American Heart Association | American Stroke Association

August 30, 2013

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CAG-00432R

Dear Sir/Madam:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed decision memo for ventricular assist devices (VADs) for bridge-to-transplant and destination therapy.

We applaud CMS for carefully evaluating the issue of VAD therapy in patients with advanced heart failure. This group of patients already represents a major healthcare concern for society and will become even more important with the aging of the American population. AHA however, has several concerns with the proposed coverage policy, which we would like to take the opportunity and raise to your attention. Specifically, we are concerned that the revised policy:

1. Fails to acknowledge and provide coverage for a large group of patients, the bridge-to-decision group, who clinically are in need of this therapy but may not clearly fit one of the other two designated indications. This issue also relates to the requirement that bridge-to-transplant patients be active on the waitlist maintained by the Organ Procurement and Transplantation Network.

2. Eliminates the requirement that facilities participate in the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS).

3. Does not address board certification as a qualification for the cardiologist member of the multidisciplinary team required for destination therapy.

We expand upon these concerns below.

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Coverage for Bridge-to-Decision Patients

AHA is concerned that the proposed coverage policy does not include "bridge-to-decision" as a covered indication. As stated in our previous comments to the Agency, clinically, over one-third of all patients who receive VAD therapy fall into the category of bridge-to-decision where providers are not certain if the patient will eventually be a transplant candidate or not, or if the VAD will remain implanted for the remainder of the patient's life. In certain circumstances, a patient's heart function may improve sufficiently to even warrant removal of the device. To provide coverage for these patients, we recommended that CMS remove the requirement that destination therapy patients cannot be candidates for a heart transplant, or revise the covered indications to distinguish between a VAD as bridge-to-transplant for patients already on the transplant waiting list and a VAD as "therapy for advanced heart failure" in all other patients, without arbitrary designation of likelihood for transplantation in the future. We understand that other groups have made similar recommendations to the Agency.

CMS did not propose any changes to the covered indications or the patient selection criteria, instead choosing to continue to model Medicare coverage on the device trials used to secure FDA approval of these devices. Because those trials focused on bridge-to-transplant and destination therapy separately and did not enroll what CMS refers to as bridge-to-candidacy patients, the Agency felt it did not have sufficient evidence to justify expansion. While we understand the Agency's reasoning, we disagree on clinical grounds that it is necessary for Medicare to follow the paradigm set by the FDA. Doing so simply perpetuates arbitrary distinctions and ignores how these devices are used in the actual clinical setting. CMS itself has acknowledged that VADs are increasingly being used for the bridge-to-decision indication (36% of all VADs and 18% of VADs in patients age 65 and older). Importantly, the most recent clinical practice guidelines for heart failure give VADs used for bridge-to-decision or bridge-to-recovery a class IIa recommendation,[1] calling VAD implantation in these patients "reasonable". This is same terminology CMS uses to determine if a procedure should be covered by Medicare.

Limiting Medicare coverage to bridge-to-transplant and destination therapy strictly does a serious disservice to patients with predictably negative impact. For example, when urgent therapy is required, providers may feel compelled to prematurely classify patients as bridge-to-transplant or destination therapy even if it is not clear at that point and it may not be in the best interest of the patient; however these decisions usually cannot wait for the duration to make those judgments due to the severity of illness. An unintended and deleterious result would be an artificial inflation of the number of patients being listed for transplant and sub-optimal utilization of the limited donor supply. On the contrary, requiring other patients to be classified prematurely as destination therapy to obtain access to life-saving support may result in the patient not being closely followed by transplant centers to evaluate the possibility of future transplantation or recovery, as their clinical course evolves.

These issues are also related to the Agency's proposal to require that bridge-to-transplant patients be active on the waitlist maintained by the Organ Procurement and Transplantation Network (OPTN). This change may compound the problems inherent in a system that requires providers to pick from two narrowly-defined coverage indications, especially when the decision must be made quickly to address an urgent therapy need. For example, a patient may be a good transplant candidate, but due to the

[1] Yancy CW, et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure.*Circulation*.2013; 128.

patient's worsening health condition, the provider must implant a VAD before the transplant evaluation and listing on OPTN can be completed, forcing the provider to inaccurately classify the patient as destination therapy. Or, a provider may feel compelled to prematurely list a patient on the OPTN to meet the requirements for bridge-to-transplant, resulting in poor stewardship of the limited donor supply. Under current practice, almost 50% more patients are listed each year than actually undergo transplantation; mandating further additions would result inevitably in further bloating of the transplant list and lengthening wait times. Premature listing on the OPTN may also inflate the already unwieldy heart transplant list with new VAD recipients who are in varying stages of post-operative recovery and complications going through multiple status changes.

Thus, we urge CMS to revise the covered indications for VADs. The revised indications should provide coverage for bridge-to-decision or bridge-to-candidacy patients, as well as patients for whom a VAD may potentially help reverse the advanced heart failure state. In addition, the policy should recognize that patients may transition from one category to another over time as the disease progresses or improves or the comorbid conditions change. (See Attachment A). We further recommend that CMS consider revising the bridge-to-transplant language to include coverage for patients who are approved for transplant, as well as those who are under evaluation for transplantation, and remove the required active listing on the OPTN.

INTERMACS Participation

According to the proposed decision memo, CMS believes that participation in INTERMACS should no longer be required for Medicare coverage. We humbly disagree with this assertion. We recognize the Agency's rationale – that the INTERMACS data has already validated the original indications and is therefore no longer necessary for CMS reimbursement. However, we are still in the early stages of the evolution of this field, for which coordinated and timely data collection and analysis remains vital to ensure responsible use of this expensive technology. Required reporting in standardized format is essential to alert and inform both quality practice and reimbursement regarding patient selection and longer-term outcomes, changing rates of anticipated and new adverse events, and the impact of newer devices. We are seriously concerned that eliminating this mandate will discourage facilities from participating in INTERMACS for any reason, and we believe there are multiple benefits that are accrued by participating in this national registry.

INTERMACS is an extremely valuable source of data that has been used to help identify the appropriate patient population for VADs, risk factors that determine outcomes of patients undergoing VAD implantation, and when in the course of disease a VAD should or should not be implanted. INTERMACS has also been instrumental in facilitating consensus on developing definitions of VAD-related outcomes and adverse events. INTERMACS is poised to help answer important questions about efficacy as they arise. VAD technology and process of care (both pre and post VAD) are continuously evolving and therefore many known data become obsolete relatively quickly. We need ongoing data collection to continually optimize outcomes related to this therapy. We believe it would be a mistake to eliminate mandatory participation in this registry just as we are at the critical juncture of having enough patients to start to fill-in remaining evidence gaps, such as for outcomes beyond the 1-2 years of trials for pre-market and post-market approval. There is widespread agreement that we do not want to return to the days when the only level of evidence was that selected by individual device manufacturers and individual centers. It should be emphasized also that the type of standardized national outcome data stratified by patient characteristics in INTERMACS is exactly what is needed to

facilitate the shared decision-making process, as we move towards better patient-centered care for advanced heart failure.

We are also concerned that removing the incentive for participating in INTERMACS and instead allowing facilities to self-track patient outcomes, adverse events, functional status, and quality of life, would result in non-standardized and un-validated approaches, and the inevitable apple-to-orange comparison of non-comparable data. A third party reporting and monitoring system that allows for the systematic provision and analysis of outcome data in a uniform manner across all facilities and all devices is imperative. Furthermore, we regard this as the most effective way to help individual centers understand and refine their own practices, by comparison of their own experience to national benchmarks for 30-day, 1, 2, and 3 year survival, adverse event rates, compliance with quality of life and functional capacity assessment and patient-rated satisfaction with VAD therapy.

Please see Attachment B for tables demonstrating the type of data that INTERMACS provides to hospitals on a regular basis for use in their own quality improvement initiatives.

Requiring facilities to participate in INTERMACS is the only way to ensure that we will continue to have access to the valuable data that is needed to care for these patients, and centers will have access to the data needed for ongoing quality improvement guided by national standards. We therefore urge CMS to maintain the requirement that VAD facilities participate in INTERMACS as part of the coverage policy.

Multidisciplinary Team Requirements

CMS has proposed that patients who receive VADs for destination therapy must be managed by a multidisciplinary team that includes, among others:

> At least one cardiologist trained in advanced heart failure with clinical competence in medical and device-based management including VADs, and clinical competence in the management of patients before and after heart transplant.

The requirement does not, however, explain how the cardiologist's training and clinical competence will be determined.

AHA strongly recommends that the cardiologist training requirement specifically be American Board of Internal Medicine (ABIM) certification in the secondary subspecialty of Advanced Heart Failure and Transplant. Cardiologists who seek this certification are specially trained in heart failure, transplant, and VAD management. Requiring ABIM certification would provide better assurance that the cardiologist is highly trained and can appropriately care for a VAD patient. We therefore recommend that CMS add ABIM certification in Advanced Heart Failure and Transplant to the definition of a qualified heart failure cardiologist.

Conclusion

In closing, we appreciate the Agency's efforts to continue to refine the coverage policy for VADs. VADs are an important therapy option for patients with advanced heart failure, and when used in the appropriate patient population, can lead to significant improvement in health outcomes. We are however concerned that several of the changes proposed by CMS may limit patient access to these

devices, undermine the collection of data necessary to enhance quality and maintain progress, or have other unintentional adverse consequences.

To ensure that this therapy option is available to patients who would benefit from a VAD, CMS should revise the covered indications to include bridge-to-decision or bridge-to-candidacy patients by removing the current restriction that destination therapy patients cannot be candidates for a heart transplant. Alternatively, as discussed in detail at the MEDCAC meeting in November 2012, CMS could update the destination therapy category to better reflect contemporary utilization of VADs as life-saving therapy for end-stage heart failure in patients not currently on the active list for cardiac transplantation. Further, CMS should remove the impractical restrictive requirement that bridge-to-transplant patients be active on the OPTN waitlist.

To make certain that valuable quality and outcomes data remain available, CMS should keep the INTERMACS requirement. These data will help providers identify patients who are most likely to have a positive outcome, as well as compare their facility's performance with others.

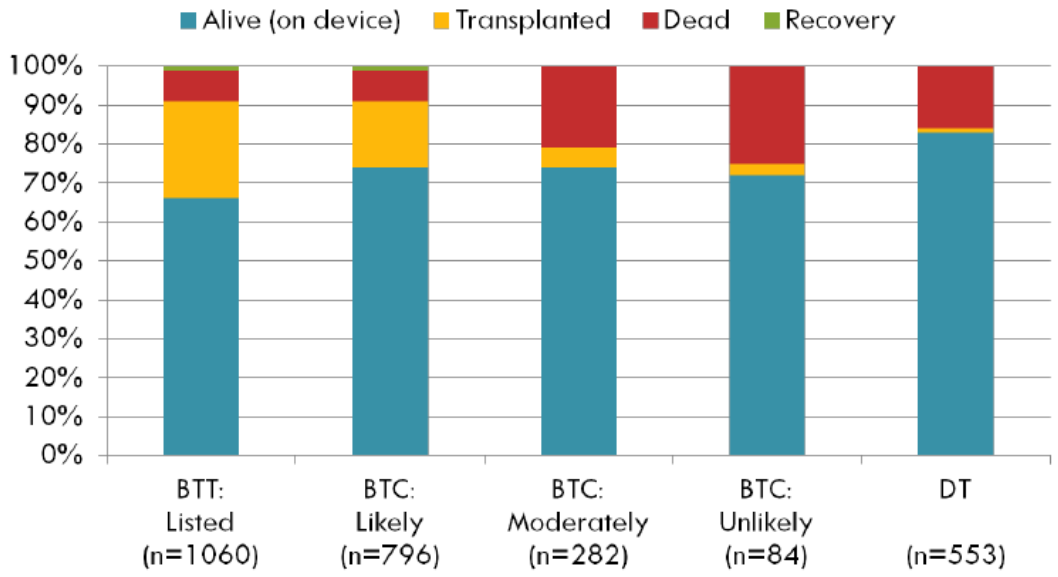
Finally, to ensure that VAD patients are cared for by cardiologists with the appropriate training and clinical competence, CMS should require ABIM certification in Advanced Heart Failure and Transplant.

Thank you for consideration of our comments. If you have any questions or require any additional information, please contact AHA staff Susan Bishop at (202) 785-7908 or susan.k.bishop@heart.org.

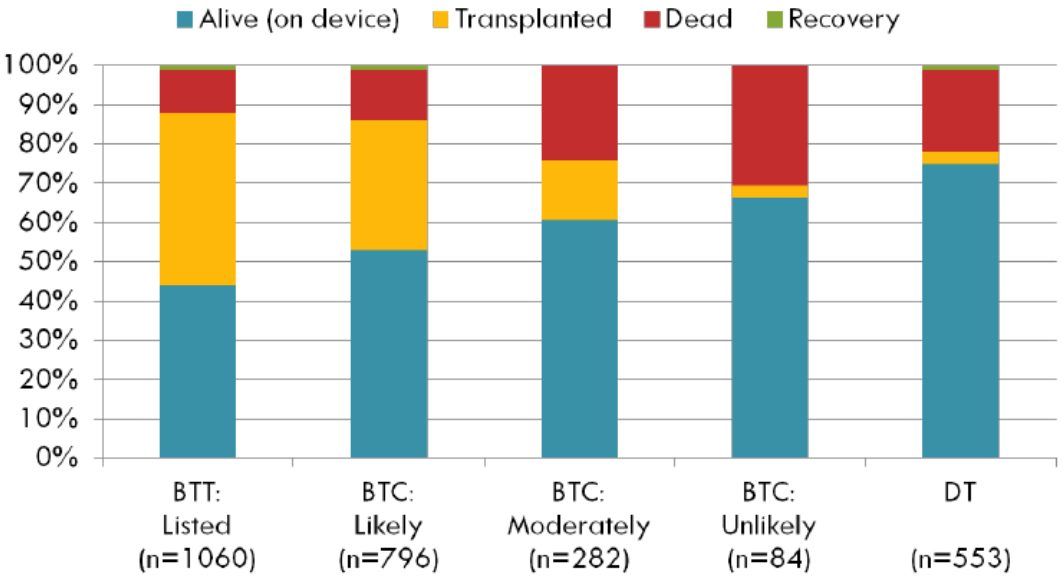
Sincerely,

Mariell Jessup, MD, FAHA
President
American Heart Association

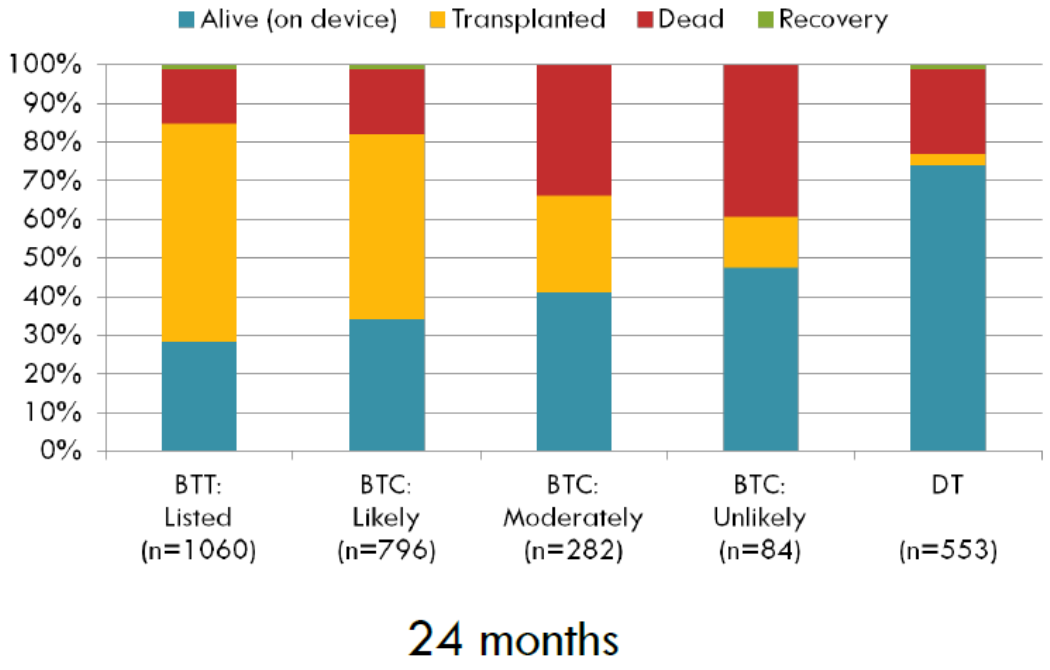
Competing Outcomes Over Time by Initial Implant Strategy



6 months



12 months



Tables reproduced from Jeffrey Teuteberg's presentation entitled "Clinical Indications for MCS: Do They Facilitate Understanding or Muddy the Waters?" delivered at the November 14, 2012 MEDCAC meeting.

Sample of Information Provided Quarterly by INTERMACS to Each Hospital for Comparison to National Benchmarks:

Focus for Internal Quality Assurance and Improvement

Patient Selection Before VAD – Examples of fields for comparison

	Your Hospital	National INTERMACS*
Age > 60		43%
African-American recipients		22%
% RVAD inserted with LVAD		6%
% beta blocker use in past yr		73%
Contra-indications to transplant		e.g. Age 18% Obesity 15% Chronic renal disease 15% Pulmonary HTN 11% Current smoker 5% Limited social support 5%
% Patients on dialysis		2.3%
% moderate-severe TR		43%

	Your Hospital Before 2010	Your Hospital 2010-2011	Your Hospital 2012	INTERMACS Before 2010	INTERMACS 2010-2011	INTERMACS 2012
% Profile 1				29%	15%	15%
Profile 2				43	40	38
Profile3				15	26	28
Profile 4				9	13	14
Profile 5				2	3	3
%Listed for transplant				48%	25%	19%
Likely				27	23	23
Moderately				10	10	10
Unlikely				3.9	3.5	3.0
Destination Therapy				8.0	36	44

***Through 2012**

Outcomes – Survival
(Available for each Profile and Intent for comparison to National outcomes)

	Your Program	INTERMACS National Data* Continuous Flow Only (N=6581 pts)
30 Days		**96%**
180 days		**87%**
360 days		**81% (N=2628)**
2 years		**70% (N=1001)**
3 years		**59% (N=252)**

	Your Program	INTERMACS National Data*
Length of Stay All LVAD only		**26 days (includes pulsatile)**
Length of Stay All BiVAD		**53 (includes pulsatile)**

*Through 2012

Examples of Adverse Event Tracking – Rate per 100 patient months in interval

	Your Program Per First 100 days	Your Program After 100 Days	INTERMACS Per First 100 Days	INTERMACS After 100 Days
Infection			19	5.3
Bleeding			26	1.3
Neuro event			4.1	1.7
Device malfunction			2.5	3.5
Rehospitalization			17	15