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March 8, 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) national coverage analysis for ventricular assist devices for bridge-to-transplant and destination therapy.

According to the coverage analysis, CMS is soliciting public comment on the clinical evidence supporting identification of patients expected to experience improved health outcomes with VAD placement, as well as the healthcare team and hospital standards that optimize patient outcomes. AHA addressed both of these issues at a recent meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC), and we are pleased to again provide input on these important issues.

### ***Identification of the Appropriate Patient Population***

Ventricular assist devices are an important treatment option for select patients with advanced heart failure. Due to the limited number of donor hearts, cardiac transplantation is only available to a very small percentage of these patients, and medical therapy alone does not suffice for many patients. For individuals with life-threatening advanced heart failure despite optimal medical and device therapy, implantation of a VAD is an important therapeutic option. In the appropriate patient population, VAD implantation has been shown to improve survival, quality-of-life, and functional status.

There have been several criteria developed to assist with the evaluation of a heart failure patient, including assessment of functional status (e.g. the New York Heart Association – NYHA classification, cardiopulmonary exercise test, and 6-minute walk test), stage of advanced heart failure (e.g. the Interagency Registry for Mechanically Assisted Circulatory Support - INTERMACS Advanced Heart Failure Profiles), prognosis in heart failure patients (e.g. the Seattle Heart Failure Model or the Heart Failure Survival Score), and risk factors for adverse outcomes for patients

undergoing VAD implantation.<sup>1,2</sup> These various characteristics and scores help providers identify the patients at highest risk for dying with heart failure and therefore needing additional advanced therapeutic consideration, as well as guide them to those that are likely to have better outcomes than others.

However, VAD technology continues to evolve. The most common type of permanent VAD now implanted in the United States uses a completely different rotary pump technology than the earlier pulsatile pumps. Rotary pumps currently account for greater than 95% of durable (appropriate for out-of-hospital support) devices implanted in the United States.<sup>3</sup> Many more studies are needed to determine whether the same pre-implantation patient characteristics predict risk for adverse outcomes among individuals implanted with the newer devices vs. the older devices from which these high-risk characteristics were identified. Hence, providers currently have several characteristics they can rely on, based on clinical trial inclusion and exclusion criteria and other publications looking at predictors of heart failure and post VAD outcomes predominantly from earlier device models. For example, recent data from INTERMACS has identified cardiogenic shock at time of implant, severe right heart failure, and renal dysfunction as important risk factors for mortality after VAD implantation.<sup>4</sup> However, these risk factors are also markers for poor outcomes with *any* therapies for advanced heart failure, and VAD therapy often represents the *only* option for extended survival. Since durable rotary pumps have been FDA approved only since 2008, risk modeling is not yet mature, and there is no one single variable or risk profile that is sufficiently predictive of either good or bad outcomes.

We have, nevertheless, learned several general lessons with the VAD therapy experience thus far. This therapy currently does not uniformly guarantee good outcomes for patients in pre-morbid cardiogenic shock. At the other end of the spectrum, patient profiles for good outcomes are not yet sufficiently robust to guarantee favorable outcomes in patients who are stable on oral medications and have class III symptoms. Similarly, comorbidity status, age, right ventricular function, and other characteristics including social support and self-care habits, influence patient outcomes, but relevant information from INTERMACS is available in less than one-half of patients. In summary, we may know characteristics that are predictive of patients that are likely to not survive with the pulsatile pumps, and we are learning which patients may not survive with the continuous flow pumps, but we are not yet at the stage where we can predict which patient will do well with the continuous flow VADs. Many efforts are ongoing to develop new risk scores, including from the INTERMACS data, to help us understand the ideal patient to receive a VAD and when in the course of their disease a VAD should be implanted.<sup>5,6</sup>

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<sup>1</sup> Leitz et al, Outcomes of left ventricular assist implantation as destination therapy in post-REMATCH era. *Circulation* 2007;116:497-505.

<sup>2</sup> Kirklin et al, Third INTERMACS Annual Report: The evolution of destination therapy in the U.S. *Journal of Heart and Lung Transplantation* 30;2:115-123.

<sup>3</sup> Kirklin JK, et al: The Fourth INTERMACS Annual Report: 4,000 implants and counting. *J Heart Lung Transplant* 2012;31:117-26.

<sup>4</sup> Ibid.

<sup>5</sup> Kirklin et al. Long-term mechanical circulatory support (destination therapy): On track to compete with heart transplantation? *J Thorac Cardiovasc Surg.* 2012; Sep;144(3):584-603.

<sup>6</sup> Holman, WL. INTERMACS: What have we learned and what will we learn? *Circulation* 2012; 126:1401.

We expect that implant criteria will likely be updated as providers gain additional experience with the newer devices and data from ongoing trials informs us further. However until then, AHA recommends that Medicare coverage for VADs as bridge-to-transplantation should remain the same. The current coverage policy requires that a patient be approved and listed for heart transplant before receiving a VAD. In order to qualify as a heart transplant candidate, the patient must undergo an extensive evaluation that, among other things, examines the severity of heart failure and the status of other organs. We agree that this evaluation is sufficient to determine if the patient is a VAD candidate, and no further changes or additional patient criteria are necessary. Moreover, the bridge-to-transplant approach has resulted in better survival for patients who might otherwise have succumbed while waiting for transplant.

With respect to destination therapy, Medicare currently requires that a patient have chronic end-stage heart failure with NYHA class IV symptoms and have either failed to respond to optimal medical management for at least 45 of the last 60 days, or have been balloon pump-dependent for 7 days, or is dependent on intravenous inotropes for 14 days. Additionally, the patient should have a left ventricular ejection fraction < 25% and have demonstrated functional limitation with a peak exercise oxygen consumption of  $\leq 14$  ml/kg/min unless balloon pump- or inotrope-dependent or physically unable to perform the test.

In general we agree that these criteria are appropriate and note that there is not enough evidence at this time to support the use of VADs in patients who are less sick. This is an area under active investigation through the NIH-funded REVIVE-IT trial and other industry supported studies.

However, CMS should consider removing the current requirement for destination therapy that these patients cannot be candidates for a heart transplant. As noted above, there are not enough heart donors to meet the need, so some patients may be offered a VAD instead of transplantation even if they might have been eligible for transplantation. Approximately one-third of all patients who receive a VAD fall into the category of “bridge-to-decision”<sup>7</sup> where the providers are not certain if the patient will eventually be a transplant candidate or not; however the patient’s worsening condition does not provide an opportunity to wait without the placement of a VAD in the face of imminent death. For example, patients may have modifiable risk factors for adverse transplant outcomes such as kidney, lung, or liver disease that may or may not be resolved with time or with therapy once circulation is improved with a VAD. Other conditions like obesity or smoking status may change over time as well. It may also require time to determine whether or not the patient has family or friends who would be able to help them through a transplant. Moreover, if there is a recent history of alcohol or drug abuse, the patient may need time to demonstrate that they will (or won’t) be able to abstain, or go through a formal rehabilitation program. In addition, it should also be noted that it is rare that a patient’s heart function improves enough to have a VAD removed without receiving a heart transplant. Finally, eligibility for cardiac transplantation (or recovery in a small percentage of patients) at a later time, but not at the present time, may be a critical requirement for ongoing assessment at a cardiac transplantation site, or a requirement for ongoing communication / co-management between centers approved to insert destination VADs, but not approved to perform cardiac transplantations and their cardiac transplantation centers. In other words, a VAD may need to be implanted so the patient is

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<sup>7</sup> Kirklin et al. Long-term mechanical circulatory support (destination therapy): On track to compete with heart transplantation? *J Thorac Cardiovasc Surg.* 2012; Sep;144(3):584-603.

stable enough to travel to a transplant center. AHA, therefore, encourages CMS to revise the coverage decision to recognize the role of the VAD as therapy for advanced heart failure in patients not currently listed for transplant. A revised coverage decision could make a distinction between a VAD as “bridge-to-transplantation” for patients already on the waiting list for transplantation, and a VAD as “therapy for advanced heart failure” in all other patients, without arbitrary designation of likelihood for transplantation in the future.

### ***Healthcare Team and Hospital Standards***

CMS is also interested in whether there are facility and/or operator characteristics that can predict clinically meaningful improvements in health outcomes for patients who receive a VAD.

Under the current Medicare coverage policy, facilities that implant VADs must meet the following criteria:

- Have at least one member of the VAD team with experience implanting at least 10 VADs (as bridge-to-transplant or destination therapy) or artificial hearts over the course of the previous 36 months,
- Must be a member of INTERMACS, and
- Must have been credentialed by the Joint Commission under the Disease Specific Certification Program for VADs

AHA supports these criteria because we recognize that it is extremely important to have an appropriate infrastructure and demonstrated expertise in caring for patients who need advanced circulatory support. Whether or not there should be certification criteria for the individual team members, e.g. heart failure cardiologists or cardiothoracic surgeons or transplant coordinators, beyond their experience alone, needs additional consideration as it has the potential to further benefit patient outcomes. However, there are currently no data to suggest if an additional certification requirement would improve outcomes over the current requirement for experience alone.

It should be noted that the American Board of Internal Medicine (ABIM) has recognized a third secondary subspecialty of cardiology, Advanced Heart Failure and Transplant, for specialty training of cardiologists in heart failure, transplant and VAD management. Additionally, the Accreditation Council for Graduate Medical Education has just officially accredited a number of training centers where these clinicians will be trained, and the second ABIM certification examination for this specialty was given in November 2012. These developments address, to an extent, the need for highly trained clinicians who care for the VAD patients.

Another important aspect of efforts to ensure optimal infrastructure in which to care for heart failure patients that are being considered for a VAD and/or transplant is the Joint Commission’s Advanced Certification in Heart Failure program, created in collaboration with the AHA. This program integrates the 2009 Focused Update incorporated into the American College of Cardiology/American Heart Association 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults.<sup>8</sup> These clinical practice guidelines include recommendations for heart failure care across settings related to assessment, monitoring, management, and performance improvement. The Advanced Certification in Heart Failure evaluation will focus on patient care in the inpatient setting as well as a

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<sup>8</sup> See <http://circ.ahajournals.org/content/119/14/e391.full.pdf>.

thorough assessment of the coordination of care, including transition to outpatient care providers. Finally, the Joint Commission's Disease-Specific Care Certification Program, launched in 2002, is designed to evaluate clinical programs across the continuum of care. The Advanced Certification in Ventricular Assist Device has been critical in the establishment of vigorous standards by which hospitals performing destination VADs can be measured, including Clinical Practice Guidelines. The program must demonstrate conformity with clinical practice guidelines or evidence-based practice that includes the VAD-specific requirements that are integrated with the Disease Specific Care requirements, and Performance Measures. All certified VAD programs will be required to comply with the Phase I requirements for performance measurement until standardized performance measures have been identified.

AHA also supports the heart team concept, which calls for a cohesive, multi-disciplinary team of medical professionals embodying collaboration and dedication across medical specialties to offer optimal patient-centered care. We strongly agree that a variety of experts need to be part of the patient selection, VAD implantation, and patient care team. Dedicated collaboration with a palliative care team is recommended to facilitate shared decision-making with patients and caregivers around goals of care and palliation of symptoms both with and without VAD. The team should also have a reasonable ratio of the number of VAD nursing support to the number of patients. It is increasingly recognized that the skill set of the VAD support team is unique, and the number of outpatient VAD patients is growing exponentially. Staffing requirements are, at the present, evolving at most centers and the resources to care for these complex patients have to include individuals comfortable with the engineering requirements of VAD trouble shooting; clinicians familiar with the management of patients with heart failure, hypertension, and arrhythmias; and clinicians who can handle the intricacies of VAD placement in the operating room.<sup>9</sup> In summary, there is a considerable amount of work already in progress to articulate, measure, and track clinical performance standards, and objective outcomes that may be sufficient at this time for this relatively young technology of mechanical circulatory support.

### ***Conclusion***

In closing, we support the Agency's decision to reexamine its coverage policy for VADs. As noted throughout this document, 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. How to identify the appropriate patient population, however, is the key question of this coverage analysis.

In general, AHA believes that the current criteria for patient selection for the bridge-to-transplant indication are adequate and we do not recommend any changes to it at this time. We do, however, urge CMS to address the unique issue related to the candidacy for destination therapy and the bridge-to-candidacy highlighted above. Because it may not be possible for providers to determine if a patient will eventually be a transplant candidate or not, a patient's candidacy for a heart transplant should not be the determining factor in whether a patient qualifies under the destination therapy indication.

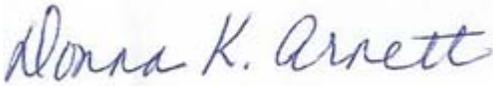
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<sup>9</sup> Jessup et al. ACCF/AHA/HFSA 2011 Survey Results: Current Staffing Profile of Heart Failure Programs, Including Programs that Perform Heart Transplant and Mechanical Circulatory Support Device Implantation. *Circ Heart Fail.* 2011;4:378-387.

Therefore, we recommend that CMS remove the requirement that patients not be a transplant candidate under the current destination therapy indication. Alternatively, Medicare could provide coverage for these patients under a new “bridge-to-decision” or “therapy for advanced heart failure” indication that do not rely on the likelihood for transplantation in the future.

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

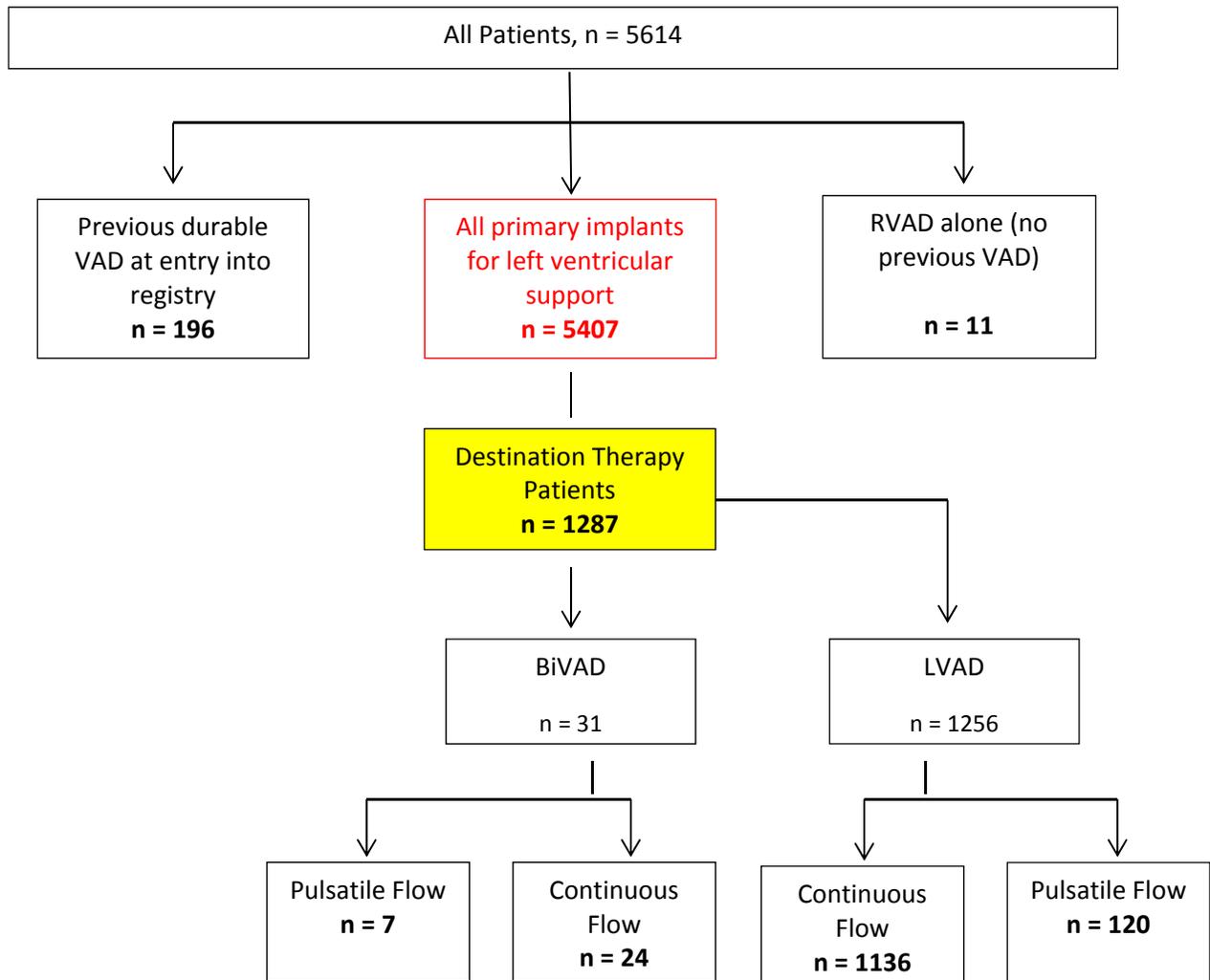
Sincerely,

A handwritten signature in blue ink that reads "Donna K. Arnett". The signature is written in a cursive style.

Donna K. Arnett, PhD  
President, American Heart Association

### Appendix

*Categorization of all 5614 patients entered into INTERMACS between June 23, 2006 and December 31, 2011. The group Destination Therapy (n = 1287) constitutes the study group.*



*INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support. VAD ventricular assist device; RVAD, right ventricular assist device; LVAD, left ventricular assist device; BiVAD, biventricular assist device.*

Figure 1 reproduced from Kirklin, et al. Long-term mechanical circulatory support (destination therapy): On track to compete with heart transplantation? *J Thorac Cardiovasc Surg.* 2012; Sep;144(3):584-603. Epub 2012 Jul 15.

*Transplant Contraindications – Adult primary implants:  
INTERMACS June 2006 – December 2011\**

<b>Contraindications</b>	<b>No. (%) (N = 1287)</b>
<b>Modifiable</b>	
Renal dysfunction	256 (20)
High body mass index	182 (14)
Pulmonary hypertension	157 (12)
Still Smoking	90 (7)
Severe diabetes	87 (7)
<b>Nonmodifiable</b>	
Advanced age	487 (38)
Peripheral vascular disease	89 (7)
Pulmonary disease	80 (6)
History of solid-organ cancer	64 (5)
Patient refuses transplant	54 (4)
Frailty	48 (4)

*INTERMACS, Interagency Registry for Mechanical Support.*

Table 3 reproduced and modified from Kirklin, et al. Long-term mechanical circulatory support (destination therapy): On track to compete with heart transplantation? J Thorac Cardiovasc Surg. 2012; Sep;144(3):584-603. Epub 2012 Jul 15.