results in equivalent survival in older patients. This experience was highlighted in the recent publication by Adamson et al (JACC 2011 Jun 21;57(25):2487-95)[4].

Figure 3: Comparison of survival between HMII patients over 70 years of age to patients under 70 years of age – Sharp Memorial Hospital Experience[5]

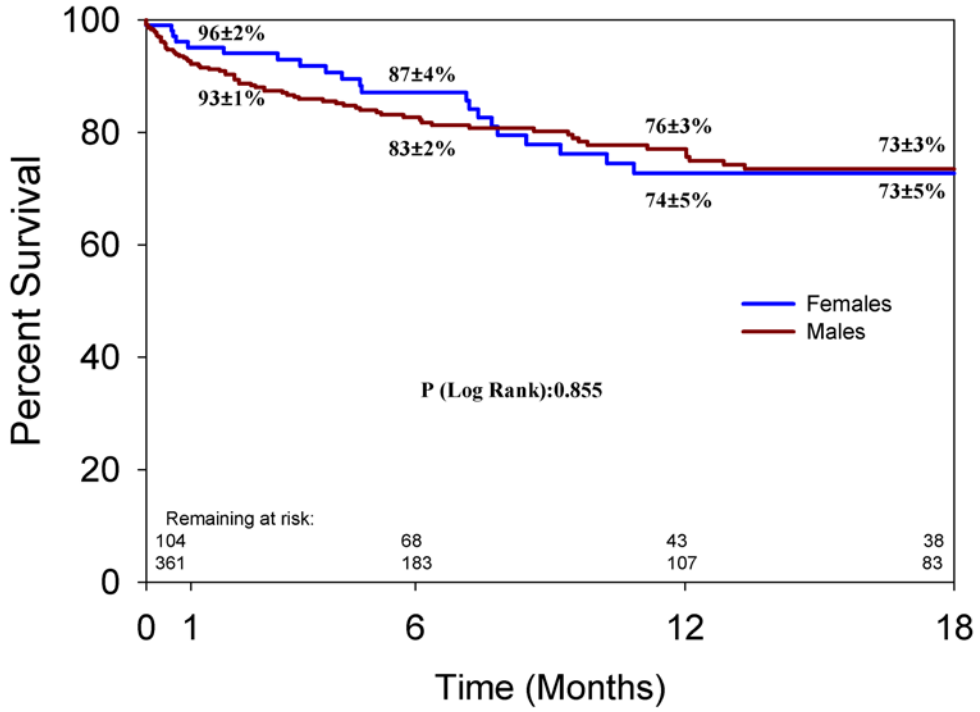


No. at Risk:

Under70 :	21	16	9	7	6
Over70 :	26	18	12	8	5

Bogaev et al. did similar comparison as a function of sex and compared outcomes between men and women receiving the HMII as a bridge to heart transplantation and found no differences in survival between the two groups[6].

Figure 4: Survival comparison between men and women receiving the HMII (Bogaeve at al. JHLT 2011 May;30(5):515-22)



C. Ongoing Support of Clinical Trials and Device Development

For the past 30 years, Thoratec has been committed to developing mechanical circulatory devices that improve the lives of patients suffering from end-stage heart failure. Historically, we have completed seven landmark trials resulting in mechanical circulatory devices being deemed safe and effective by the high bar of the Food and Drug Administration (FDA).

We continue to work not only with the FDA and CMS in ongoing efforts to evaluate patient safety and effectiveness as well as clinical benefit, but we also work with the National Heart Blood Institute to better define the appropriate population for mechanical circulatory support. Currently, we are working with the NHLBI through our sponsorship of the REVIVE-IT Trial studying survival and quality of life improvements in a slightly less sick end-stage heart failure population. This investment of $10 million is intended to move the field forward and is tangible evidence of our commitment to new science in this space. As well, we are also sponsoring the MedaMACS registry which measures the outcomes for similar patients managed by optimal medial management. Table 3 shows a summary of all the post-market studies currently sponsored by Thoratec, where the goal

is to improve patient outcomes, expand patient populations, and advance clinical science of continuous-flow left ventricular assist devices.

Table 3 VAD clinical studies

Title	Acronym	Objective	Status
Thoratec Initiated/Sponsored Studies			
Risk Assessment and Comparative Effectiveness **O**f Left Ventricular **A**ssist **D**evice and **M**edical Management in **A**mbulatory Heart Failure **P**atients	**ROADMAP**	Evaluate and compare the effectiveness of HM II LVAD support versus optimal medical management (OMM) in ambulatory non-inotrope dependent NYHA Class IIIB / IV patients	Enrollment of 200 Subjects from up to 52 sites will be completed by end of 2013
S**T**udy of **R**educed **A**nti-**C**oagulation/Anti-platel**E**t Therapy in Patients with the HeartMate II LVAS	**TRACE**	Characterize the HMII patient population who can be safely maintained on a reduced anticoagulation and/or anti-platelet regimen	Enrollment of 200 Subjects from up to 20 worldwide sites will be completed by the end of 2013
Driveline **S**ilicone **S**kin **I**nterface Registry	**SSI**	Determine the freedom from DL infection events in patients implanted with a HMII LVAD in whom only the silicone portion of the DL is externalized resulting in a silicone skin interface (SSI)	Enrollment of 400 Subjects from up to 15 sites will be completed by the end of 2013
REduce Driveline Trauma Through **S**tab**I**lization and Exit **S**ite Managemen**T**	**RESIST**	Demonstrate the wearability and usability of the HMII percutaneous lead management kit	Completed enrollment of 50 Subjects from 5 sites
Thoratec Supported Investigator Sponsored Studies			
Randomized **E**valuation of L**V**AD Inter**ve**ntion Before **I**notropic **T**herapy	**REVIVE-IT**	Evaluate and compare the effectiveness of HeartMate II LVAD support versus optimal medical management (OMM) in patients with advanced HF (class III) with illness not severe enough to qualify for transplant or permanent LVAD therapy based on current guidelines	Enrollment of 100 Subjects from up to 14 sites will start in summer 2013
The **Med**ical **A**rm of **M**ech**a**nical **C**irculatory **S**upport Study	**MEDAMACS**	Identify a population of ambulatory patients (class IIIB/IV) followed on optimal medical therapy for whom chronic HF limits both function and survival to a range where elective implantation of LVAD devices should offer meaningful benefit	Enrollment of 350 Subjects from up to 12 sites will start in 2013
REmission from **Stage** D **H**eart **F**ailure	**RESTAGE-HF**	Determine the proportion of subjects who have sufficient improvement in ventricular function after undergoing a standardized LVAD plus pharmacologic recovery treatment and testing protocol to allow removal	Enrollment of 40 Subjects from up to 7 sites will be completed in 2014

It is also important to note Thoratec's ongoing commitment to the Interagency Registry for Mechanically Assisted Circulatory Support, INTERMACS which as of September 2012 had 7,124 VAD patients enrolled into the registry.

We would ask, with the positive outcomes for NYHA Class IIIB patients as reported in the HM II trial, INTERMACS Registry and with ongoing trials such as ROADMAP and REVIVE-IT, that CMS should consider expanding coverage to include NYHA Class III B patients as defined by the FDA: cardiac disease resulting in marked limitations of physical activity. Patients are comfortable at rest but with mild physical activity develop fatigue, palpitation, dyspnea, or anginal pain. The provided additional clinical and hemodynamic characteristics further define this patient population.

2. Healthcare team and hospital standards that optimize patient outcomes.

A. Support of VAD Training and Education

Thoratec is committed in ensuring heart failure patients' access to quality care and an improved quality of life. One mechanism to assist centers in achieving high standards of care is training and education of not only surgeons and cardiologists, but also of VAD coordinators and hospital administrators. Prior to the HM II being available to a center the following support is provided with training and education.

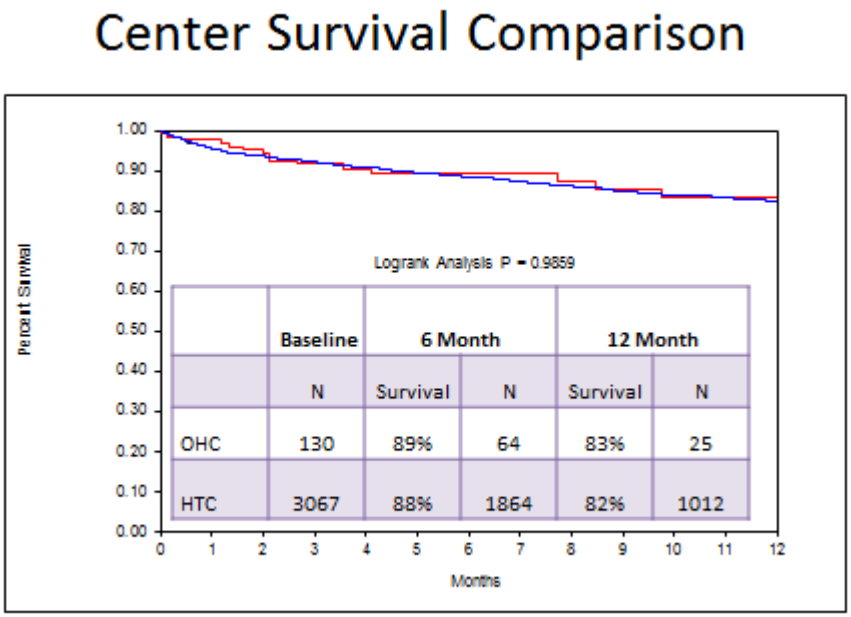
- Expansive local clinical support through clinical consultants and educators to insure excellent outcomes through center specific improvement plans.
- Training and education programs that include Surgical training, VAD Coordinator training and mentoring, Advanced Workshops, Web-based training via Thoratec eUniversity, Wet-lab programs, On-site staff in-services, Surgeon Mentoring, and implementation of published best practice guidelines.
- Annual Mechanical Circulatory Support scientific meeting that provides an opportunity for healthcare providers who manage VAD patients to review latest data, share ideas and best practices.
- Training programs for community-based cardiologists, post-hospital care facilities (Long Term Acute Care and Rehab care) and First Responders
- Fellows Training Programs that provide Heart Failure and Cardiothoracic Surgical Fellows with the most recent information on the therapeutic modalities currently available for Heart Failure, with focus on Mechanical Circulatory Support.
- Access to Foundations a VAD national benchmark program that allows centers to measure key initiatives such as quality, patient outcomes and resource allocation and then define areas for ongoing process improvement.

B. Transplant and Non-Transplant Centers as CMS DT Centers

It has been discussed whether non-transplant open heart centers (OHC) should be allowed to become DT certified. Dr. Marc Katz presented the following analysis in Table 4 during the 2012 ISHLT meeting that showed little difference between outcomes for

patient implanted for Destination Therapy in selected non-transplant open heart centers (OHC) as compared to heart transplant centers (HTC). Note the similar survival of 89% compared to 88% .

Table 4: OHC/Transplant Center Survival Comparison



Establishment of a "Heart Team" is the key to success of any LVAD program and is instrumental to the responsible set up of new programs. The following is what defines the "Heart Team" in non-transplant centers and does not differ from the "Heart Team" in a heart transplant surgery center other than in the ability to transplant hearts.

The OHCs have established high-quality LVAD programs with the guidance and assistance of experts at the experienced transplant-LVAD centers. Specific care protocols have been adopted from the numerous centers nationwide with many years of experience. The Heart Team includes the following: 1) cardiac surgeons trained in mechanical circulatory support technology before taking their responsibilities at open-heart surgery centers, 2) cardiologists with considerable heart failure care experience, 3) dedicated VAD nurses who regularly attend a VAD Coordinator Course and receive support from experienced colleagues, 4) social workers who provide a range of necessary social services, and 5) other supporting medical services such as hematology, pulmonology, nephrology, and anesthesiology are readily available as needed.
The dedicated Heart Teams at open-heart surgery centers are no different than those at a transplant center and provide high-quality care for all LVAD-supported patients.

Therefore, we would suggest that for selected open heart centers that have an infrastructure that replicates that of recognized heart transplant and VAD centers, that LVAD implantation for destination therapy is reasonable and we would encourage CMS

to support an expanded number of implanting centers. Sufficient criteria can be established to make certain that outcomes mirror those of the established programs.

3. Evidence to support the current requirement for certification of hospitals implanting VADs for destination therapy

Certification Standards

Det Norske Veritas Healthcare, Inc. (DNV) has formally requested a reconsideration of the NCD to include the DNV Mechanical Circulatory Support Certification Program as an acceptable credentialing body for facilities qualifying under this NCD.

Thoratec believes that establishing standards of care and best practices is good not only for the field but especially for patients with advanced heart failure. Thoratec supports all certifying organizations that create reasonable evidence based standards that are consistent with contemporary recommended guidelines.

The Annals of Thoracic Surgery (2013) has accepted two important documents for publication to better clarify the existing Joint Commission Standards as it pertains to surgeon requirements in meeting VAD certification and goes beyond to suggest revised standards which better reflect the clinical community;

Pagani, F.D., Kormos, R.L., Calhoon, J.H., Higgins, R.S.D.,Rich, J.B., Certification for Implantation of Durable, Implantable Ventricular Assist
Devices in the United States: The Need for Clarification of the Process.[6]

The Society of Thoracic Surgeons Workforce on the Surgical Treatment
of End Stage Cardiopulmonary Disease, Clinical Statement on the Requirements for Surgeon Certification for Implantation of Durable Ventricular Assist Devices (VADs Chair: Dr.Francis D.Pagani.[7]

The stated goal of the proposed criteria for surgeon certification is to demonstrate competency in establish a minimum standard of training and experience as recognized by CMS to permit and to provide safe VAD implantation and care of patients receiving durable, ventricular assist devices. Publications such as these should be noted when standards are created and revised.

The International Society for Heart and Lung Transplantation (ISHLT) has also made a commitment to convene an international and multidisciplinary panel of experts in MCS care resulting in the publications of MSC Standards. Feldman, et al, (JHLT 2013 Vol. 32, No.2).[8]

These published consensus documents and guidelines represent the appropriate evidence base from which certification standards should be developed. Moreover, any such

standards, much like guidelines, should be proven to accomplish the intended purpose of better quality of care and optimal patient outcomes.

Unfortunately with the relatively new heart failure cardiologist certification program there is little information published identifying the benefits of a VAD patient being seen by a certified heart failure cardiologist versus a cardiologist experienced in the treatment of heart failure patients. It appears too early to support an additional cardiologist requirement as part of the VAD certification process. A comparison of standards shows variations in criteria**.**

Table 5: Summary of proposed Joint Commission revised standards and DNV CMS submitted VAD standards.

Proposed JC and Submitted DNV Standards, Part I

Topic	The Joint Commission Current Standards	DNV Proposed Standards
Certification Platform		based on ISO 9001 Standards
Standards	based on input from professional societies and MCS clinical leaders	reviewed by 2 MCS programs and ISO 9001 Standards
Reviews	Every two years with a conference call at one year mark	every two years with onsite assistance at one year mark
Surveyors	current MCS coordinators or MCS clinical administrators	
Cost per cycle	approximately $12,000	
Process Improvement	selected by program and approved by JC	defined and managed by center, not regulated but supported
PI data for initial site visit	4 months of data collected and presented during onsite review	6 months of data collected and presented during onsite review
Community education	assessed by program, not required to measure outcomes, only participation	required to evaluate community outreach initiatives

Proposed JC and Submitted DNV Standards, Part II

Topic	The Joint Commission Current Standards	DNV Proposed Standards
EMS / ED training	requires EMS and community notification	specifically requires EMS and community ED training
HF Cardiologist requirement	must have recent experience with VAD and heart transplants	must be HF board certified
Facility requirements	appropriate infrastructure and one successful implant at center for tracer activity	15 successful implants (DT or BTT) at center to qualify for submitting application and maintain a volume of 10 implants during a 3 year period
Surgeon standards	maintain a volume of 10 implants during a rolling 36 months	each surgeon must implant 10 devices in a rolling 36 month period to maintain surgeon certification
INTERMACS	actively participating in national registry	participating in INTERMACS, failure to actively participate in INTERMACS will result in removing INTERMACS membership
Pharmacy participation	recommended	MCS program must provide pharmacy services
Excursions	not required	one successful excursion required prior to patient discharge
Staff training	hospital specific but usually annual review	every 6 month requirement

http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id268.pdf
http://www.jointcommission.org/standards_information/field_reviews.aspx?StandardsFieldReviewId=sgg%2b1XqHQr5KBqlCpfdUjGt9gFzA3qD6BULljcZYzs4%3d

The development of the new DNV standards does not reflect broad based support from the clinical community and the assignment of volume requirements is arbitrary and not evidence-based.

The DNV standards require every implanting surgeon to have implanted 10 VADs within 36 months which differs from the JC DT standards and the already existing CMS National Coverage Decision for Destination Therapy standard that requires one surgeon per center to have implanted 10 VADs within a 36 month period. The CMS MEDPAR data for 2011 reflected 1,036 LVADs were implanted. During this period there were 106 Joint Commission Certified Centers. Based upon the DNV requirement, the existing certified centers would not be able to maintain their certification based on the suggested surgeon volume. This would restrict patient access to this life saving therapy

In 2009, Lietz, et al published data from 1998-2005 analyzing center experience and its impact on patient survival using the Heartmate XVE, a pulsatile ventricular assist device, using data from the post-REMATCH trial experience. Lietz reported that a "learning curve" was most apparent between recipients of the first 4 and >9 DT implants, which correlated with improved post-operative 30-day 1-year survival after LVAD implantation[9]. These data would suggest that *center* volume not per surgeon volume is the critical determinant of outcomes.

Figure 5: Impact of center volume on LVAD outcomes[9]

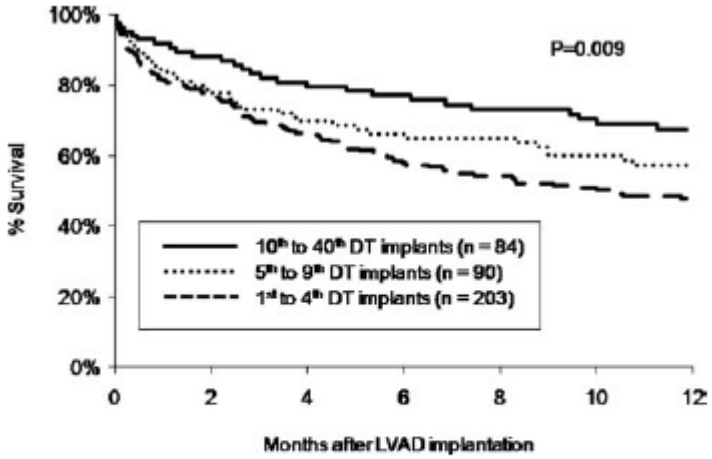


Figure 2. One-year survival after LVAD implantation as destination therapy depicted by the center experience with HeartMate VE or XVE LVAD implantation as destination therapy on the day of surgery. Thoratec Destination Therapy Registry, 1998 to 2005, n=377.

Recently, Cowger, et al. published a risk model for 90-day mortality and identified several risk factors that could contribute to lower survival.

Figure 6: Multivariable predictors of 90-day mortality derived from the HMII multi-center clinical trial

Table 3 Multivariable Predictors of 90-Day Mortality in Derivation Cohort and Formula for Calculating HMRS

Parameter	Estimate	SE	OR (95% CI)	p Value
Age (per 10 yrs)	0.274	0.12	1.32 (1.05–1.65)	0.018
Albumin (per g/dl)	−0.723	0.23	0.49 (0.31–0.76)	0.002
Creatinine (per mg/dl)	0.740	0.22	2.10 (1.37–3.21)	<0.001
INR (per unit)	1.136	0.32	3.11 (1.66–5.84)	<0.001
Center volume <15	0.807	0.34	2.24 (1.15–4.37)	0.018

Multivariable predictors ($p < 0.05$) of 90-day mortality in the derivation cohort and the formula for calculating the HeartMate II Risk Score (HMRS). Calculation of HMRS: HMRS = (0.0274 × [age in years]) − (0.723 × [albumin g/dl]) + (0.74 × [creatinine mg/dl]) + (1.136 × [INR]) + (0.807 × [center LVAD volume <15*]). *Enter value of 1 if total center LVAD volume is <15 and 0 if ≥15. Other variables entered into multivariable analysis (all $p > 0.05$ in final model): sex, LVAD indication, pre-operative inotrope, vasopressor and/or vasodilator use, pre-operative ventilator support and/or IABP support, RVSWi, hematocrit, platelets, aspartate aminotransferase, total bilirubin, and implant era. Model fit was inferior when blood urea nitrogen was entered in place of creatinine into the aforementioned model. Likewise, entering right atrial pressure and/or mean pulmonary artery pressure in place of RVSWi did not improve modeling.

Abbreviations as in Tables 1 and 2.

Center volume was defined as the volume of LVADs implanted by the center during the entire BTT or DT study period which was 2005-2010 (5years). Centers that had implanted 15 or more HMIIs during the 5 year time frame (89% of centers) had significantly better outcomes compared to centers that implanted <15 patients over the course of the trial.[10] 15 implants over 5 years are reflective of 3 implants per year average similar to the "learning curve" identified earlier by Lietz.

These types of studies help define center experience and how it can impact patient outcomes.

In view of the foregoing observations, we recommend standards for centers to become Destination Therapy Certified should be evidence based and consistent with published guidelines with further input from an advisory panel consisting of those involved in the treatment and care of VAD patients. This DT advisory panel should be formally created by the certifying body and include representatives of the "Heart Team": thoracic surgeons, cardiologists, VAD coordinators, social workers, hospital administrators, manufacturers and CMS. The DT standards should be critically reviewed annually by this panel to determine if clarifications are needed.

In summary, we request CMS consider the following:

1. Provide coverage with evidence for Destination Therapy in patients with NYHA Class III B heart failure as defined by the FDA and as characterized in this document; this would especially include those patients enrolled in, ROADMAP and REVIVE-IT clinical trials and for those patients enrolled in the INTERMACS REGISTRY.
2. Review standards to allow access to LVAD therapy in non-transplant open heart centers and as as well provide better clarification of surgeon requirements.
3. Insure certifying organizations create standards supported by clinical evidence from published data, that are consistent with contemporary guidelines and benefit from onging input from the clincal community and medical societies.

As always, we appreciate the opportunity to provide data and comment on this important coverage determination.

Sincerely,

Robin R. Bostic,
Vice President Healthcare Policy/Economics and Government Affairs

Encls.

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