



**The Society
of Thoracic
Surgeons**



**AMERICAN
COLLEGE of
CARDIOLOGY**



AATS



HFSA

HEART FAILURE SOCIETY OF AMERICA

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The Society of Thoracic Surgeons, the American College of Cardiology, the Heart Failure Society of America, and the American Association for Thoracic Surgery are submitting comments on the reconsideration of the National Coverage Decision (NCD) for Ventricular Assist Devices (VADs) for Bridge-to-Transplant and Destination Therapy.

We appreciate that the requestor has proposed a solution that would eliminate the unnecessary distinction between bridge-to-transplant (BTT) and destination therapy (DT) for coverage of durable VAD implantation by introducing the terminology of short and long term support. We believe that elimination of any terminology to characterize the intent of device implantation is in the best interest of the patient and consistent with the results of the MOMENTUM 3 clinical trial which demonstrates a strong therapeutic benefit of left ventricular assist devices regardless of device intent. We strongly advocate that durable VADs should be covered for treatment of patients with advanced stage heart failure without distinction between therapeutic goal (e.g., bridge to transplant, destination therapy, short term support or long term support). These types of definitional issues confuse the intent of the use of these devices to improve patient longevity and quality of life and further disadvantage patients with an arbitrary label that may prevent them from accessing needed care. Further, such designations often become inappropriate for individual patients who, for example, show improvement or resolutions of co-morbidities following a “destination” designation and then become candidates for transplant.

Recommendations for Indications

To ensure appropriate patient care, we believe that decisions to treat patients with durable VADs should be consistent with professional guidelines including the following:

2013 American College of Cardiology Foundation / American Heart Association guideline on heart failure maintenance¹

7.4.5 Mechanical Circulatory Support:

Class IIa

1. MCS is beneficial in carefully selected† patients with stage D HFrEF in whom definitive management (e.g., cardiac transplantation) or cardiac recovery is anticipated or planned (660–667). (Level of Evidence: B)
2. Nondurable MCS, including the use of percutaneous and extracorporeal ventricular assist devices (VADs), is reasonable as a “bridge to recovery” or “bridge to decision”

¹ Yancy, et al. J Am Coll Cardiol. 2013 Oct, 62 (16) e147-e239.

- for carefully selected‡ patients with HFrEF with acute, profound hemodynamic compromise (668–671). (Level of Evidence: B)
3. Durable MCS is reasonable to prolong survival for carefully selected‡ patients with stage D HFrEF (672–675). (Level of Evidence: B)

2013 ISHLT Guidelines for Mechanical Circulatory Support: Executive Summary²

Recommendations for the evaluation process of MCS candidates: Class I:

1. All patients should have any reversible causes of heart failure addressed prior to consideration for MCS. Level of evidence: A.
2. All patients referred for MCS should have their transplant candidacy assessed prior to implant. Level of evidence: A.

Covered Devices and Treatments

It is essential that the revised coverage decision apply to all durable VADs currently approved for hemodynamic support in patients with advanced, refractory left ventricular heart failure; either as a bridge to cardiac transplantation, myocardial recovery, or as destination therapy or for short- or long-term support. While it is our impression that the proposed language would apply to devices approved for those currently-covered indications, we ask that, if CMS accepts the recommended language, the coverage memo and future communications with Medicare Administrative Contractors make it explicitly clear that devices approved for anticipated BTT, myocardial recovery, and DT be covered under the NCD.

Another way to ensure that all devices are covered under the new coverage decision would be to adopt the following revisions to the coverage language proposed by the requestor:

The surgically implanted device must be FDA indicated for patients who require ~~short term (e.g., like bridge to transplantation or myocardial recovery) and long term (e.g., like destination therapy)~~ mechanical circulatory support.

The durable VADs are covered for patients who have advanced heart failure symptoms and meet one of the following conditions:

- *Failure to respond to guideline directed medical therapy; or*
- *Are listed for transplant or*
- *Are dependent on treatment with intravenous inotropic therapy or on intra-aortic balloon pump or on an acute mechanical circulatory assist device (e.g., external, temporary, or percutaneous).*

If the Centers for Medicare and Medicaid Services (CMS) intends to adopt language proposed by the requestors reflecting “short term” and “long term” treatment, the NCD must also make the following distinctions. “Short term” treatment does not include the category of temporary mechanical circulatory support devices used for treatment of shock or support provided during a percutaneous coronary implantation. Further, “long term” treatment must not be limited to describe destination therapy alone as patients currently designated as bridge to transplant can live for many years with durable VAD support awaiting transplantation.

² Feldman, D., et al. The Journal of Heart and Lung Transplantation. 2013, February (32) 157-187

Surgeon Volume Requirements

In addition, we believe that the requirement that surgeon members of a durable VADs team perform at least 10 implants over the course of 36 months is an arbitrary requirement that limits patients' access to care. Cowger, et al, have demonstrated an association between overall center volume and patient outcomes³, but these data do not demonstrate that ten surgeon implants are required to ensure good patient outcomes. In addition, centers may also be inappropriately focusing on surgeon experience rather than devoting resources to the overall infrastructure necessary to support a durable VAD program. It is more important that facilities demonstrate a substantive commitment to the care of these complex patients utilizing a multidisciplinary care team than for an individual operator maintain a specific volume standard. Further exploration of this volume requirement would be appropriate as part of the reconsideration.

Data Collection

Finally, the societies recommend that Medicare coverage of durable VADs include a requirement that physicians and hospitals participate in a nation-wide, audited clinical data registry to track patient outcomes during their time on mechanical circulatory support. Specifically, we request that the NCD require that:

The team and hospital are participating in a prospective, national, audited registry that:
1) consecutively enrolls all durable VAD patients; 2) accepts all manufactured devices; 3) follows the patient for the duration of the durable VAD implantation; and, 4) complies with relevant regulations relating to protecting human research subjects, including 45 CFR Part 46 and 21 CFR Parts 50 & 56.

Ensuring that patient outcomes are being captured in a national registry will help to alleviate any concerns about the applicability of the Momentum 3 study definitions to other durable VAD devices and will help to monitor patient outcomes as utilization of durable VADs is likely to expand outside of transplant centers, among other benefits.

Participation in a national clinical data registry is the effective way for centers to continue to track patient outcomes including survival, adverse events (e.g., bleeding, infection, stroke, device malfunction, and cardiovascular complications including recurrent heart failure), functional status, and quality of life in a way that allows comparisons with other institutions and facilitates internal quality monitoring and improvement. Collection and analysis of these data points may allow the development of risk adjustment models which can be utilized in patient selection and management.

Registry participation will also provide appropriate risk modelling that allows sites to be compared on patient population characteristics for key outcome metrics. This modeling has to be sensitive to changes in therapeutic application as well as new devices. Accurate risk modeling and quality assessment will be increasingly important if durable VADs utilization is expanded into centers that do not maintain transplant programs.

We believe that registry participation as a condition of coverage is important to address unanswered questions in the field; e.g., 1) outcomes of durable VAD therapy for less advanced stages of heart failure;

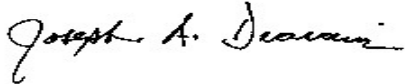
³ Cowger JA, et al. JACC Heart Failure 2017 Oct;5(10):691-99

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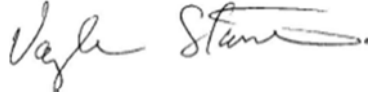
2) outcomes of durable biventricular VAD therapy; and 3) appropriate timing and identification of high risk populations. We would propose these questions be adopted for coverage with evidence development to advance our knowledge and application of durable VADs technology.

Thank you for the opportunity to provide comments. Should you have any questions, please contact Courtney Yohe Savage, Director of Government Relations for The Society of Thoracic Surgeons at 202-787-1222 or cyohe@sts.org.

Sincerely,



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