April 25, 2019

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

RE: Proposed National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430R)

Dear Ms. Syrek Jensen:

The Advanced Medical Technology Association (AdvaMed) is pleased to offer the following comments on the Centers for Medicare & Medicaid Services’ (CMS) proposed National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR).¹

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.

AdvaMed applauds CMS’ decision to reopen the existing TAVR NCD and commends the Agency’s efforts to modernize, streamline and simplify many key elements of the TAVR NCD, particularly in light of how this therapy has evolved over time, and the evidence that has been generated in the years since the issuance of the original NCD in 2012. We support CMS’ efforts to modify requirements for hospital and providers to be more flexible and less burdensome. We appreciate this opportunity to comment on the proposed TAVR NCD.


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The benefits of TAVR have been clearly demonstrated and strongly support the use of this therapy in the Medicare population.

It is well known that aortic stenosis is a deadly disease that is often underdiagnosed and undertreated. Access to comprehensive care remains a significant challenge for many. TAVR has dramatically improved the care of Medicare patients with aortic stenosis and has led to better outcomes, improved quality of care, and decreased costs. Recent data published on the low risk population further affirms the benefits this procedure provides.

AdvaMed agrees with CMS that the totality of evidence strongly supports the benefits of TAVR for patients with aortic stenosis. We also agree with CMS that the available evidence does not definitively identify procedural volume thresholds for hospitals or operators to begin or maintain TAVR programs. As noted below, AdvaMed would support a transition to direct measurement of quality at TAVR centers, in place of relying solely on procedural volumes as a proxy.

**AdvaMed supports CMS’ proposal that a single cardiac surgeon independently evaluate a patient.**

AdvaMed commends CMS’ proposal to reduce from two to one the number of cardiac surgeons that must independently examine the patient face-to-face and evaluate the patient’s suitability for SAVR, TAVR or medical or palliative therapy. Last year, we recommended that the requirement that two cardiac surgeons evaluate the patient should be removed.

Ultimately, the need for adequate patient access to necessary medical care cannot be understated. We emphasize that, with respect to the examination and evaluation of patients with aortic stenosis, the evaluating clinician must have expertise in and knowledge of all available treatment options, in order to ensure that patients have access to the most appropriate care.

**AdvaMed supports proposals that provide greater flexibility in achieving required procedural volumes.**

More flexible volume requirements to start and maintain a TAVR program will reduce or diminish improper incentives and allow for the continued evolution of aortic valve disease treatment. This will help to ensure appropriate and timely access for a broader group of patients in need, especially as aortic stenosis remains an underdiagnosed and undertreated disease. AdvaMed supports the proposals in the draft NCD that are intended to provide greater flexibility in achieving or maintaining certain required procedural volumes.

**As CMS evaluates the TAVR NCD, the Agency should consider potential future indications for TAVR.**

The proposed NCD specifically covers TAVR for symptomatic aortic valve stenosis and could unintentionally preclude this NCD from applying to future TAVR indications for aortic stenosis.
currently being studied. AdvaMed recommends that as CMS continues to evaluate modifications to the existing NCD, it should acknowledge that additional indications for TAVR (e.g., for asymptomatic aortic stenosis patients) are under consideration. As this therapy continues to evolve, and as more evidence is generated for a broader range of patients, it will be important to ensure that the NCD does not create a barrier to appropriate access to the right treatment for the right patient.

AdvaMed supports additional efforts by CMS to modernize key elements of the TAVR NCD.

AdvaMed supports the continued coverage under Coverage with Evidence Development (CED) for evidence development and data collection, including participation in a prospective, national, audited registry.

We also note that certain elements of the NCD have worked well and should be preserved as proposed, including coverage for FDA-approved indications (coverage to label); the requirement for a cohesive, multi-disciplinary heart team; appropriate hospital infrastructure; and the registry participation.

While the proposed TAVR decision does not ensure uniform policy standards across all AVR therapies, we believe that the proposal will facilitate greater patient access to care. In the case of patients seeking treatment of symptomatic aortic valve stenosis, the choice of proceeding with surgical aortic valve replacement (SAVR) as opposed to TAVR is based on multiple factors, including the surgical risk, patient frailty, comorbid conditions, and patient preferences and values. Noting the importance of shared decision-making for this patient population, we encourage CMS to continue to work with stakeholders to ensure the development and implementation of validated shared decision-making tools that speak to the needs of patients in their decision-making.

AdvaMed supports CMS’ movement toward quality measurement.

Finally, we agree with CMS that validated outcome measures are the most appropriate way to ensure excellent patient outcomes, and that ultimately such measures should be applied to all aortic stenosis therapies. Flexible volume requirements are a reasonable alternative in the short term; however, the infrastructure is in place to be able to measure program outcomes and quality. The availability of robust quality measures would reduce the need to rely on less precise measures, such as procedural volumes. AdvaMed supports replacing procedural volume requirements with validated quality metrics in the future. This could reasonably coincide with the discontinuation of the existing CED requirements.
Summary

Thank you for the opportunity to provide our comments on this important topic. AdvaMed is pleased with the direction of the proposed NCD and commends CMS once again for its efforts to improve coverage for this challenging health condition, especially in light of the growing body of evidence in recent years. If you have questions regarding these comments or if you require additional information, please contact me or Chandra Branham, JD, Vice President, Payment and Health Care Delivery Policy, at (202) 434-7219 or cbranham@AdvaMed.org.

Sincerely,

Donald May
Executive Vice President
Payment and Health Care Delivery Policy