

701 Pennsylvania Avenue, Ste. 800  
Washington, DC 20004-2654  
Tel: 202 783 8700  
Fax: 202 783 8750  
www.AdvaMed.org



March 4, 2020

Tamara Syrek Jensen, JD  
Director, Coverage & Analysis Group  
Center for Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
Mailstop S3-02-01  
7500 Security Blvd  
Baltimore MD 21244

**RE: Proposed National Coverage Analysis (NCA) for Artificial Hearts and Related Devices, including Ventricular Assist Devices (VADs) for Bridge-to-Transplant and Destination Therapy (CAG-00453N)**

Dear Ms. Jensen:

The Advanced Medical Technology Association (AdvaMed) is pleased to offer the following comments on the Centers for Medicare & Medicaid Services' (CMS) National Coverage Analysis (NCA) for *Artificial Hearts and Related Devices, including Ventricular Assist Devices (VADs) for Bridge-to-Transplant and Destination Therapy (CAG-00453N)*.<sup>1</sup>

AdvaMed's member companies produce the life-saving and life-enhancing medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

Our comments below relate to the indications covered under the NCD and use of coverage with evidence development. We look forward to reviewing the proposed NCD in the coming months and providing more detailed comments at that time.

We offer the following comments for CMS's consideration:

---

<sup>1</sup> CMS Tracking Sheet for *Artificial Hearts and related devices, including Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy (CAG-00453N)*, see <https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=298> (accessed February 3, 2020).

### **LVAD Covered Indications**

AdvaMed supports the expansion of coverage to include patients who require short-term and long-term mechanical circulatory support. We would recommend that VADs with approved indications for bridge-to-transplant (BTT) and destination therapy (DT) be covered under such an expansion.

Evidence from large, prospective randomized trials supporting LVADs (published after NCD 20.9.1 and finalized in 2013) demonstrates that patients receive strong therapeutic benefit from LVAD therapy regardless of pre-implant intent.<sup>2, 3, 4</sup> These studies show that advancements in the technology not only have increased survival rates for these extremely acute patients but also have mitigated some of the common adverse events associated with earlier generation LVADs including ischemic stroke, hemorrhagic stroke, thrombosis, and GI bleeding.

AdvaMed has long supported policies that enhance appropriate patient access based on advancements in technology and the medical landscape. Therefore, we would urge CMS to consider updating its current NCD for VADs to reflect new evidence on the evolving patient indications, as supported by the public literature and clinical evidence, as well as specialty society input.

### **General CED Comments**

Regarding the use of coverage with evidence development (CED) in Medicare's coverage determinations, AdvaMed has previously commented that when Medicare coverage is contingent on the collection of additional clinical or scientific evidence (beyond FDA requirements for safety and efficacy), CMS should:

- 1) collaborate with stakeholders to clearly identify the data collection objectives;
- 2) consider the minimum data necessary to achieve those objectives;
- 3) clearly identify, with input from interested stakeholders, scientifically supported study endpoints and the duration of data collection in advance (including clear stopping rules for data collection under CED); and
- 4) identify appropriate mechanisms to ensure continuous coverage of an item or service after a study ends, to avoid disruption in coverage and continue to allow Medicare beneficiaries to benefit from important FDA-approved technologies and services until a new or revised coverage determination is issued.

---

<sup>2</sup> Mehra MR, et al. MOMENTUM 3 Investigators. A fully magnetically levitated left ventricular assist device - final report. N Engl J Med. 2019; 380:1618–1627. <https://www.nejm.org/doi/full/10.1056/NEJMoa1900486>

<sup>3</sup> Rogers JG, et al. Intrapericardial left ventricular assist device for advanced heart failure. N Engl J Med. 2017; 376(5):451–460. <https://www.nejm.org/doi/full/10.1056/NEJMoa1602954>

<sup>4</sup> Milano CA, et al. HVAD: The ENDURANCE Supplemental Trial JACC Heart Fail. 2018 Sep;6(9):792-802. <http://heartfailure.onlinejacc.org/content/6/9/792>

March 4, 2020

Page 3

As CED generates evidence supporting the use of a new innovation or services, Medicare's coverage policies should reflect these outcomes and minimize additional requirements.

AdvaMed greatly appreciates the opportunity to comment on these issues, and we look forward to providing more detailed comments on the proposed NCD when it is issued in the coming months. If you have questions regarding these comments or if you require additional information, please contact me at (202) 434-7219 or [cbranham@AdvaMed.org](mailto:cbranham@AdvaMed.org).

Sincerely,

A handwritten signature in blue ink that reads "Chandra N. Branham". The signature is fluid and cursive, with a long horizontal stroke at the end.

Chandra N. Branham, JD  
Vice President, Payment & Health Care Delivery Policy  
AdvaMed