September 11, 2020

Tamara Syrek-Jensen
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear Ms. Syrek Jensen,

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 proposed revisions to the National Coverage Decision (NCD) for Ventricular Assist Devices (VADs)

We appreciate that CMS has proposed to 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 also appreciate that these changes may result in utilization of durable VADs expanding outside of transplant centers The policy change, which may make VADS more accessible to the general population, could have the unintended consequence of limiting some patients' access to transplants if they do not seek care at a certified transplant center. CMS must take steps to ensure that patients are presented with all possible treatment options, including VAD implantation at all certified VAD centers.

Indications, Covered Devices and Treatments

We support the revisions to approved indications as follows:
2. Left ventricular assist devices (LVADs) are covered if they are FDA approved for short-term (e.g., bridge-to-recovery and bridge-to-transplant) or long-term (e.g., destination therapy) mechanical circulatory support for heart failure patients who meet the following criteria:

- Have New York Heart Association (NYHA) Class IV heart failure;
- Have a left ventricular ejection fraction (LVEF) ≤ 25%;
- *[Are inotrope dependent]*[1]
  OR have a Cardiac Index (CI) < 2.2 L/min/m2, while not on inotropes, and also meet one of the following:
    - Are on optimal medical management (OMM), based on current heart failure practice guidelines for at least 45 out of the last 60 days and are failing to respond; or

[1] Please note that the bracketed phrase appears to be missing from the decision summary.

- Have advanced heart failure for at least 14 days and are dependent on an intra-aortic balloon pump (IABP) or similar temporary mechanical circulatory support for at least 7 days.

We also appreciate that CMS has clarified that this coverage decision does not include temporary VADs or extracorporeal membrane oxygen (ECMO).

Data Collection

We maintain that 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. Data collection to monitor patient outcomes could serve to help ensure that patients are receiving the right type of intervention. As mentioned above, expanding VADs access outside of transplant centers may have the unintended consequence of creating health care disparities. Patients who are in underserved segments of society tend to have more modifiable risk factors prohibiting direct transplant. Using Intermacs data 2012-2015, only 8.5% of Caucasians undergoing LVAD were ages 20-39 yet 18.6% of African Americans and 17.9% of Hispanics fell into this young age group.[2] Those with modifiable risk factors are now reviewed regularly at transplant centers for listing potential. In the renal transplant field, health care disparities are a concern. In one study[3], access to transplant within the first year of ESRD was 65% lower in nonhispanic blacks and 43% lower in Hispanics compared with Caucasians.

One means of reducing the risk for health care disparities is to ensure patients have appropriate referral for transplant consideration before or after LVAD implant. In addition, participation in a national clinical data registry is an effective way for CMS to track patient characteristics as they relate to health care disparities, as well as allow 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; 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.

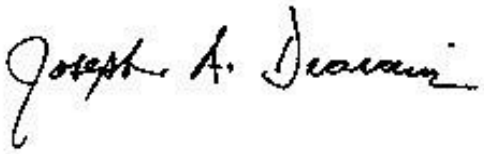
[2] Breathett et al Circ HF 2018
[3] Ku, Transplantation 2020;104:1437-44

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[4], have demonstrated an association between overall center volume and patient outcomes[3], 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. Measuring quality performance through data collection as discussed above will also inform better care more meaningfully than a volume surrogate. Further exploration of this volume requirement would be appropriate as part of the reconsideration.

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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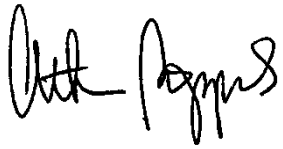

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[4] Cowger JA, et al. JACC Heart Failure 2017 Oct;5(10):691-99